



IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

SYRENTHIA THRASH)
)
Plaintiff,) C.A. No.:
)
v.) Jury Trial Demanded
)
JOHNSON & JOHNSON; JOHNSON & JOHNSON)
CONSUMER COMPANIES, INC.; IMERYYS TALC)
AMERICA, INC., F/K/A LUZENAC AMERICA,)
INC.; IMERYYS TALC DELAWARE, INC.; U.S.)
BORAX, INC.; RIO TINTO MINERALS INC., RIO)
TINTO MINERAL SERVICES INC.; AND)
VALEANT PHARMACEUTICALS NORTH)
AMERICA, LLC;)
Defendants.)

COMPLAINT

COMES NOW, the Plaintiff by and through undersigned counsel, and files this Complaint against the Defendants, Johnson & Johnson; Johnson & Johnson Consumer Companies, Inc.; Imerys Talc America, Inc., f/k/a Luzenac America, Inc.; Imerys Talc Delaware, Inc.; U.S. Borax, Inc.; Rio Tinto Minerals, Inc.; Rio Tinto Mineral Services, Inc.; and Valeant Pharmaceuticals North America, LLC and in support thereof allege as follows:

I. PARTIES

1. The Plaintiff, Syrenthia Thrash, is a resident of the State of Alabama.
2. The Defendant, Johnson & Johnson (Hereinafter “Johnson & Johnson” or “The Johnson Defendants”), is a New Jersey corporation that is registered to do business and conducts substantial business in this State.

3. Johnson & Johnson may be served pursuant to 10 Del. C. § 3104 via its registered agent, located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

4. The Defendant, Johnson & Johnson Consumer Companies, Inc. (Hereinafter “Johnson & Johnson Consumer Companies, Inc.” or “The Johnson Defendants”), is a New Jersey corporation that is registered to do business and conducts substantial business in this State.

5. Johnson & Johnson Consumer Companies, Inc. may be served via its registered agent, The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

6. The Defendant Imerys Talc America, Inc. f/k/a Luzenac America, Inc. (Hereinafter Imerys Talc America” or “The Imerys Defendants”), is a Delaware corporation, with its principal place of business in the State of Georgia that conducts substantial business in this State.

7. Imerys Talc America may be served via its registered agent, The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801.

8. The Defendant, Imerys Talc Delaware, Inc. (Hereinafter Imerys Talc Delaware” or “The Imerys Defendants”) is a Delaware corporation that is registered to do business and conducts substantial business in this State.

9. Imerys Talc Delaware, Inc. may be served via its registered agent, The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware 19801. Imerys Talc America and Imerys Talc Delaware are collectively referred to herein as “The Imerys Defendants”.

10. The Defendant U.S. Borax, Inc. is a Delaware corporation that is registered to do business and conducts substantial business in this state, which has its principle place of business in the State of Colorado.

11. U.S. Borax, Inc. may be served via its registered agent, Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808.

12. The Defendant Rio Tinto Minerals Inc. is a Delaware corporation that is registered to do business and conducts substantial business in this state, which has its principle place of business in the United Kingdom.

13. Rio Tinto Minerals Inc., may be served via its registered agent, Corporation Service Company, 2711 Centerville Road Suite 400, Wilmington, Delaware 19808.

14. Rio Tinto Mineral Services Inc. is a Delaware corporation that is registered to do business and conducts substantial business in this state, which has its principle place of business in the United Kingdom.

15. Rio Tinto Mineral Services Inc. may be served via its registered agent, Corporation Service Company, located at 2711 Centerville Road Suite 400, Wilmington, Delaware 19808.

16. Valeant Pharmaceuticals North America, LLC, hereinafter referred to as “Valeant Pharmaceuticals NA”, is a Delaware Corporation that is registered to do business and conducts substantial business in this state, which has its principle place of business in the State of New Jersey.

17. Valeant Pharmaceuticals NA, may be served via its registered agent, The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, Delaware, 19801.

II. JURISDICTION AND VENUE

18. Venue in this action properly lies in Delaware because, *inter alia*, Defendants Johnson & Johnson Consumer Companies, Inc.; Imerys Talc Delaware; Imerys Talc America; U.S. Borax, Inc.; Rio Tinto Minerals Inc.; Rio Tinto Mineral Services Inc.; and Valeant Pharmaceuticals North America, LLC are domestic corporations and Imerys Talc Delaware, Inc. has its principal place of business in the State of Delaware.

III. FACTS

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

22. Imerys Talc America produces a range of talc products in North America.

23. Imerys Talc America offers modified products for specific applications.

24. Luzenac America was formally known as Cyprus Talc Corporation and changed its name to Luzenac America in June 1992.

25. Defendant Imerys Talc America, mined the talc at issue in this case.

26. In 2006 Luzenac America, joined forces with sister company US Borax to form Rio Tinto Minerals, Inc.

27. US Borax and Rio Tinto Minerals produced a wide range of talc products.

28. Luzenac America was a subsidiary of the Rio Tinto group until 2011 when it was sold to Imerys Talc America, Inc.

29. In the 1840's, Imerys Talc America, converted a flour mill in Luzenac, France and used it to grind talc ore from a nearby mine for sale to local apothecaries in the nearby City of Toulouse.

30. Imerys Talc America mountain top mine, Trimouns, has since become the largest working talc operation in the world.

31. Imerys Talc America is the world's leading talc producer, supplying 15% of the world's talc from 9 mines and 15 processing facilities worldwide.

32. In the U.S. and Canada Imerys Talc America operates three mines and has five processing plants with a consolidated annual production of around 400,000 metric tons.

33. Imerys Talc America Yellowstone open-case mine in Montana is America's largest talc mining operation.

34. Imerys Talc America was owned by Defendants Rio Tinto Minerals Inc. and Rio Tinto Mineral Services, Inc. for over thirty (30) years.

35. In October 2012, Defendant Valeant Pharmaceuticals NA purchased the rights to Shower to Shower from Johnson and Johnson.

36. Talc is the main substance in talcum powders.

37. Defendants, Johnson & Johnson, Johnson & Johnson Consumer Companies, Inc., and Defendant Valeant Pharmaceuticals NA, manufactured the Talc Products that are in issue in this case namely, "Johnson's Baby Powder" and "Shower to Shower." All of these Talc Products are composed of almost entirely talc.

IV. DEFENDANTS MARKET TALC PRODUCTS AS SAFE

38. In 1893, Johnson & Johnson developed Johnson's Baby Powder as a daily use powder intended to eliminate friction on the skin and to absorb unwanted excess moisture for both babies and women.

39. Johnson & Johnson registered the term "Shower to Shower" as its trademark for talcum powder on March 28, 1966.

40. After its first use of the "Shower to Shower" trademark, Johnson & Johnson test-marketed its talcum powder in New Orleans and Indianapolis in late 1966.

41. Thereafter marketing was extended to include New England, the middle and South Atlantic States and New York in May 1967.

42. Since July 1967, distribution of the products in issue has been nationwide. *See Johnson & Johnson v. Colgate-Palmolive Co.*, 345 F. Supp 1216 (D. N.J. 1972).

43. At all times relevant, a feasible alternative to the Defendants' products have existed. Cornstarch is an organic carbohydrate that is quickly broken down by the body. Cornstarch powders have been sold and marketed for the same uses with nearly same effectiveness during all relevant times.

44. The Imerys Talc Defendants have continually advertised and marketed talc as safe for human use.

45. The Imerys Talc Defendants provide customers with material safety data sheets for talc.

46. The material safety data sheets are required to convey adequate and accurate health and warning information to customers.

47. Since Johnson's Baby Powder's introduction, Johnson & Johnson has consistently marketed it for women's use to maintain freshness and cleanliness.

48. Historically, the Johnson Baby Powder label and advertising encouraged women to dust themselves with the Baby Powder daily to mask odors.

49. Traditionally, “Johnson’s Baby Powder” has been a symbol of freshness, cleanliness, and purity.

50. During the time in question, the Johnson & Johnson Defendants advertised and marketed its product as the beacon of “freshness” and “comfort”, eliminating friction on the skin, absorbing “excess wetness” helping keep skin feeling dry and comfortable, and touted as “clinically proven gentle and mild”.

