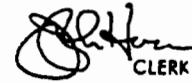


IN THE UNITED STATES DISTRICT COURT  
DISTRICT OF SOUTH DAKOTA  
SOUTHERN DIVISION

**FILED**

SEP 23 2016

  
CLERK

CAROL SHOUP, as Personal  
Representative of the Estate of  
THERESA CUNNINGHAM, Deceased.

Plaintiff,

v.

JOHNSON & JOHNSON, and  
JOHNSON & JOHNSON CONSUMER  
COMPANIES, INC.,

Defendants.

Case Number: CIV 16-4141

JURY TRIAL DEMANDED

COMPLAINT

COMES NOW Plaintiff, Carol Shoup, as the personal representative of the estate of Theresa Cunningham, deceased, by and through undersigned counsel, who brings this action against Defendants Johnson & Johnson ("J&J") and Johnson & Johnson Consumer Companies, Inc. ("J&J Consumer") as follows:

INTRODUCTION

1. This action arises out of Theresa Cunningham's diagnosis of endometrial uterine cancer and her subsequent death. Ms. Cunningham's cancer and death were directly and proximately caused by her regular and prolonged exposure to talcum

powder, contained in Johnson & Johnson Baby Powder (hereinafter "J&J Baby Powder") and Shower to Shower. Plaintiff Carol Shoup brings this cause of action against Defendants for claims arising from the direct and proximate result of Defendants' and/or their corporate predecessors' negligent, willful, and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of the product known as J&J Baby Powder (hereinafter referred to as the "Product").

### **PARTIES**

2. Ms. Cunningham was born in 1922, and used J&J Baby Powder, the "Product," for over a decade of her life. As a direct and proximate result of using the Product, Ms. Cunningham was diagnosed with endometrial uterine cancer, and ultimately died of endometrial uterine cancer on September 26, 2013. Ms. Cunningham resided in Faulk County, South Dakota at the time of her diagnosis and death, and she purchased and used the Product in Faulk County, South Dakota.

3. Plaintiff Carol Shoup resides in Sully County, South Dakota, and is Ms. Cunningham's surviving daughter and the duly appointed personal representative of her estate.

4. Defendant, Johnson & Johnson ("J&J"), is a New Jersey corporation with its principal place of business in the State of New Jersey.

5. At all pertinent times, Johnson & Johnson was engaged in the business of manufacturing, marketing, testing, promoting, selling, and/or distributing the Product. At all pertinent times, Johnson & Johnson regularly transacted, solicited, and conducted business in all States of the United States, including the State of South Dakota.

6. Defendant, Johnson & Johnson Consumer Companies, Inc. is a New Jersey corporation with its principal place of business in the State of New Jersey.

7. At all pertinent times, Johnson & Johnson Consumer Companies, Inc. was engaged in the business of manufacturing, marketing, testing, promoting, selling, and/or distributing the Product. At all pertinent times, Johnson & Johnson regularly transacted, solicited, and conducted business in all States of the United States, including the State of South Dakota.

8. At all pertinent times, all Defendants were engaged in the research, development, manufacture, design, testing, sale and marketing of the Product, and introduced the Product into interstate commerce with knowledge and intent that the Product be sold in the State of South Dakota.

#### **JURISDICTION AND VENUE**

9. This Court has original jurisdiction pursuant to 28 U.S.C. § 1332(d) because complete diversity exists between Plaintiff and Defendants, and the matter in controversy, exclusive of interest and costs, exceeds the sum or value of \$75,000.

10. This Court has personal jurisdiction over Defendants because Defendants are authorized to conduct and do conduct business in the State of South Dakota. Defendants have marketed, promoted, distributed, and sold the Product in the state of South Dakota and Defendants have sufficient minimum contacts with this State and/or sufficiently avail themselves of the markets in this State through their promotion, sales, distribution and marketing within this State to render the exercise of jurisdiction by this Court permissible.

11. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(a) and (b) because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in this judicial district. Venue is also proper under 18 U.S.C. § 1965(a) because Defendants transact substantial business in this judicial district.

### **FACTS COMMON TO ALL COUNTS**

#### **A. Background: Talc as a Carcinogen and Defendants' Knowledge**

12. Talc is a magnesium trisilicate and is mined from the earth. Talc is an inorganic mineral.

13. Talc is the main substance in talcum powders. The Johnson & Johnson Defendants manufactured the Product. The Product is composed almost entirely of talc.

14. At all pertinent times, a feasible alternative to the Product has existed. For example, cornstarch is an organic carbohydrate that is quickly broken down by the

body with no known health effects. Cornstarch powders have been sold and marketed for the same uses as the Product with nearly the same effectiveness.

15. Historically, "Johnson's Baby Powder" has been a symbol of freshness, cleanliness, and purity. During the time in question, the Johnson & Johnson Defendants advertised and marketed this product as the beacon of "freshness" and "comfort", eliminating friction on the skin, absorbing "excess wetness" helping keep skin feeling dry and comfortable, and "clinically proven gentle and mild." The Johnson & Johnson Defendants instructed women through advertisements to dust themselves with this product to mask odors. The bottle of "Johnson's Baby Powder" specifically targets women by stating, "For you, use every day to help feel soft, fresh, and comfortable."