51. Johnson & Johnson induced women through advertisements to dust themselves with its product to mask feminine odors.

52. The bottle of “Johnson’s Baby Powder” specifically targets women by stating, “For you, use every day to help feel soft, fresh, and comfortable”.

53. Although the label has changed over time, the message is the same: that the product is safe for use on woman as well as babies without limitation or warning.

54. The Johnson Baby Powder label currently states that “Johnson’s Baby Powder is designed to gently absorb excess moisture helping skin feel comfortable. Our incredibly soft, hypoallergenic, dermatologist and allergy-tested formula glides over skin to leave it feeling delicately soft and dry while providing soothing relief.” Defendants instruct consumers on the product labeling to “Shake powder directly into your hand, away from the face, before smoothing onto baby’s skin.”

55. Through other marketing, including on their website for Johnson’s Baby Powder, Defendants similarly encouraged women to use the product daily. Defendants state that “Johnson’s Baby powder helps eliminate friction while keeping skin cool and comfortable. It’s

made of millions of tiny slippery plates that glide over each other to help reduce the irritation caused by friction.” Under the heading “How to use: For that skin that feels soft, fresh and comfortable, apply Johnson’s Baby Powder close to the body, away from the face. Shake the powder into your hand and smooth onto skin. “Under the heading “When to use, “Defendants recommend that consumers “use anytime you want skin to feel soft, fresh and comfortable. For baby, use after every bath and diaper change.”

56. Defendant Valeant Pharmaceuticals NA state on www.showertoshower.com/common-questions “Where on my body can I use the powder? SHOWER to SHOWER can be used all over your body”.

57. Johnson & Johnson seek to convey an image as a safe and trusted family brand. For example, on their website for Johnson’s Baby Powder, it states the product is “Clinically proven to be safe, gentle and mild.”

58. Defendants also have a website, www.safetyandcarecommitment.com devoted to “Our Safety & Care Commitment.” According to Defendants, “safety is our legacy” and “[y]ou have our commitment that every beauty and baby care product from the Johnson & Johnson Family of Consumer Companies is safe and effective when used as directed.” Defendants market a “Five-Level Safety Assurance Process,” which they describe as follows: “for decades, ours has been one of the most thorough and rigorous product testing processes in our industry- to ensure safety and quality of every single product we make. “Defendants’ so-called “promise to Parents and their Babies” provides that “[w]hen you bring our baby care products into your home, you can be assured of our commitment to the safety of your family and families around the world.”

59. The website also touts the safety of talc stating that “[f]ew ingredients have demonstrated the same performance, mildness and safety profile as cosmetic talc”.

60. Nowhere do Defendants warn of the increased risk of ovarian cancer linked to the use of Johnson's Baby Powder.

61. On May 12, 2014, the Johnson & Johnson Defendants and Defendant Valeant Pharmaceuticals NA issued the following statement: "We have no higher responsibility than the health and safety of consumers who rely on our products. It is important for consumers to know that the safety of cosmetic talc is supported by decades of scientific evidence and independent peer-reviewed studies. "See Fox 32 Chicago, *Popular Baby Powder Allegedly Caused Cancer In Pro-Figure Skater* (May 12, 2014), available at: <http://www.myfoxchicago.com/story/25497847/popular-baby-powder-allegedly-caused-cancerin-po-figure-skater>.

62. During the time in question, the Johnson & Johnson Defendants and Defendant Valeant Pharmaceuticals NA, also advertised and marketed its 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."

Plaintiff Used Defendants' Products Believing They Were Safe

63. Syrenthia Thrash used "Johnson's Baby Powder" and "Shower to Shower" (hereinafter "the Talc Products") to dust her perineum for feminine hygiene purposes from her childhood until approximately 2016 as she was led to believe would be safe. This was an

intended and foreseeable use of the Johnson & Johnson products based on their advertising, marketing, and labeling.

64. Syrenthia Thrash developed ovarian cancer and suffered effects attendant thereto, as a direct and proximate result of the unreasonably dangerous and defective nature of talcum powder and Defendants' wrongful and negligent conduct in the research, development, testing, manufacture, production, promotion, distribution, marketing, and sale of talcum powder.

65. As a direct and proximate result of these injuries, Plaintiff incurred medical expenses, has endured pain and suffering and loss of enjoyment of life.

66. On or around May, 2016 Syrenthia Thrash was diagnosed with Ovarian cancer. At the time of her diagnosis Syrenthia Thrash was fifty six (56) years old and did not have any risk factors, genetic or otherwise, for the disease.

**Defendants Knew of the Increased Risk of Ovarian Cancer From
Use of Talcum Powder in the Genital Area**

67. As detailed below, beginning in at least 1982, Defendants were aware of several studies that demonstrated that women who used talc-based baby powder in the genital area had a significant increased risk of ovarian cancer.

68. Since 1982, there have been 21 studies by doctors and scientists throughout the world (including 19 case-control studies, 1 cohort study, and 1 combined case-control and cohort study) that reported an elevated risk for ovarian cancer with genital talc use. The majority of these studies show a statistically significant increased risk of ovarian cancer.

69. In 1997 Defendant Johnson & Johnson was informed that several investigators had independently reported talc particles in ovarian tissue. *See* September 17, 1997 letter from A. Wehner to Johnson & Johnson attached hereto as Exhibit “1”.

70. In 1997 Defendant Johnson & Johnson was informed by its retained consultant that had no evidence to believe that “there is no basis to conclude that talc is capable of migrating to the ovaries...: *See* Exhibit 1.

71. However, Defendants do not warn or otherwise inform consumers anywhere, including on the product labeling or in their marketing or advertising for the product, that use of their products may be harmful to health, including significantly increasing the risk of ovarian cancer.

Scientific Evidence linking Talcum Powder to Ovarian Cancer

72. Research done as early as 1961 has shown that particles, similar to talc, can translocate from the exterior genital area to the ovaries in women. Ego GE, Newton M. “The transport of carbon particles in the human female reproductive tract.” *Fertility Sterility* 12:151-155, 1961.

73. Because of the potential for transmission, researchers remained concerned about the carcinogenic nature of talc and the effects of talc use. In 1968, a study concluded that “[a]ll of the 22 talcum products analyzed have a...fiber content...averaging 19%. The fibrous material was predominantly talc but contained minor amounts of tremolite, anthophyllite, and chrysotile [asbestos-like fibers] as these are often present in fibrous talc mineral deposits...Unknown significant amounts of such materials in products that may be used without precautions may create an unsuspected problem”. Cralley LJ, Key M, Groth DH, Lainhart WS, Ligo, RM.

“Fibrous and mineral content of cosmetic talcum products.” *Am Industrial Hygiene Assoc J.* 29:350-354, 1968. A 1976 follow up study concluded that “[t]he presence in these products of asbestiform anthophyllite and tremolite, chrysotile, and quartz indicates the need for a regulatory standard for cosmetic talc.... We also recommend that evaluation be made to determine the possible health hazards associated with the use of these products.” Rohl AN, et al, “Consumer talcums and powders: mineral and chemical characterization.” *J Toxicol Environ Health* 2:255-284, 1976.

74. In 1971, the first study was conducted that suggested an association between talc and ovarian cancer. This study was conducted by WJ Henderson and others in Cardiff, Wales. That study found talc particles “deeply embedded” in 10 of 13 ovarian tumors, 12 of 21 cervical tumors, one primary carcinoma of the endometrium and 5 of 12 “normal” ovaries from women with breast cancer. Henderson, W.J, et al. “talc and carcinoma of the ovary and cervix”, 78 (3) *J. Obstet, Gynaecol. Br. Commonw.* 266-272, 1971.

75. The scientific evidence linking talc use and ovarian cancer continued to build. In 1982, the first epidemiologic study was performed by Dr. Daniel Cramer et al. on talc powder use in the female genital area. This National Institute of Health (NIH) funded case-control study found a statistically significant 92 % increased risk in ovarian cancer with women who reported genital talc use. Additionally, it found that talc application directly to the genital area around the time of ovulation might lead to talc particles becoming deeply imbedded in the substance of the ovary and perhaps causing foreign body reaction capable of causing growth of epithelial ovarian tissue. This study proved an epidemiologic association between the use of cosmetic talc in genital hygiene and ovarian cancer. Cramer OW, Welch WR, Scully RE, Wojciechowski CA. “Ovarian cancer and talc” a case control studies.” *Cancer* 50:372-376, 1982.

76. In 1983, Patricia Hartage and Robert Hoover of the National Cancer Institute and Linda Lester and Larry McGowan of the George Washington University Medical Center, performed a case-control interview study regarding ovarian cancer. Although no association was proven due to the small sample size, the study found an “excess relative risk” of 2.5 (95% CI-0.7 to 10.0) of ovarian cancer.” Letter JAMA 250: 1844, 1983.

77. 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 perineum before their cancer diagnosis. The study showed that women using talc daily, showing a positive dose-response relationship. See Whittenmore AS, et.al., “Personal and environmental characteristics related to epithelial ovarian cancer. II. Exposures talcum powder, tobacco, alcohol, and coffee.” *Am J Epidemiol* 1128:1228-1240, 1988.

78. A case control study conducted in 1989 found similar results. The study looked at 235 women diagnosed with epithelial ovarian cancer and 451 controls and found an increased risk in ovarian cancer with women who reported genital talcum powder use more than once per week. Booth, M. et. Al., “Risk factors for ovarian cancer: a case-control study,” *Br.J. Cancer*, 592-598, 1989.

79. Another case control study conducted in 1989 by Bernard Harlow, et al., of Harvard Medical School at Brigham and Women’s Hospital, found an increased risk of ovarian cancer generally from genital talc use after bathing and found an increased risk of ovarian cancer generally from genital talc use after bathing and found a statistically significant increased risk of ovarian cancer from women that used talc-containing powders in combination with deodorizing powders on their perineum. This study also found positive dose-response relationship. Harlow,

B.L. & Weiss, N.S., “A case-control study of borderline ovarian tumors: the influence of perineal exposure to talc”, *Am. J. Epidemiology*, 390-394 (1989).

80. A 1992 study, also by Dr. Harlow, found that frequent and long term talc use directly on the genital area during ovulation increased a woman’s risk of ovarian cancer threefold. The study also found “[t]he most frequent method of talc exposure was use as a dusting powder directly to the perineum (genitals). Brand or generic ‘baby powder’ was used most frequently and was the category associated with a statistically significant risk for ovarian cancer.” This study looked at 235 ovarian cancer cases and compared to 239 controls. This study concluded that “given the poor prognosis for ovarian cancer, any potentially harmful exposures should be avoided, particularly those with limited benefits. For this reason, we discourage the use of talc in genital hygiene, particularly as a daily habit.” Harlow BL, Cramer DW, bell DA, Welch WR. “Perineal exposure to talc and ovarian cancer risk.” *Obstet Gynecol* 80:19-26, 1992.

81. Also in 1992, a case-control study was conducted by Karin Rosenblatt, et. al., of the Johns Hopkins School of Hygiene and Public Health, Department of Epidemiology. This study showed that the development of ovarian cancer may be associated with genital fiber exposure (especially talc on sanitary napkins) finding a relative risk of 4.8 for talc use on sanitary napkins. Rosenblatt KA, Szklo M, Rosenheim NB. “Mineral fiber exposure and the development of ovarian cancer.” *Gynecol Oncol* 45:30-25, 1992.

82. Another 1992 case-control study conducted by Yong Chen, et al., of 112 diagnosed epithelial ovarian cancer cases and 223 age-matched community controls, found an elevated risk for ovarian cancer for women who applied talc-containing dusting powder to the lower abdomen

and perineum for longer than 3 months. Yong Chen et al., “Risk Factors for Epithelial Ovarian Cancer in Beijing, China”, *Int. J. Epidemiol.*, 23-29 (1992).

83. 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. The study found “some evidence of carcinogenic activity in male rats” and “clear evidence of carcinogenic activity in female rats.” Talc was found to be a carcinogen, with or without the presence of asbestos-like fibers. National Toxicology Program. “Toxicology and carcinogenesis studies of talc (CAS No 14807-96-6) In F344N rats and B6C3F1 mice (inhalation studies).” *Technical Report Series No 421*, September 1993.

84. In 1995, a case control study was conducted in Australia by David Purdie, et. al., which involved over 1600 women. This was the largest study of its kind to date. This study found a statistically significant 27% increased risk in ovarian cancer for women who regularly use talc in the region of the abdomen or perineum. 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”, 62(6) *Int. J. Cancer* 678-684 (1995).

85. In 1996, a case-control study similarly found a statistically significant increased risk of ovarian cancer in women who used talc-based powders on their genital area. See Shushan, A., et al, “Human menopausal gonadotropin and the risk of epithelial ovarian cancer”, 65 (1) *Fertil. Steril.* 13-18 (1995).

86. In 1996, the condom industry stopped dusting condoms with talc due to the health concerns of ovarian cancer. “Concern about talc as an ovarian carcinogen goes back 50 years in the medical literature. By the 1970s, evidence was mounting that talc particles might migrate into a woman’s fallopian tubes where they could cause scarring and irritation in the ovaries.

Scientists believed in some cases that the scarring led to infertility or cancer. “McCullough, Marie, “Women’s health concerns prompt condom makers to stop using talc”, Knight Ridder, tribune New Service, January 10, 1996.

87. 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, Kamb ML, Weiss NS. “Perineal powder exposure and the risk of ovarian cancer”. *Am J. Epidemiol*, 145:459-465 (1997).

88. In 1997, a case-control study was conducted by Stella Chang and Harvey Risch from the Department of Epidemiology and Public HEALTH, Yale University School of Medicine which included over 1,000 women. The study found a statistically significant increased risk for ovarian cancer for women who applied talc via sanitary napkins to their perineum. The study indicated that commercial talc substitutes often replace talc with cornstarch. Furthermore, women may choose to powder or dust with cornstarch instead of talc. When cornstarch was assessed in relation to risk of ovarian carcinoma, no associations were found.” The study concluded, “[T]he results of this study appear to support the contention that talc exposure increases risk of ovarian carcinoma. Dusting with talcum powder is not an unusual practice for women, and, given the heterogeneity of the etiology and course of ovarian carcinoma, any possible harmful practices, particularly those with little benefit, should be deliberated.” Chang, S. & Risch, H.A., “Perineal talc exposure and risk of ovarian carcinoma”, 79 (12) *Cancer* 2396-2401 (1997).

89. In a 1998 case-control study conducted in Canada by Beatrice Godard, et al., an increased risk of ovarian cancer was found in women who used talc-based powders on their

perineum. Godard, B., et. Al., *Risk factors for familial and sporadic ovarian cancer among French Canadians: a case-control study*, 179(2) Am.J.Obstet. Gynecol. 403-210 (1998).

90. In 1999, Dr. Cramer conducted a funded case control study of 563 women newly diagnosed with epithelial ovarian cancer and 523 control women. The study found a statistically significant 60 % increased risk of ovarian cancer in women that used talc-based body powders on their perineum. “We conclude that there is a significant association between the use of talc in genital hygiene and risk of epithelial ovarian cancer that, when viewed in perspective of published data on this association, warrants more formal public health warnings,” The study was funded by a grant from the National Cancer Institute (NCI) Cramer, D.W., et al, “Genital talc exposure and risk of ovarian cancer”, 81(3) Int.J. Cancer 351-356 (1999).

91. In 2000, Roberta Ness, et al., from University of Pennsylvania, produced a case control study of over 2,000 women. This study found a statistically significant 50% increased risk of ovarian cancer from genital talc use in women. The study also found that talc causes inflammation and that inflammation contributes to cancer cell development. Ness, R.B., et al. “Factors related to inflammation of the ovarian epithelium and risk of ovarian cancer”, 11 (2) Epidemiology 111-117 (2000).

92. Also in 2000, a prospective cohort study, considered to be the most informative study to date, found a 40% increase in invasive serious cancers from women who applied talcum powder to their perineum Getrg DM,et al. Prospective study of talc use and ovarian cancer. J Natl Cancer Inst; 2000:92:249-252.

93. In 2003, a meta-analysis was conducted which re-analyzed data from 16 studies published prior to 2003 found a 33% increase in ovarian cancer risk among talc users. Huncharek M, et al. “Perineal application of cosmetic talc and risk of invasive epithelial ovarian

cancer: a meta-analysis of 11,933 subjects from sixteen observational studies”. *Anticancer Res.*, 23: 1955-60(2003).