16. During the time in question, the Johnson & Johnson Defendants advertised and marketed the product "Shower to Shower" as safe for use by women as evidenced in its slogan "A sprinkle a day keeps odor away", and through advertisements such as "Your body perspires in more places than just under your arms. Use SHOWER to SHOWER to feel dry, fresh, and comfortable throughout the day." And "SHOWER to SHOWER can be used all over your body."

17. In 1971, the first study was conducted that suggested an association between talc and ovarian cancer. This study was conducted by Dr. W.J. Henderson and others in Cardiff, Wales.

18. In 1982, the first epidemiologic study was performed on talc powder use in the female genital area. This study was conducted by Dr. Daniel Cramer and others. This study found a 92% increased risk in ovarian cancer with women who reported genital talc use. Shortly after this study was published, Dr. Bruce Semple of Johnson & Johnson came and visited Dr. Cramer about his study. Dr. Cramer advised Dr. Semple that Johnson & Johnson should place a warning on its talcum powders about the ovarian cancer risks so that women can make an informed decision about their health.

19. Since 1982, there have been approximately twenty-two (22) additional epidemiologic studies providing data regarding the association of talc and ovarian cancer. Nearly all of these studies have reported an elevated risk for ovarian cancer associated with genital talc use in women.

- a. In 1983, a case-control study found a 150% increased risk of ovarian cancer for women who use talcum powder in the genital area. Hartge, P., *et al.* Talc and Ovarian Cancer. *JAMA*. 1983; 250(14):1844.
- b. In 1988, a case control study of 188 women diagnosed with epithelial ovarian cancer and 539 control women found that 52% of the cancer patients habitually used talcum powder on the genital area before their cancer diagnosis. The study showed a 50% increase in risk of ovarian cancer in women that used talcum powder on their genital area and a positive dose-response relationship. Whittemore AS, *et al.* Personal and

environmental characteristics related to epithelial ovarian cancer. II. Exposures to talcum powder, tobacco, alcohol, and coffee. *Am. J. Epidemiol.* 1988 Dec; 128(6):1228-40.

- c. A 1989 study looked at 235 women diagnosed with epithelial ovarian cancer and 451 controls, and found a 29% increased risk in ovarian cancer with women who reported genital talcum powder use more than once each week. Booth, M., *et al.* Risk factors for ovarian cancer: a case-control study. *Br J Cancer.* 1989 Oct; 60(4):592-8.
- d. In 1992, a case-control study found a statistically significant 80% increased risk of ovarian cancer in women with more than 10,000 lifetime perineal applications of talc, demonstrating a positive dose-response relationship. Harlow BL, *et al.* Perineal exposure to talc and ovarian cancer risk. *Obstet Gynecol.* 1992 Jul; 80(1):19-26.
- e. Another 1992 case-control study reported a 70% increased risk from genital talc use and a 379% increased risk of ovarian cancer of women who used talc on sanitary napkins in their genital area. Rosenblatt, K.A. *et al.* Mineral fiber exposure and the development of ovarian cancer. *Gynecol Oncol.* 1992 Apr; 45(1):20-5.
- f. In 1995, the largest study of its kind to date found a statistically significant 27% increased risk in ovarian cancer for women who regularly



use talc in the abdominal or perineal area. Purdie, D., *et al.* Reproductive and other factors and risk of epithelial ovarian cancer: An Australian case-control study. Survey of Women's Health Study Group. *Int J Cancer*. 1995 Sep 15; 62(6):678-84.

- g. In 1996, a case-control study found a statistically significant 97% increased risk of ovarian cancer in women who used what they described as a "moderate" or higher use of talc-based powders in their genital area. See Shushan, A., *et al.* Human menopausal gonadotropin and the risk of epithelial ovarian cancer. *Fertil. Steril.* 1996 Jan; 65(1):13-8.
- h. In 1997, a case control study of 313 women with ovarian cancer and 422 without this disease found that the women with cancer were more likely to have applied talcum powder to their external genitalia area. Women using these products had a statistically significant 50% to 90% higher risk of developing ovarian cancer. Cook, LS, *et al.* Perineal powder exposure and the risk of ovarian cancer. *Am. J Epidemiol.* 1997 Mar 1; 145(5):459-65.
- i. In 1997, a case-control study involving over 1,000 women found a statistically significant increased risk of 42% for ovarian cancer for women who applied talc via sanitary napkins to their perineal area. Chang, S, *et al.* Perineal talc exposure and risk of ovarian carcinoma. *Cancer.* 1997 Jun 15; 79(12):2396-401.