94. In 2004, a case-control study of nearly 1400 women from 22 counties was performed in Central California. This study found a statistically significant 37% increased risk of epithelial ovarian cancer from women’s genital talc use. The study also found a 77% increased risk of serious invasive ovarian cancer from women’s genital talc use. The study looked at women’s use of cornstarch powders and found no increased risk in ovarian cancer in women who used these types of powders on the perineum as “Cornstarch is also not thought to exert the same toxicological reaction in human tissue as does talc.” This study concluded by stating that “users should exercise prudence in reducing or eliminating use. In this instance, the precautionary principle should be invoked, especially given that this is a serious form of cancer, usually associated with a poor prognosis, with no current effective screening tool steady incidence rates during the last quarter century and no prospect for successful therapy. Unlike other forms of environmental exposures, talcum powder use is easily avoidable.” Mills, P.K., et al., “Perineal talc exposure and epithelial ovarian cancer risk in the Central Valley of California”, 112 *Int. J. Cancer* 458-64 (2004).

95. Interestingly, this study also found a 54% increased risk in ovarian cancer from talc use in women who had not undergone a tubal ligation, whereas the study found no impact on women who had their tubes tied because it had been found in previous studies that talc particles migrate up the fallopian tubes in women this finding provided strong evidence to support the idea that talc is a carcinogen.

96. In 2008, Margaret Gates performed a combined study of over 3,000 women from a New England based case control study and a prospective Nurses’ health Study with additional

cases and years of follow up from these studies (The “Gates Study”). This study was funded by the National Cancer Institute (NCI), and found a general 36% statistically significant increased risk of epithelial ovarian cancer from genital talc use. A 60% increased risk of the serious invasive subtype was also found. Dr. Gates found a strong and positive dose-response relationship whereby increased risk was seen with higher talc usage in women. Dr. Gates stated that these latest results “provide additional support for a main effect of genital talc exposure on epithelial ovarian cancer” She also stated that “the finding of highly significant trends between increasing frequency of use and risk ‘strengthens the evidence of an association, because most previous studies have not observed a dose response.’” It was concluded that, “We believe that women should be advised not to use talcum powder in the genital area, based on our results and previous evidence supporting an association between genital talc use and ovarian cancer risk. Physicians should ask the patient about talc use history and should advise the patient to discontinue using talc in the genital area if the patient has not already stopped.” Dr. Gates further stated that “An alternative to talc is cornstarch powder, which has not been shown to increase ovarian cancer risk, or to forgo genital powder use altogether.” Gates, M.A., et al., “Talc Use, Variants of the GSTM1, GST1, and NAT2 Genes, and Risk of Epithelial Ovarian Cancer”, 17 (9) *Cancer Epidemiology, Biomarkers & Prev.* 2436-2444 (2008).

97. In October of 2008, Michael Thun, Vice-President of Epidemiology and surveillance Research at the American Cancer Society commented on the Gates Study. He stated the dose-response relationship between talc and ovarian cancer had finally been satisfied by this study. Dr. Thun said, “there are very few modifiable risk factors for ovarian cancer.” Others include tubal ligation, hysterectomy, and parity. Then there are factors that ‘probably’ increase the risk for ovarian cancer, and this is where talc fits in, alongside asbestos, postmenopausal

hormone therapy, and radiation.” Chustecka, Zosia & Lie, Desiree, “Talc Use in Genital are Linked to Increased Risk for Ovarian Cancer”, Medscape Medical News (2008).

98. In 2008, Melissa Merritt, from the Australian Cancer Study (Ovarian Cancer) and Australian Ovarian Cancer Study Group, conducted a case control study of over 3,000 women where a statistically significant increased risk of ovarian cancer for women who used talc on their perineum was confirmed. This study also confirmed a statistically significant increased risk of ovarian cancer of a serious subtype in women who used talc on their perineum. Merritt, M.A., et al., “Talcum powder, chronic pelvic inflammation and NSAIDs in relation to risk of epithelial ovarian cancer”, 122(1) Int.J. Cancer 170-176 (2008).

99. In 2009, a case- control study of over 1,200 women found the risk of ovarian cancer increased significantly with increasing frequency and duration of talc use. The study found an overall statistically significant 53% increased risk of ovarian cancer from genital talc use. The study also found a 108 % statistically significant increased risk of ovarian cancer in women with the longest duration and most frequent talc use. The study concluded by stating “that risk of ovarian cancer is significantly associated with talc use and with a history of endometriosis, as has been found in recent studies. “Wu, A.H., et al., “Markers of inflammation and risk of ovarian cancer in Los Angeles County”, 124(6) Int. J. Cancer 1409-1415(2009).

100. Additionally, various meta-analyses have been conducted that found positive associations between the use of talcum powder in the genital area and ovarian cancer. Harlow, B.K. et al., *Perineal exposure to talc and ovarian cancer risk*, Obstet. Gynecol, 19-26 (1992); Gross, A.J. & Berg, P.H., *A meta-analytical approach examining the potential relationship between talc exposure and ovarian cancer*, 5(2) *J. Expo. Anal. Environ Epidemiol.* 181-195 (1995). Huncharek, M., et al., “Perineal application of cosmetic talc and risk of invasive

epithelial ovarian cancer: a meta-analysis of 11,933 subjects from sixteen observational studies”,
23 anticancer Res. 1955-60(2003).

**Leading Authorities Agree on the Link Between Ovarian Cancer and
Perineal Use of Talc Powder**

101. On November 17, 1994, the Cancer Prevention Coalition joined by Chair and National Advisor Cancer Early Detection and Prevention Foundation along with members of the (OCEDPF) filed a “Citizen Petition Seeking Carcinogenic Labeling on All Cosmetic Talc Products” stating that research dating back to 1961 had shown that cosmetic grade talc could translocate to the ovaries in women and increase the risk of developing ovarian cancer. This petition was submitted to the Commissioner of the Food and Drug Administration under the Federal Food, Drug and Cosmetic Act. The petition requested that the FDA take the following action: “(1) [I]mmediately require cosmetic talcum powder products to bear labels with a warning such as “Talcum powder causes cancer in laboratory animals. Frequent talc application in the female genital area increases the risk of ovarian cancer.”

102. 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 talc users ranging from 30-60 %. IARC concluded with this “Overall evaluation” ”Perineal use of talc-based body powder is possibly carcinogenic to humans (Group 2B).”

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

104. In May 2008, the CPC, joined by its chairman and numerous other physicians and chairs of public health and medical associations, submitted a citizen’s petition “seeking a cancer warning on cosmetic talc products.” *The petition sought to require all cosmetic talc products to bear labels with warnings* such as “frequent application of talcum powder in the female genital area substantially increases the risk of ovarian cancer” or “Frequent talc application in the female genital area *is responsible* for major risks of ovarian cancer.” (Emphasis added). The petition cited numerous studies and publications and sought a hearing to present scientific evidence.

105. As of today, both the National Cancer Institute and American Cancer Society list genital talc use as a “risk factor” for ovarian cancer.

Defendants Awareness of the Dangers of Talcum Powder

106. Upon information and belief, shortly after Dr. Cramer’s 1982 study was published, Dr. Bruce Semple of Johnson & Johnson contacted 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.

107. The Johnson & Johnson Defendants publicly recognized the studies linking the use of its product to ovarian cancer. On August 12, 1982, In a New York Times article entitled “Talcum Company Calls Study on Cancer Link Inconclusive” the Defendants admitted being aware of the 1982 Cramer et al. article that concluded women were three (3) times more likely to contract ovarian cancer after daily use of their talcum powder in the genital area.

108. In 1992, after these various studies, the Personal Care Products Council f/k/a Cosmetic, Toiletry and Fragrance Association (CTFA) created the Talc Interested Party Task Force to defend the talc industry and help with public relations and talking points for press releases regarding the connection between talc and ovarian cancer. Defendant Johnson & Johnson and Imerys Talc America are members of this organization. Upon information and belief, this organization lobbied various organizations including the National Toxicology Program to prevent talc from being labeled a carcinogen.

109. On November 10, 1994, the Cancer Prevention Coalition (“CPC”) mailed a letter to then Johnson and Johnson CEO, Ralph Larson, informing Johnson & Johnson that studies as far back as 1960’s “show conclusively that the frequent use of talcum powder in the genital area poses a serious risk of ovarian cancer.” The letter cited a 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 the ovarian cancer risk they pose.

110. On September 17, 1997, Alfred Wehner a toxicology consultant retained by Johnson & Johnson, wrote a letter to Michael Chudowski, manager of Pre- Clinical Toxicology at Johnson & Johnson Consumer Products, Inc., stating that on three separate occasions the Talc Interested Party Task Force (TIPTF) of the Cosmetic, Toiletry, and Fragrance Association (CTFA) which included Johnson & Johnson Defendants and Imerys Talc America, had released false information to the public about the safety of talc. Specifically addressing a November 17, 1994, statement released by the CTFA, Dr. Wehner said the following:

The response statement dated November 17, 1994, is just as bad. The second sentence in the third paragraph reads: "The workshop concluded that, although some of these studies suggested a weak association might exist, when taken together the results of the studies are insufficient to demonstrate any real association." This statement is also inaccurate, to phrase it euphemistically. At that time there had been about 9 studies (more by now) published in the open literature that did show a statistically significant association between hygienic talc use and ovarian cancer. Anybody who denies this risks that the talc industry will be perceived by the public like it perceives the cigarette industry: denying the obvious in the face of all evidence to the contrary.

The workshop did not conclude that "the results of the studies are insufficient to demonstrate any real association." As pointed out above, a "real" statistically significant association has been undeniably established independently by several investigators, which without doubt will be readily attested to by a number of reputable scientists/clinicians, including Bernard Harlow, Debra Novotoy, Candace Sue Kasper, Debra Heller, and others.

111. In 2002, E. Edward Kavanaugh, The President of The Cosmetic, Toiletry, and Fragrance Association (CTFA), wrote a letter to Dr. Kenneth Olden, Director of the National Toxicology Program (NTP) and National Institute of Environmental Health Sciences, U.S. Department of Health and Human Services, in an attempt to stop the NTP from listing cosmetic talc for this classification. Upon information and belief, in this letter the CTFA admitted that talc was "toxic", that "some talc particles...can reach the human ovaries", and acknowledged

and agreed that prior epidemiologic studies have concluded that talc increases the risk of ovarian cancer in women.

112. In 2006, Imerys began placing an ovarian cancer warning on its Material Safety Data Sheets (MSDS) it provides to its talc customers, including Johnson & Johnson. *See* Exhibit “2”. A MSDS is a document that contains information on the potential health effects of exposure chemicals, or other potentially dangerous substances, and on the safe working procedures when handling chemical products. These MSDS sheets 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 2A” classification of talc as well. At the very least, the Johnson & Johnson Defendants would have received these MSDS or otherwise knew or should have known about them. Johnson & Johnson did not pass this warning information on to the consumers. On September 26, 2012, the corporate representative of Imerys testified in open court that his company exclusively supplied the Johnson & Johnson Defendants with talc used for its Baby Powder product and that ovarian cancer is a potential hazard associated with a women’s perineal use of talc-based body powders, like Johnson & Johnson’s Baby Powder.

113. On October 19, 2012, Johnson & Johnson Defendants’ former in-house toxicologist and current consulting toxicologist, Dr. John Hopkins, testified on Defendants’ behalf that Defendants “are and were aware of... all publications related to talc use and ovarian cancer.”

**Defendants Failed to Warn Consumers and the Public about the
Risks of Using Talcum Powder**

114. The Defendants had a duty to know and warn about the hazards associated with the use of its products, including their talc based products.

115. Despite the mounting scientific and medical evidence regarding talc use and ovarian cancer that has developed over the past several decades, none of Defendants' warnings on the product label or in other marketing informed Plaintiffs that use of the product in the genital area, as was encouraged and intended by Defendants, could lead to an increased risk of ovarian cancer. For example, the only warning on the Baby Powder label are to "Keep powder away from child's face to avoid inhalation, which can cause breathing problems," and to "avoid contact with eyes." The label also states: "SAFETY TIP: Keep out of reach of children. "Keep powder away from child's face to avoid inhalation, which can cause breathing problems. Avoid contact with the eyes. For external use only. Keep out of reach of children. Do not use if quality seal is broken". See <https://www.johnsonsbaby.com/powder/johnsons-baby-powder#safety-tip>).

116. The Johnson & Johnson Defendants continue to represent on the labeling and other marketing materials that Johnson's Baby Powder is "clinically proven mildness," "clinically proven to be safe, gentle and mild," and "that the safety of cosmetic talc is supported by decades of scientific evidence and independent peer reviewed studies."

117. All of the Defendants failed to inform their customers and end users of their products of a known catastrophic health hazard associated with the use of their products.

118. In addition, all of the Defendants procured and disseminated false, misleading, and biased information regarding the safety of their products to the public.

119. As a result of all of the Defendants calculated and reprehensible conduct Syrenthia Thrash incurred and suffered damages from contracting ovarian cancer which has required multiple surgeries and treatments.

120. All of the Defendants spent enormous amounts of money to market and promote a profitable drug, notwithstanding the known or reasonably known risks detailed above. Plaintiff 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 and did rely on all of the Defendants' representations.

Causes of Action - Theories of Recovery

COUNT ONE -STRICT LIABILITY- FAILURE TO WARN

(All Defendants)

121. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

122. At all pertinent times, Imerys Talc America mined and sold talc to the Johnson & Johnson Defendants, which it knew was then packaged and sold to consumers as Johnson's Baby Powder and "Shower to Shower", and it knew that consumers of these products were using it to powder their perineal regions.

123. At all pertinent times, Imerys Talc America knew or should have known of the unreasonably dangerous and carcinogenic nature of the talc it was selling to the Johnson & Johnson Defendants, especially when used on a women's perineal region, and it knew or should have known that Johnson & Johnson was not warning its consumers of this danger.

124. At all pertinent times, all of the Defendants were manufacturing, marketing, testing, promoting, selling and/or distributing the Talc Products in the regular course of business.

125. At all pertinent times, Syrenthia Thrash used the Talc Products to powder her perineal area which was a reasonably foreseeable use in a manner normally intended by the Defendants.

126. At all pertinent times, all 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 ovarian cancer based upon scientific knowledge dating back to the 1960's.

127. At all pertinent times, including the time of sale and consumption, the Talc Products, when used in a reasonably foreseeable manner, were in an unreasonably dangerous and defective condition because they failed to contain adequate and proper warnings and/or instructions regarding the increased risk of ovarian cancer associated with the use of the Talc Products by women when powder was applied to their perineal area. All of the Defendants failed to properly and adequately warn and instruct the Plaintiff about the risks and benefits of the Talc Products. Had Syrenthia Thrash received a warning that the use of the Talc Products on her genital area or on sanitary napkins would have significantly increased her risk of ovarian cancer, she would not have used the Talc Products in that manner. Her use of the Talc Products was a substantial factor in her development of ovarian cancer. As a proximate result of Defendants' design, manufacture, marketing, sale and distribution of the Talc Products, Syrenthia Thrash has been injured catastrophically, and has been caused severe pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort and economic damages.

128. The development of ovarian cancer by the Plaintiff was the direct and proximate result of the unreasonably dangerous and defective condition of the Talc Products at the time of

sale and consumption, including their lack of warnings; Plaintiff has suffered injuries and damages including but not limited to conscious pain, suffering and medical expenses.

129. All of the Defendants' Talc Products were defective because they failed to contain warnings and/or instructions, and breached express warranties and/or failed to conform to express factual representations upon which the Plaintiff justifiably relied in electing to use the products. The defect or defects made the products unreasonably dangerous to those persons, such as Syrenthia Thrash, who could reasonably be expected to use and rely upon the safety of such products. As a result, the defect or defects were a producing cause of the Plaintiff's injuries and damages.

130. All of the Defendants' Talc Products failed to contain, and continue to this day do not contain adequate warnings and/or instructions regarding the increased risk of ovarian cancer associated with the use of their products by women. The Talc Products also do not carry any warning advising that women avoid powder in the genital/perineum area or that it is unsafe to use the powders on sanitary napkins or feminine products. All of the Defendants continue to market, advertise, and expressly represent to the general public that talcum powders are safe for women to use regardless of application area. All of the Defendants continue to disseminate false and misleading marketing and advertising campaigns despite the scientific knowledge that dates back to the 1960's that their products increase the risk of ovarian cancer in women when used in the perineal area.