- j. In 1998, a case-control study found a 149% increased risk of ovarian cancer in women who used talc-based powders on their perineal area. Godard, B., *et al.* Risk factors for familial and sporadic ovarian cancer among French Canadians: a case-control study. *Am J Obstet Gynecol.* 1998 Aug; 179(2):403-10.
- k. Dr. Daniel Cramer conducted another case-control study in 1999, observing 563 women newly diagnosed with epithelial ovarian cancer and 523 women in a control. The study found a statistically significant 60% increased risk of ovarian cancer in women that used talc-based body powders on their perineal area and an 80% increase in risk for women with over 10,000 lifetime applications. Cramer, DW, *et al.* Genital talc exposure and risk of ovarian cancer. *Int J Cancer.* 1999 May 5; 81(3):351-56.
- l. In 2000, a case-control study of over 2,000 women found a statistically significant 50% increased risk of ovarian cancer from genital talc use in women. Ness, RB, *et al.* Factors related to inflammation of the ovarian epithelium and risk of ovarian cancer. *Epidemiology.* 2000 Mar; 11(2):111-7.
- m. In 2004, a case-control study of nearly 1,400 women from 22 counties in Central California found a statistically significant 37% increased risk of

epithelial ovarian cancer from women's genital talc use, and a 77% increased risk of serous invasive ovarian cancer from women's genital talc use. Importantly, this study also examined at women's use of cornstarch powders as an alternative to talc, and found no increased risk in ovarian cancer in women in the cornstarch group, further supporting the causal connection between genital talc use and ovarian cancer. Mills, PK, *et al.* Perineal talc exposure and epithelial ovarian cancer risk in the Central Valley of California. *Int J Cancer*. 2004 Nov 10; 112(3):458-64.

- n. In 2008, a combined study of over 3,000 women from a New England-based case-control study found a general 36% statistically significant increased risk of epithelial ovarian cancer from genital talc use and a 60% increased risk of the serous invasive ovarian cancer subtype. The study also found a strong dose-response relationship between the cumulative talc exposure and incidence of ovarian cancer, adding further support to the causal relationship. Gates, MA, *et al.* Talc Use, Variants of the GSTM1, GSTT1, and NAT2 Genes, and Risk of Epithelial Ovarian Cancer. *Cancer Epidemiol Biomarkers Prev*. 2008 Sep; 17(9):2436-44.
- o. A 2009 case-control study of over 1,200 women found the risk of ovarian cancer increased significantly with increasing frequency and duration of talc use, with an overall statistically significant 53% increased risk of

ovarian cancer from genital talc use. That increased risk rose dramatically, to 108%, in women with the longest duration and most frequent talc use. Wu, AH, *et al.* Markers of inflammation and risk of ovarian cancer in Los Angeles County. *Int. J Cancer*. 2009 Mar 15; 124(6):1409-15.

p. In 2011, another case-control study of over 2,000 women found a 27% increased risk of ovarian cancer from genital talc use. Rosenblatt, KA, *et al.* Genital powder exposure and the risk of epithelial ovarian cancer. *Cancer Causes Control*. 2011 May; 22(5):737-42.

q. In June of 2013, a pooled analysis of over 18,000 women in eight case-control studies found a 20% to 30% increased risk of women developing epithelial ovarian cancer from genital powder use. The study concluded by stating, "Because there are few modifiable risk factors for ovarian cancer, avoidance of genital powders may be a possible strategy to reduce ovarian cancer incidence." Terry, KL, *et al.* Genital powder use and risk of ovarian cancer: a pooled analysis of 8,525 cases and 9,859 controls. *Cancer Prev Res (Phila)*. 2013 Aug; 6(8):811-21.

20. More recently, researchers have also examined the link between endometrial cancer, a form of uterine cancer, and the application of talcum powder to the perineal area.

21. In 2010, one such study analyzed data from a 1976 cohort study of over 66,000 women, and found a statistically significant 21% increased risk of endometrial (uterine) cancer in postmenopausal women who had ever applied talcum powder in the perineal area. This risk rose to 24% for postmenopausal women who applied talc in the perineal area “regularly,” defined as at least once a week. Karageorgi S., *et al.* (2010) Perineal use of talcum powder and endometrial cancer risk. *Cancer Epidemiol Biomarkers Prev.* 2010 May; 19:1269–1275.

22. In 1993, the United States National Toxicology Program published a study on the toxicity of non-asbestiform talc and found clear evidence of carcinogenic activity. Talc was found to be a carcinogen, with or without the presence of asbestos-like fibers.

23. In response to the United States National Toxicology Program’s study, the Cosmetic Toiletry and Fragrance Association (CTFA) formed the Talc Interested Party Task Force (TIPTF). Johnson & Johnson, Inc., and Johnson & Johnson Consumer Companies, Inc. were members of the CTFA. The stated purpose of the TIPTF was to pool financial resources of these companies in an effort to collectively defend talc use at all costs and to prevent regulation of any type over this industry. The TIPTF hired scientists to perform biased research regarding the safety of talc, members of the TIPTF edited scientific reports of the scientists hired by this group prior to the submission of these scientific reports to governmental agencies, members of the TIPTF knowingly released false information about the safety of talc to the consuming public, and used

political and economic influence on regulatory bodies regarding talc. All of these activities have been well coordinated and planned by these companies and organizations over the past four (4) decades in an effort to prevent regulation of talc and to create confusion to the consuming public about the true hazards of talc relative to cancer.

24. On November 10, 1994, the Cancer Prevention Coalition mailed a letter to then Johnson & Johnson C.E.O, Ralph Larson, informing his company that studies as far back as 1960's ". . . show[ ] conclusively that the frequent use of talcum powder in the genital area pose[ ] a serious health risk of ovarian cancer." The letter cited a recent study by Dr. Bernard Harlow from Harvard Medical School confirming this fact and quoted a portion of the study where Dr. Harlow and his colleagues discouraged the use of talc in the female genital area. The letter further stated that 14,000 women per year die from ovarian cancer and that this type of cancer is very difficult to detect and has a low survival rate. The letter concluded by requesting that Johnson & Johnson withdraw talc products from the market because of the alternative of cornstarch powders, or at a minimum, place warning information on its talc-based body powders about ovarian cancer risk they pose.