131. Alternatively, if this honorable Court finds that all of the Defendants did not have a duty to warn when Syrenthia Thrash began using the Talc Products or at each time she purchased them thereafter, they had a post-sale duty to warn, through advertising or public announcements as the science developed about the dangers of ovarian cancer from using talc products.

COUNT TWO -STRICT LIABILITY-DEFECTIVE DESIGN

(All Defendants)

132. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

133. At all pertinent times, all of the Defendants were responsible for designing, developing, manufacturing, marketing, testing, packaging, promoting, marketing, labeling, selling and/or distributing the Talc Products in the regular course of business.

134. The Talc Products are defective and unreasonably dangerous to consumers because the utility of the Talc Products does not outweigh the danger of developing ovarian cancer.

135. The Talc Products are defective in their design and/or formulation because they are not reasonably fit, suitable or safe for their intended purpose (including for use in the genital area or on the perineum) and their foreseeable risks including ovarian cancer exceed the benefits associated with their design and formulation.

136. At all pertinent times, Syrenthia Thrash used the Talc Products to powder her perineal area and her sanitary napkins, which was a reasonably foreseeable use in a manner intended by all of the Defendants.

137. At all pertinent times, all of the 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 ovarian cancer based upon scientific knowledge and data dating back to the 1960's.

138. At all pertinent times, the Talc Products were expected to reach, and did reach consumers in the State of, Delaware and throughout the United States, without substantial change in the condition in which they were sold.

139. At all times material to this action, the Talc Products were designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled and/or sold by all of the Defendants in a defective and unreasonably dangerous condition at the time they were placed in the stream of commerce in ways which include but are not limited to the following:

- a) When placed in the stream of commerce, the Talc Products contained unreasonably dangerous design defects and were not reasonably safe as intended to be used including dusting the perineum, subjecting Plaintiff to risks that exceeded the benefits of the subject product.
- b) When placed in the stream of commerce, the Talc Products were defective in design and formulation, specifically that the Talc Products contained Talc, making the use of the Talc Products more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other non-talc options on the market.
- c) The subject products 'design defects existed before they left the control of the Talc Products;
- d) The Talc Products were insufficiently tested;
- e) The Talc Products caused harmful side effects including ovarian cancer that outweighed any potential utility of deodorizing, preventing chaffing or other possible benefits; and
- f) The Talc Products were not accompanied by adequate instructions and/or warnings to fully apprise consumers, including Plaintiff herein, of their true nature and extent of the risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiffs.

140. As a result, the defect or defects were a producing cause of the Plaintiff's injuries and damages. Therefore, the Defendants are liable under the Doctrine of Strict Liability in Tort.

141. Johnson & Johnson continue to market, advertise, and expressly represent to the general public that it is safe for women to use their products regardless of application. Johnson

& Johnson continue to engage in false and misleading marketing and advertising campaigns despite having scientific knowledge that dates back to the late 1960's that their products increase the risk of ovarian cancer in women when used in the perineal area.

142. In addition, at the time the subject products left the control of Johnson & Johnson there were practical and feasible alternative designs including cornstarch based powders that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the product. These safer alternative designs were economically and technologically feasible, and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the product's utility.

143. As a direct and proximate result of the Talc Products' defective design, Plaintiff suffered severe and permanent physical injuries. The Plaintiff endured substantial pain and suffering. She incurred significant expenses for medical care and treatment. The Plaintiff seeks actual and punitive damages from the Defendants for the reasons alleged herein.

COUNT THREE – NEGLIGENCE

(As to Imerys Defendants)

144. The Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

145. At all pertinent times, Defendants had a duty to exercise reasonable care toward consumers, including Plaintiff herein, in the design, development, manufacture, testing,

inspection, packaging, promotion, marketing, distribution, labeling and/or sale of the Talc Products.

146. At all pertinent times, Imerys Talc America mined and sold talc to the Johnson & Johnson Defendants, which it knew and/or should have known was then packaged and sold to consumers as the Talc Products by the Johnson and Johnson Defendants. Further, Imerys Talc America knew and/or should have known that consumers of the Talc Products were using it to powder their perineal regions.

147. At all pertinent times, Imerys Talc America knew or should have known that the use of talcum powder based products in the perineal area significantly increases the risk of ovarian cancer in the perineal area based upon scientific knowledge dating back to the 1960s.

148. At all pertinent times, Imerys Talc America knew or should have known that the Johnson & Johnson Defendants were not providing warnings to consumers of the Talc Products of the risk of ovarian cancer posed by talc contained therein.

149. At all pertinent times, Imerys Talc America was negligent in providing talc to the Johnson & Johnson Defendants, because it knew or should have known that the talc would be used in the Talc Products, without adequately taking steps to ensure that ultimate consumers of the Talc Products, including Plaintiff, received the information that Imerys Talc America possessed or could have possessed concerning the carcinogenic properties of talc, including its risk of causing ovarian cancer.

150. As a direct and proximate result of Imerys Talc's negligence Plaintiff purchased and used the Talc Products that caused her to develop ovarian cancer; Plaintiff incurred medical bills, conscious pain, and suffering. Plaintiff was caused to sustain damages as a direct and proximate result of Imerys Talc Defendants negligence.

COUNT FOUR – NEGLIGENCE

(Johnson & Johnson Defendants)

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

152. The Johnson & Johnson Defendants were negligent in marketing, designing, manufacturing, packaging, labeling, supplying, inspecting testing, selling and/or distributing the Talc Products in the following ways, each of which was a proximate cause of Plaintiff's injuries and damages:

- a) In failing to warn Plaintiff of the hazards associated with the use of their product, including the risk of ovarian cancer when the product is used in the genital area, in the perineal area or on sanitary napkins;
- b) In failing to properly test their Talc Products to determine adequacy and effectiveness or safety measures, if any, prior to releasing these products for consumer use;
- c) In failing to properly test their products to determine the increased risk of ovarian cancer during the normal and/or intended use of the Talc Products;
- d) In failing to inform ultimate users, such as Plaintiff as to the safe and proper methods of handling and using their Talc Products;
- e) In failing to remove their products from the market or adding proper warnings when the Defendants knew or should have known their Talc Products were defective;
- f) In failing to instruct the ultimate users, such as Plaintiff, as to the methods for reducing the type of exposure to the Defendants' Talc Products which caused increased risk in ovarian cancer;
- g) In failing to inform the public in general and the Plaintiff in particular of the known dangers of using the Defendants' Talc Products for dusting the perineum;

- h) In failing to advise users how to prevent or reduce exposure that caused increase risk for ovarian cancer;
- i) Marketing and labeling their product as safe for all users despite knowledge to the contrary; and,
- j) In failing to act like a reasonably prudent company under similar circumstances.

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

154. At all pertinent times, the Defendants knew or should have known that the Talc Products were unreasonably dangerous and defective when put to their reasonably anticipated and intended use.

155. As a direct and proximate result of Defendants' negligence Plaintiff purchased and used the Talc Products that caused her to develop ovarian cancer; Plaintiff incurred medical bills, conscious pain and suffering. Plaintiff was caused to sustain damages as a direct and proximate result of Defendants' negligence.

COUNT FIVE– BREACH OF EXPRESS WARRANTY

(Johnson & Johnson Defendants and Defendant Valeant Pharmaceuticals NA)

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

157. The Johnson & Johnson Defendants and Defendant Valeant Pharmaceuticals NA, expressly warranted through direct-to-consumer marketing, advertisements, and labels, that the Talc Products were safe and effective for reasonably anticipated uses, including use by women on the perineal area and on sanitary napkins.

158. Syrenthia Thrash saw these advertisements, including television commercials, and believed the Talc Products were safe and effective to use on her perineal area.

159. The Talc Products did not conform to these express representations in Violation of **Alabama statutory and common law** because they cause serious injury when used by women in the perineal area in the form of ovarian cancer and were not fit for the ordinary purpose for which the Talc Products were sold.

160. As a direct and proximate result of Defendants' breach of warranty, Plaintiff purchased and used, the Talc Products that directly and proximately caused Plaintiff to develop ovarian cancer.

COUNT SIX– BREACH OF IMPLIED WARRANTY

(Johnson & Johnson Defendants and Defendant Valeant Pharmaceuticals NA)

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

162. At the time the Defendants designed, manufactured, assembled, fabricated, labeled, packaged, sold and/or distributed the Talc Products, the Defendants knew of the uses for which the Talc Products were intended, including use by women in the perineal area, and impliedly warranted the Talc Products to be of merchantable quality and safe for such intended and foreseeable use.

163. The Defendants, as sellers were merchants with respect to the Talc Products which they sold.

164. Defendants sold these Talc Products in a defective condition and therefore breached an implied warranty of fitness and an implied warranty of merchantability. Additionally, Defendants breached their implied warranties of the Talc Products sold to Plaintiff because the Talc Products were not fit for their common, ordinary and intended uses, included use by women on the perineal area.

165. Therefore the Defendants have breached the implied warranty or merchantability as well as the implied warranty of fitness for a particular purpose as in **Violation of** Alabama statutory and common law. Such breach by the Defendants was a proximate cause of the injuries and damages sustained by Plaintiff.

166. As a direct and proximate result of Defendants' breach of implied warranty, Plaintiff purchased and used the Talc Products that caused her to develop ovarian cancer; Plaintiff incurred medical bills and conscious pain and suffering. Plaintiff was caused to sustain damages as a direct and proximate result of Defendants' negligence.

COUNT SEVEN– CIVIL CONSPIRACY

(All Defendants)

167. All of the allegations contained in the previous paragraphs are re-alleged herein.

168. Defendants and/or their predecessors-in-interest knowingly agreed, contrived, combined, confederated and conspired among themselves to cause Plaintiff's injuries, disease, and/or illnesses by exposing Plaintiff to harmful and dangerous products. Defendants further knowingly agreed, contrived, confederated and conspired to deprive

Plaintiff of the opportunity of informed free choice as to whether to use said products or to expose themselves to said dangers. Defendants committed the above described wrongs by willfully misrepresenting and suppressing the truth as to the risks and dangers associated with the use of and exposure to Defendants' products.

169. In furtherance of said conspiracies, Defendants performed the following overt acts:

- a) For many decades, Defendants, individually, jointly, and in conspiracy with each other, have been in possession of medical and scientific data, literature and test reports which clearly indicated that use of their products by women resulting from the ordinary and foreseeable use of the above described products were unreasonable dangerous, hazardous, deleterious to human health, carcinogenic, and potentially deadly;
- b) Despite the medical and scientific data, literature, and test reports possessed by and available to Defendants, Defendants individually, jointly, and in conspiracy with each other, fraudulently, willfully and maliciously:
 - i. Withheld, concealed and suppressed said medical information regarding the increased risk of ovarian cancer from Plaintiff. In addition, on July 27, 2005 the Johnson and Johnson Defendants as part of the TIPTF corresponded and agreed to edit and delete portions of scientific papers being submitted on their behalf to the United States Toxicology Program in an attempt to prevent talc from being classified as a carcinogen;
 - ii. The Johnson and Johnson Defendants through the TIPTF instituted a "defense strategy" to defend talc at all costs. Admittedly, the Defendants through the TIPTF used their influence over the NTP subcommittee, and the threat of litigation against the NTP to prevent the NTP from classifying talc as a carcinogen on its 10th ROC. According to the Defendants, "...we believe these strategies paid off"; and,
 - iii. Caused to be released, published and disseminated medical and scientific data, literature, and test reports containing information and statements regarding the risks of ovarian cancer which defendants knew were incorrect, incomplete, outdated, and misleading. Specifically, the Defendants through the TIPTF collectively agreed to release false information to the public regarding the safety of talc on July 1, 1992; July 8, 1992; and November 17, 1994. In a letter dated September 17, 1997, the Defendants were criticized by their own Toxicologist consultant for releasing this false information to the public, yet nothing was done by the

Defendants to correct or redact this public release of knowingly false information.

- c) By these false and fraudulent representations, omissions, and concealments, Defendants intended to induce the Plaintiff to rely upon said false and fraudulent representations, omissions and concealments, and to continue to expose herself to the dangers inherent in the use of and exposure to Defendants' products.

170. Plaintiff reasonably and in good faith relied upon false and fraudulent representations, omissions, and concealments made by Defendants regarding the nature of their products.

171. As a direct and proximate result of Plaintiff's reliance, Plaintiff has sustained damages including injuries, illnesses and was deprived of the opportunity of informed free choice in connection with the use of and exposure to Defendants' Talc Products.

COUNT EIGHT- CONCERT OF ACTION

(All Defendants)

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

173. At all pertinent times, Defendants, and the Personal care and Products Council (PCPC) knew that the Talc Products should contain warnings concerning the risk of ovarian cancer posed to women using the product to powder the perineal region, but purposefully sought to suppress such information and omit from talc based products any such warnings so as not to negatively affect sales and maintain the profits of the Defendants.

174. Additionally and/or alternatively, the Defendants aided and abetted each other in the negligence, and reckless misconduct. Pursuant to the Restatement (second) of Torts section 876, each of the Defendants is liable for the conduct of the other Defendants for whom they aided and abetting.

COUNT NINE- GROSS NEGLIGENCE

(All Defendants)

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

176. The Defendants' conduct was in conscious disregard for the rights, safety and welfare of the Plaintiff. The Defendants acted with willful and wanton disregard for the safety of the Plaintiff. The Defendants' conduct constitutes gross negligence. Defendants' gross negligence was a proximate cause of Plaintiff's injuries, and as such the Defendants are liable for exemplary and punitive damages.

177. The Johnson & Johnson Defendants have a pattern and practice of this type of conduct. Specifically, these Defendants built their company on the credo, "We believe our first responsibility is to the doctors, nurses, and patients, to mothers and fathers and all others who use our products and services." The Defendants place emphasis on shareholders believing that if they take care of everything the ethical and correct way profits will follow. However, over the past few decades, the Defendants have sharply deviated from their original credo, and instituted a corporate pattern and practice of placing premium on profits over the health and well-being of its customers as evidenced

by the Propulsid litigation, Ortho Evra litigation, 2006 Pennsylvania Tylenol litigation, 2006 TMAO investigation, and 2007 violation of the Foreign Corrupt Practices Act.

178. The above listed evidence indicates a pattern and practice of the Johnson & Johnson Defendants to place corporate profits over the health and well-being of its customers. Such a pattern and practice has been followed by the Defendants regarding “Johnson’s Baby Powder” and “Shower to Shower”.

COUNT TEN- NEGLIGENT MISREPRESENTATIONS

(All Defendants)

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

180. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff and the public that the products at issue 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.

181. Defendants failed to exercise ordinary care in the representations concerning the Talc Products while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented the Talc Products high risk of unreasonable, dangerous, adverse side effects, including the risk of ovarian cancer.

182. Defendants breached their duty in representing that the Talc Products have no serious side effects.

183. As a foreseeable, direct and proximate result of the negligent misrepresentations of Defendants as set forth herein, Defendants knew, and had reason to know, that the Talc Products had been insufficiently tested, or had not been tested at all, and that they lacked adequate and accurate warning, and that it created a high risk, and/or higher than acceptable risk, and/or higher than reported and represented risk, or adverse side effects.

184. As a direct and proximate result of Defendants' conduct, Plaintiff has been injured and sustained severe pain, suffering, loss of enjoyment of life, loss of care and comfort and economic damages.

COUNT ELEVEN- PUNITIVE DAMAGES

(All Defendants)

185. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein.

186. The Defendants have acted willfully, wantonly, with an evil motive, and recklessly.

187. In one or more of the following ways:

- a. Defendants knew of the unreasonably high risk of ovarian cancer posed by the Talc Products before manufacturing, marketing, distributing and/or selling the Talc Products, yet purposefully proceeded with such action;
- b. Despite their knowledge of the high risk of ovarian cancer associated with the Talc Products, Defendants affirmatively minimized this risk through marketing and promotional efforts and product labeling; and,
- c. Through the actions outlined above, Defendants exhibited a reckless indifference to the safety of users of the Talc Products, including Plaintiff, as described herein,

knowing the dangers and risks of the Talc Products, yet concealing and/or omitting this information in furtherance of their conspiracy. The concerted action was outrageous because of Defendants' evil motive or a reckless indifference to the safety of users of the Talc Products, including Plaintiff.