25. In 1996, the condom industry stopped dusting condoms with talc due to the growing health concerns.

26. In February of 2006, the International Association for the Research of Cancer (IARC) part of the World Health Organization published a paper whereby they classified perineal use of talc based body powder as a "Group 2B" human carcinogen. IARC which is universally accepted as the international authority on cancer issues, concluded that studies from around the world consistently found an increased risk of ovarian cancer in women from perineal use of talc. IARC found that between 16-52% of women in the world were using talc to dust their perineum and found an increased risk of ovarian cancer in women talc users ranging from 30-60%. IARC concluded with this "Evaluation": "There is limited evidence in humans for the carcinogenicity of perineal use of talc-based body powder." By definition "Limited evidence of carcinogenicity" means "a positive association has been observed between exposure to the agent and cancer for which a causal interpretation is considered by the Working Group to be credible, but chance, bias or confounding could not be ruled out with reasonable confidence."

27. In approximately 2006, the Canadian government under The Hazardous Products Act and associated Controlled Products Regulations classified talc as a "D2A," "very toxic," 51 "cancer causing" substance under its Workplace Hazardous Materials Information System (WHMIS). Asbestos is also classified as "D2A".

28. In 2006, Imerys Talc began placing a warning on the Material Safety Data Sheets (MSDS) it provided to the Johnson & Johnson Defendants regarding the talc it

sold to them to be used in the Product. These MSDSs not only provided the warning information about the IARC classification but also included warning information regarding “States Rights to Know” and warning information about the Canadian Government’s “D2A” classification of talc as well.

29. Defendants had a duty to know and warn about the hazards associated with the use of the Product.

30. Defendants failed to inform customers and end users of the Product of a known catastrophic health hazard associated with the use of the Product.

31. In addition, Defendants procured and disseminated false, misleading, and biased information regarding the safety of the Product to the public and used influence over governmental and regulatory bodies regarding talc.

**B. Ms. Cunningham’s Use of the Product**

32. Ms. Cunningham was born in 1922, and was a resident of Faulk County, South Dakota.

33. Ms. Cunningham began the practice of applying Defendants’ Product to her perineal area as an adult. She applied the Product to her perineal area on a daily basis for over a decade, exactly as instructed and advertised by the Johnson & Johnson Defendants.



34. There was never any indication, on the Product's packaging or otherwise, that this normal use could and would cause Ms. Cunningham to develop endometrial uterine cancer.

35. Ms. Cunningham was ultimately diagnosed with endometrial uterine cancer.

36. Ms. Cunningham died as a result of endometrial uterine cancer on September 26, 2013.

37. As noted above, Plaintiff Carol Shoup is Ms. Cunningham's daughter and the personal representative of her estate.

**COUNT ONE - STRICT LIABILITY**  
**(FAILURE TO WARN)**

38. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

39. At all pertinent times, the Johnson & Johnson Defendants were manufacturing, marketing, testing, promoting, selling and/or distributing the Product in the regular course of business.

40. At all pertinent times, Ms. Cunningham used the Product to powder her perineal area, which is a reasonably foreseeable use.

41. At all pertinent times, Defendants in this action knew or should have known that the use of talcum powder based products in the perineal area significantly

increases the risk of cancer, including, but not limited to, ovarian and uterine cancer, based upon scientific knowledge dating back for decades.

42. At all pertinent times, including the time of sale and consumption, the Product, when put to the aforementioned reasonably foreseeable use, was in an unreasonably dangerous and defective condition because it failed to contain adequate and proper warnings and/or instructions regarding the increased risk of cancer, including, but not limited to, ovarian and uterine cancer, associated with the use of the Product by women to powder their perineal area. Defendants themselves failed to properly and adequately warn and instruct Ms. Cunningham as to the risks and benefits of the Product given her need for this information.

43. Had Ms. Cunningham received a warning that the use of the Product would significantly increase her risk of developing cancer, she would not have used it. As a proximate result of Defendants' design, manufacture, marketing, sale, and distribution of the Product, Ms. Cunningham was injured catastrophically, and was caused severe pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, economic damages, and death.

44. The development of endometrial uterine cancer by Ms. Cunningham was the direct and proximate result of the unreasonably dangerous and defective condition of the Product at the time of sale and consumption, including its lack of warnings; Ms.

Cunningham suffered injuries and damages including, but not limited to, physical and mental pain and suffering, medical expenses, and death.

45. Defendants' Product was defective because it failed to contain warnings and/or instructions, and breached express warranties and/or failed to conform to express factual representations upon which Ms. Cunningham justifiably relied in electing to use the Product. The defect or defects made the Product unreasonably dangerous to persons, such as Ms. Cunningham, who could reasonably be expected to use and rely upon the Product. As a result, the defect or defects were a producing cause of Ms. Cunningham's injuries and damages.

46. Defendants' Product failed to contain, and continues to this day not to contain, adequate warnings and/or instructions regarding the increased risk of cancer, including, but not limited to, ovarian and uterine cancer, with the use of the Product by women. Defendants continue to market, advertise, and expressly represent to the general public that it is safe for women to use the Product regardless of application. The Defendants continue with these marketing and advertising campaigns despite having scientific knowledge that dates back to the 1960's that the Product increases the risk of ovarian cancer in women when used in the perineal area.

47. Ms. Cunningham sustained the following damages as a foreseeable, direct, and proximate result of Defendants' acts and/or omissions:

- a. Economic losses including medical care; and

- b. Noneconomic losses including physical and mental pain and suffering, emotional distress, inconvenience, loss of enjoyment and impairment of quality of life, past and future, and death.

**COUNT TWO – STRICT LIABILITY**  
**(DESIGN AND/OR MANUFACTURING DEFECT)**

48. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

49. Defendants engaged in the design, development, manufacture, marketing, sale, and distribution of the Product in a defective and unreasonably dangerous condition to consumers, including Ms. Cunningham.

50. Defendants caused the Product to enter the stream of commerce and to be sold through various retailers, where Ms. Cunningham purchased the Product.

51. The Product was expected to, and did, reach consumers, including Ms. Cunningham, without change in the condition in which it was manufactured and sold by Defendants and/or otherwise released into the stream of commerce.

52. Ms. Cunningham used the Product in a manner normally intended, recommended, promoted, and marketed by Defendants.

53. The Product failed to perform safely when used by Ms. Cunningham in a reasonably foreseeable manner, specifically increasing her risk of developing endometrial uterine cancer.

54. The propensity of talc fibers to translocate into the female reproductive system, including, but not limited to, the ovaries, thereby substantially increasing the risk of cancer, including, but not limited to, ovarian and uterine cancer, renders the Product unreasonably dangerous when used in the manner it was intended and to an extent beyond that would be contemplated by the ordinary consumer.

55. Importantly, the Product is an inessential cosmetic product that does not treat or cure any serious disease. Further, safer alternatives, including corn-starch based powders, have been readily available for decades.

56. Defendants have known, or should have known, that the Product is unreasonably dangerous when used by a woman in her perineal area but have continued to design, manufacture, sell, distribute, market, promote, and supply the Product so as to maximize sales and profits at the expense of public health and safety in conscious disregard of the foreseeable harm to the consuming public, including Ms. Cunningham.

57. As a direct and proximate result of Defendants' conduct, including actions, omissions, and misrepresentations, Ms. Cunningham sustained the following damages:

- a. Economic losses including medical care; and
- b. Noneconomic losses including physical and mental pain and suffering, emotional distress, inconvenience, loss of enjoyment

and impairment of quality of life, past and future, and death.

**COUNT THREE-NEGLIGENCE**

58. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

59. The Johnson & Johnson Defendants were negligent in marketing, designing, manufacturing, producing, supplying, inspecting, testing, selling and/or distributing the Product in one or more of the following respects:

- In failing to warn Ms. Cunningham of the hazards associated with the use of the Product;
- In failing to properly test their Product to determine adequacy and effectiveness or safety measures, if any, prior to releasing the Product for consumer use;
- In failing to properly test their Product to determine the increased risk of ovarian and uterine cancer during the normal and/or intended use of the Product;
- In failing to inform ultimate users, such as Ms. Cunningham as to the safe and proper methods of handling and using the Product;
- In failing to remove the Product from the market when Defendants knew or should have known the Product was defective;

- In failing to instruct the ultimate users, such as Ms. Cunningham, as to the methods for reducing the type of exposure to the Product which caused increased risk of cancer, including, but not limited to, ovarian and uterine cancer;
- In failing to inform the public in general and Ms. Cunningham in particular of the known dangers of using the Product for dusting the perineum;
- In failing to advise users how to prevent or reduce exposure that caused increased risk for cancer, including, but not limited to, ovarian and uterine cancer;
- In marketing and labeling the Product as safe for all uses despite knowledge to the contrary.
- In failing to act like a reasonably prudent company under similar circumstances.

Each and all of these acts and omissions, taken singularly or in combination, were a proximate cause of the injuries and damages sustained by Ms. Cunningham.

60. At all pertinent times, the Johnson & Johnson Defendants knew or should have known that the Product was unreasonably dangerous and defective when put to its reasonably anticipated use.

61. Ms. Cunningham sustained the following damages as a foreseeable,



direct, and proximate result of Defendants' acts and/or omissions:

- a. Economic losses including medical care; and
- b. Noneconomic losses including physical and mental pain and suffering, emotional distress, inconvenience, and loss of enjoyment and impairment of quality of life, past and future, and death.

#### **COUNT FOUR- BREACH OF EXPRESS WARRANTY**

62. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

63. The Johnson & Johnson Defendants expressly warranted, through direct-to-consumer marketing, advertisements, and labels, that the Product was safe and effective for reasonably anticipated uses, including use by women in the perineal area.

64. The Product did not conform to these express representations because it causes serious injury when used by women in the perineal area in the form of cancer, including, but not limited to, ovarian and uterine cancer.

65. Ms. Cunningham sustained the following damages as a foreseeable, direct, and proximate result of Defendants' acts and/or omissions:

- a. Economic losses including medical care; and
- b. Noneconomic losses including physical and mental pain and suffering, emotional distress, inconvenience, loss of enjoyment

and impairment of quality of life, past and future, and death.

**COUNT FIVE – BREACH OF IMPLIED WARRANTIES**

66. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

67. At the time the Defendants manufactured, marketed, labeled, promoted, distributed and/or sold the Product, the Johnson & Johnson Defendants knew of the uses for which the Product was intended, including use by women in the perineal area, and impliedly warranted the Product to be of merchantable quality and safe for such use.

68. Defendants breached their implied warranties of the Product sold to Ms. Cunningham because it was not fit for its common, ordinary and intended uses, including use by women in the perineal area.

69. Ms. Cunningham sustained the following damages as a foreseeable, direct, and proximate result of Defendants' acts and/or omissions:

- a. Economic losses including medical care; and
- b. Noneconomic losses including physical and mental pain and suffering, emotional distress, inconvenience, loss of enjoyment and impairment of quality of life, past and future, and death.

**COUNT SIX – PUNITIVE DAMAGES**  
**(S.D. Codified Laws § 21-3-2)**

70. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

71. Defendants have acted willfully, wantonly, with an evil motive, and recklessly in one or more of the following ways:

- a. Defendants knew of the unreasonably high risk of cancer, including, but not limited to, ovarian and uterine cancer, posed by the Product before manufacturing, marketing, distributing and/or selling the Product, yet purposefully proceeded with such action;
- b. Despite their knowledge of the high risk of cancer, including, but not limited to, ovarian and uterine cancer, associated with the Product, Defendants affirmatively minimized this risk through marketing and promotional efforts and product labeling;
- c. Through the actions outlined above, Defendants expressed a reckless indifference to the safety of users of the Product, including Ms. Cunningham. Defendants' conduct, as described herein, knowing the dangers and risks of the Product, yet concealing and/or omitting this information, in furtherance of their conspiracy and concerted action was outrageous because of Defendants' evil motive or a reckless indifference to the safety of users of the Product.

72. Ms. Cunningham sustained the following damages as a foreseeable, direct, and proximate result of Defendants' acts and/or omissions:

- a. Economic losses including medical care; and
- b. Noneconomic losses including physical and mental pain and suffering, emotional distress, inconvenience, loss of enjoyment and impairment of quality of life, past and future, and death.

**COUNT SEVEN – NEGLIGENT MISREPRESENTATION**

73. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

74. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Ms. Cunningham, and the public, that the Product had been tested and found to be safe and effective for use in the perineal area. The representations made by Defendants, in fact, were false.

75. Defendants failed to exercise ordinary care in the representations concerning the Product while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented the Product's high risk of unreasonable, dangerous, adverse side effects.

76. Defendants breached their duty in representing that the Product has no serious side effects.

77. As a foreseeable, direct and proximate result of the negligent misrepresentation of Defendants as set forth herein, Defendants knew, and had reason to know, that the Product had been insufficiently tested, or had not been tested at all, and that it lacked adequate and accurate warnings, and that it created a high risk, and/or higher than acceptable risk, and/or higher than reported and represented risk, of adverse side effects, including, but not limited to, ovarian and uterine cancer.

78. Ms. Cunningham sustained the following damages as a foreseeable, direct, and proximate result of Defendants' acts and/or omissions:

- a. Economic losses including medical care; and
- b. Noneconomic losses including physical and mental pain and suffering, emotional distress, inconvenience, loss of enjoyment and impairment of quality of life, past and future, and death.

**COUNT EIGHT – FRAUDULENT CONCEALMENT**

79. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

80. Defendants owed consumers, including Ms. Cunningham, a duty to fully and accurately disclose all material facts regarding the Product, not to conceal material defects related thereto, not to place this defective Product into the stream of commerce, and to fully and accurately label product packaging. To the contrary, Defendants explicitly and/or implicitly represented that the Product was safe and effective.

81. Defendants actively and intentionally concealed and/or suppressed material facts, in whole or in part, to induce consumers, including Ms. Cunningham, to purchase and use the Product and did so at her expense. Specifically:

- a. Defendants have been aware of the positive association between feminine talc use and cancer demonstrated by epidemiology studies since at least 1982 and more than a dozen such published

studies, including meta- analyses, have been published demonstrating similar results;

- b. Defendants have been aware, for decades, of the propensity for talc particles to translocate from the perineum through the vaginal tract into the ovaries;
- c. IARC, the recognized world authority of agent carcinogenicity, has determined that there is a credible causal connection between feminine talc use and ovarian and uterine cancer; and
- d. Johnson & Johnson's own paid consultant, Dr. Alfred Wehner, advised the company on multiple occasions, by at least 1997, that Johnson & Johnson's denial of a positive association between feminine talc use and ovarian and uterine cancer was "technically and factually incorrect."

82. Defendants made the misrepresentations and/or omissions for the purpose of deceiving and defrauding Ms. Cunningham and with the intention of having her act and rely on such misrepresentations and/or omissions.

83. Defendants knew that their concealments, misrepresentations and/or omissions were material, and that they were false, incomplete, misleading, deceptive, and deceitful when they were made. Alternatively, Defendants concealed information, and/or made the representations with such reckless disregard for the truth that

knowledge of the falsity can be imputed to them.

84. Defendants profited, significantly, from their unethical and illegal conduct that caused Ms. Cunningham to purchase and habitually use a dangerous and defective product.

85. Defendants' actions, and Ms. Cunningham's justifiable reliance thereon, were substantial contributing factors in causing injury and incurrence of substantial damages.

86. Ms. Cunningham sustained the following damages as a foreseeable, direct, and proximate result of Defendants' acts and/or omissions:

- a. Economic losses including medical care; and
- b. Noneconomic losses including physical and mental pain and suffering, emotional distress, inconvenience, loss of enjoyment and impairment of quality of life, past and future, death.

**COUNT NINE – FRAUD**  
**(INTENTIONAL MISREPRESENTATION)**

87. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

88. Defendants, who engaged in the development, manufacture, marketing, sale and distribution of personal hygiene products, including the Product, owed a duty to provide accurate and complete information regarding said Product.



89. Defendants fraudulently misrepresented the use of the Product as safe and effective, specifically:

- a. Johnson & Johnson's website calls it a "misconception" that talc in baby powder can be "absorbed into the body";
- b. Johnson & Johnson print advertisements directed at adult women asserted that, because Johnson & Johnson Baby Powder is used on babies, women can "trust" that Johnson & Johnson will take "just as much care" of their skin;
- c. Misleading consumers in advertisements that the talc in Johnson & Johnson Baby Powder is safe because it comes from "nature" and is "pure";
- d. Johnson & Johnson, on its website, claims that "30 years of research by independent scientists, review boards and global authorities [] have concluded that talc can be used safely in personal care products," failing to mention the dozens of studies demonstrating a relationship between feminine talc use and ovarian and uterine cancer, as well as the decision by IARC to label feminine talc powder use as "possibly carcinogenic"; and
- e. On the Johnson & Johnson Baby Powder bottle, Defendants include a conspicuous warning to mothers to prevent babies from

inhaling the powder and the inclusion of this lone warning implies to the consumer that Johnson & Johnson Baby Powder is safe in all other manners of use.

90. Defendants knew that these misrepresentations and/or omissions were material, and that they were false, incomplete, misleading, deceptive and deceitful when they were made.

91. Defendants made the misrepresentations and/or omissions for the purpose of deceiving and defrauding consumers, including Ms. Cunningham, with the intention of having them act and rely on such misrepresentations and/or omissions.

92. Ms. Cunningham relied, with reasonable justification, on the misrepresentations by Defendants, which induced her to purchase and use the Product on a regular basis for decades.

93. Defendants profited, significantly, from their unethical and illegal conduct that fraudulently induced Ms. Cunningham, and millions of other consumers, to purchase a dangerous and defective product.

94. Defendants' actions, and Ms. Cunningham's justifiable reliance thereon, were substantial contributing factors in causing injury and incurrence of substantial damages.

95. As a foreseeable, direct, and proximate result of the aforementioned fraudulent misrepresentations by Defendants, Ms. Cunningham sustained the

following damages:

- a. Economic losses including medical care; and
- b. Noneconomic losses including physical and mental pain and suffering, emotional distress, inconvenience, loss of enjoyment and impairment of quality of life, past and future, and death.

**COUNT TEN – VIOLATION OF SOUTH DAKOTA CONSUMER PROTECTION –  
DECEPTIVE TRADE PRACTICES ACT (S.D. Codified Laws § 37-24-1 et seq.)**

96. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

97. Ms. Cunningham purchased and used Defendants' Product primarily for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

98. Defendants knowingly acted, used, and employed deceptive acts and practices, fraud, false pretenses, false promises, and misrepresentations in connection with the sale and advertisement of the Product, and knowingly suppressed and omitted material facts regarding the risks associated with the use of the Product in connection with their sale and advertisement of the Product.

99. Had Defendants not engaged in the deceptive conduct described herein, Ms. Cunningham would not have purchased and/or paid for Defendants' product, and would not have incurred related injuries and damages.

100. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, monetary gain from Ms. Cunningham for the Product that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

101. Defendants engaged in unfair methods of competition and deceptive acts or practices that were proscribed by law, including the following:

- a. Representing that goods or services have characteristics, ingredients, uses, benefits, or quantities that they do not have;
- b. Advertising goods or services with the intent not to sell them as advertised; and
- c. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

102. Defendants intended for Ms. Cunningham to rely on their representations and advertisements regarding the Product in order to achieve monetary gain from Ms. Cunningham through her purchase of the Product.

103. Ms. Cunningham was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at Ms. Cunningham and other consumers was to create demand for and sell the Product. Each aspect of Defendants' conduct combined to artificially create sales of the product.

104. Defendants have a statutory duty to refrain from unfair or deceptive acts

or trade practices in the design, labeling, development, manufacture, promotion, and sale of the Product.

105. Had Defendants not engaged in the deceptive conduct described above, Ms. Cunningham would not have purchased and/or paid for the Product, and would not have incurred related injuries and damages.

106. Defendants' intentional, deceptive, unconscionable, and fraudulent representations and material omissions to Ms. Cunningham, physicians, and consumers, constituted unfair and deceptive acts and trade practices in violation of S.D. Codified Laws § 37-24-1 *et seq.*

107. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of the South Dakota consumer protection statute.

108. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices, or have made false representations in violation of S.D. Codified Laws § 37-24-1 *et seq.*

109. Under this statute, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

110. Defendants violated the statutes that were enacted in these states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and

business practices and false advertising, by knowingly and falsely representing that Defendants' Product was fit to be used for the purpose for which it was intended, when in fact it was defective and dangerous, and by other acts alleged herein. These representations were made in marketing and promotional materials.

111. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

112. Defendants had actual knowledge of the defective and dangerous condition of Defendants' product and failed to take any action to cure such defective and dangerous conditions.

113. Ms. Cunningham relied upon Defendants' misrepresentations and omissions in determining which product to use.

114. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to Ms. Cunningham and other consumers constituted deceptive acts and practices.

115. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Ms. Cunningham, suffered ascertainable losses and damages.

116. As a direct and proximate result of Defendants' violations of the states'

consumer protection laws, Ms. Cunningham sustained the following damages:

- a. Economic losses including medical care; and
- b. Noneconomic losses including physical and mental pain and suffering, emotional distress, inconvenience, loss of enjoyment and impairment of quality of life, past and future.

**COUNT ELEVEN –WRONGFUL DEATH ACTION**  
**(S.D. Codified Laws § 21-5-1 et. seq.)**

117. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

118. Plaintiff Carol Shoup brings this claim in her capacity as personal representative of the estate of Theresa Cunningham on behalf of Ms. Cunningham's beneficiaries pursuant to S.D. Codified Laws § 21-5-5.

119. As a direct and proximate result of the conduct of Defendants and the defective nature of the Product as described above, Ms. Cunningham suffered bodily injuries resulting in death.

120. As a direct and proximate cause of the conduct of Defendants, Ms. Cunningham's beneficiaries have incurred grief, sorrow, mental suffering, as well as hospital, nursing and medical expenses, funeral expenses, and estate administration expenses as a result of Ms. Cunningham's death. Ms. Cunningham's beneficiaries have suffered the loss of the love, companionship, comfort, affection, society, solace, and



moral support of Ms. Cunningham as a result of her wrongful death. Plaintiff brings this claim for these damages and for all pecuniary losses sustained.

**COUNT TWELVE – SURVIVAL ACTION**  
**(S.D. Codified Laws § 15-4-1 *et. seq.*)**

121. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

122. This claim is brought by Plaintiff Carol Shoup as the personal representative of the estate of Ms. Cunningham.

123. As a direct and proximate result of the aforementioned acts and omissions of Defendants and the defective nature of the Product, Ms. Cunningham suffered serious injuries of a personal nature, including, but not limited to, great pain and suffering before her death, and incurred economic damages, including medical expenses, thereby subjecting Defendants to liability pursuant to S.D. Codified Laws § 15-4-1 *et. seq.*

**TOLLING OF STATUTE OF LIMITATIONS**

124. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

125. Ms. Cunningham suffered an illness that had a latency period and did not arise until many years after exposure. Ms. Cunningham was not aware at the time of her diagnosis or death that her endometrial uterine cancer and death were caused by

her use of the Defendants' Product. Similarly, Plaintiff Carol Shoup was not aware at the time of Ms. Cunningham's diagnosis or death that her endometrial uterine cancer was caused by her use of the Defendants' Product. Consequently, the statute of limitations period has been tolled until the day that Plaintiff knew or had reason to know that Ms. Cunningham's endometrial uterine cancer was linked to her use of Defendants' Product.

126. Furthermore, the running of any statute of limitations period has been equitably tolled by reason of Defendants' fraudulent concealment and conduct. Through their affirmative misrepresentations and omissions, Defendants actively concealed from Plaintiff Carol Shoup and Ms. Cunningham the true risks associated with the Product.

127. As a result of Defendants' actions, Ms. Cunningham and her prescribing physicians were unaware, and could not reasonably know or have learned through reasonable diligence that she had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

128. Furthermore, Defendants are estopped from relying on any statute of limitations period because of their concealment of the truth, quality and nature of the Product. Defendants were under a duty to disclose the true character, quality and nature of the Product because this was non-public information over which the Defendants had and continue to have exclusive control, and because the Defendants

knew that this information was not available to Ms. Cunningham, her medical providers and/or her health facilities.

129. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing and promoting a profitable product, notwithstanding the known or reasonably known risks. Ms. Cunningham and medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and were forced to rely on Defendants' representations.

#### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff demands judgment against Defendants on each of the above-referenced claims and causes of action, and as follows:

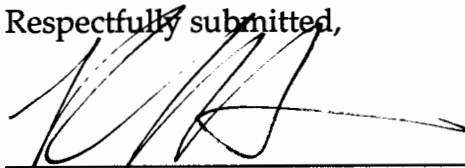
- a. Awarding compensatory damages in excess of \$75,000, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, death and other non-economic damages in an amount to be determined at trial of this action;
- b. Awarding economic damages in the form of medical expenses, out of pocket expenses, funeral expenses, and other economic damages in an amount to be determined at trial of this action;
- c. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and

reckless indifference for the safety and welfare of the general public and Ms. Cunningham in an amount sufficient to punish Defendants and deter future similar conduct;

- d. Prejudgment interest;
- e. Postjudgment interest;
- f. Awarding Plaintiff's reasonable attorneys' fees;
- g. Awarding Plaintiff the costs of these proceedings; and
- h. Such other and further relief as this Court deems just and proper.

Dated: September 23, 2016

Respectfully submitted,



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