188. As a direct and proximate result of the willful, wanton, evilly motivated and/or reckless conduct of the Defendants, the Plaintiff has sustained damaged as set forth above.

189. All of the Defendants have been or should have been aware for nearly forty (40) years of independent scientific studies linking the use of their products to the increased risk of ovarian cancer in women when used in the perineal area. Despite this overwhelming body of evidence all of the Defendants have failed to inform their consumers of this known hazard. As such, all of the Defendants should be liable for punitive damages to the Plaintiff.

DAMAGES

190. Plaintiff respectfully requests the following damages be considered separately and individually for the purpose of determining the sum of money that will fairly and reasonably compensate plaintiff:

- a. Medical Expenses;
- b. Pain and Suffering;
- c. Mental Anguish, Anxiety, and Discomfort;
- d. Physical Impairment;
- e. Loss of Enjoyment of Life;
- f. Pre and post judgment interest;

- g. Exemplary and Punitive Damages;
- h. Treble damages and;
- i. Reasonable and necessary attorneys fees.

WHEREFORE, Plaintiff demands judgment against each of the Defendants jointly and severally for such sums, including, but not limited to prejudgment and post-judgment interest, as would be necessary to compensate the Plaintiff for the injuries suffered or will suffer. Plaintiff further demands judgment against each of the Defendants for punitive damages. Plaintiff further demands payment by each of the Defendants jointly and severally of the costs and attorney fees of this action. Plaintiff further demands payment by each Defendant jointly and severally of interest on the above and such other relief as the Court deems just.

DEMAND FOR JURY TRIAL

The Plaintiffs hereby demand a trial by jury on all counts and as to all issues.

NAPOLI SHKOLNIK, LLC

By: /s/ James D. Heisman
James D. Heisman (#2746)
919 North Market Street, Suite 1801
Wilmington, DE 19801
(302) 330-8025
JHeisman@NapoliLaw.com
Attorney for Plaintiff

OF COUNSEL

Hunter Shkolnik
Napoli Shkolnik, PLLC
400 Broadhollow, Suite 305
Melville, NY 11747

(631) 224-1131
HShkolnik@Napolilaw.com

Dated: May 1, 2017

**SUPERIOR COURT
CIVIL CASE INFORMATION STATEMENT (CIS)**

E-Filed: May 02 2017 02:23PM EDT
Transaction ID 60544640
Case No. N17C-05-029 TAL



COUNTY: N K S

CIVIL ACTION NUMBER: _____

<p>Caption: Syrenthia Thrash v.</p> <hr/> <p>JOHNSON & JOHNSON; JOHNSON & JOHNSON CONSUMER COMPANIES, INC.;</p> <hr/> <p>IMERYS TALC AMERICA, INC., F/K/A LUZENAC AMERICA, INC.; IMERYS TALC DELAWARE, INC.;</p> <hr/> <p>U.S. BORAX, INC.; RIO TINTO MINERALS INC.; RIO TINTO MINERAL SERVICES INC.;</p> <hr/> <p>AND VALEANT PHARMACEUTICALS NORTH AMERICA, LLC;</p> <hr/> <p>_____</p> <hr/> <p>_____</p>	<p>Civil Case Code: <u>CTAL</u></p> <p>Civil Case Type: <u>CTAL - Talc Products Liability</u> (SEE REVERSE SIDE FOR CODE AND TYPE)</p> <p>Name and Status of Party filing document: Syrenthia Thrash</p> <hr/> <p>Document Type: (E.G.; COMPLAINT; ANSWER WITH COUNTERCLAIM) Complaint</p> <hr/> <p>JURY DEMAND: YES <input checked="" type="checkbox"/> NO <input type="checkbox"/></p>
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<p>ATTORNEY NAME(S): James D. Heisman</p> <hr/> <p>ATTORNEY ID(S): 2746</p> <hr/> <p>FIRM NAME: Napoli Shkolnik, LLC</p> <hr/> <p>ADDRESS: 919 North Market Street, Suite 1801</p> <hr/> <p>Wilmington, DE 09801</p> <hr/> <p>TELEPHONE NUMBER: 302-330-8025</p> <hr/> <p>FAX NUMBER: 646-843-7603</p> <hr/> <p>E-MAIL ADDRESS: JHeisman@Napolilaw.com</p> <hr/> <p>_____</p>	<p>IDENTIFY ANY RELATED CASES NOW PENDING IN THE SUPERIOR COURT OR ANY RELATED CASES THAT HAVE BEEN CLOSED IN THIS COURT WITHIN THE LAST TWO YEARS BY CAPTION AND CIVIL ACTION NUMBER INCLUDING JUDGE'S INITIALS:</p> <hr/> <p>_____</p> <hr/> <p>EXPLAIN THE RELATIONSHIP(S):</p> <hr/> <p>_____</p> <hr/> <p>OTHER UNUSUAL ISSUES THAT AFFECT CASE MANAGEMENT:</p> <hr/> <p>_____</p> <hr/> <p>_____</p> <hr/> <p>(IF ADDITIONAL SPACE IS NEEDED, PLEASE ATTACH PAGE)</p>
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THE PROTHONOTARY WILL NOT PROCESS THE COMPLAINT, ANSWER, OR FIRST RESPONSIVE PLEADING IN THIS MATTER FOR SERVICE UNTIL THE CASE INFORMATION STATEMENT (CIS) IS FILED. THE FAILURE TO FILE THE CIS AND HAVE THE PLEADING PROCESSED FOR SERVICE MAY RESULT IN THE DISMISSAL OF THE COMPLAINT OR MAY RESULT IN THE ANSWER OR FIRST RESPONSIVE PLEADING BEING STRICKEN.

SUPERIOR COURT CIVIL CASE INFORMATION STATEMENT (CIS) INSTRUCTIONS

CIVIL CASE TYPE

Please select the appropriate civil case code and case type (e.g., **CODE** - **AADM** and **TYPE** - **Administrative Agency**) from the list below. Enter this information in the designated spaces on the Case Information Statement.

<p>APPEALS AADM - Administrative Agency ACER - Certiorari ACCP - Court of Common Pleas AIAB - Industrial Accident Board APSC - Public Service Commission AUIB - Unemployment Insurance Appeal Board</p> <p>COMPLAINTS CABT - Abatement CASB - Asbestos CAAA - Auto Arb Appeal CMIS - Civil Miscellaneous CACT - Class Action CCON - Condemnation CCLD - Complex Commercial Litigation Division (NCC ONLY) CDBT - Debt/Breach of Contract CDEJ - Declaratory Judgment CDEF - Defamation CEJM - Ejectment CATT - Foreign & Domestic Attachment CFJG - Foreign Judgment CFRD - Fraud Enforcement CINT - Interpleader CLEM - Lemon Law CLIB - Libel CMAL - Malpractice CMED - Medical Malpractice CPIN - Personal Injury CPIA - Personal Injury Auto CPRL - Products Liability CPRD - Property Damage CRPV - Replevin CSPD - Summary Proceedings Dispute CCCP - Transfer from CCP CCHA - Transfer from Chancery</p> <p>MASS TORT CBEN - Benzene Cases CPEL - Pelvic Mesh Cases CPLX - Plavix Cases CXAR - Xarelto Cases</p> <p>INVOLUNTARY COMMITMENTS INVC - Involuntary Commitment</p>	<p>MISCELLANEOUS MAGM - AG Motion - Civil/Criminal Investigations * MADB - Appeal from Disability Board * MAFF - Application for Forfeiture MAAT - Appointment of Attorney MGAR - Appointment of Guardianship MCED - Cease and Desist Order MCON - Civil Contempt/Capias MCVP - Civil Penalty MSOJ - Compel Satisfaction of Judgment MSAM - Compel Satisfaction of Mortgage MCTO - Consent Order MIND - Destruction of Indicia of Arrest * MESP - Excess Sheriff Proceeds MHAC - Habeas Corpus MTOX - Hazardous Substance Cleanup MFOR - Intercept of Forfeited Money MISS - Issuance of Subpoena MLEX - Lien Extension MMAN - Mandamus MWIT - Material Witness * MWOT - Material Witness - Out of State MRAT - Motion for Risk Assessment MROP - Petition for Return of Property MCRO - Petition Requesting Order MROD - Road Resolution MSEL - Sell Real Estate for Property Tax MSEM - Set Aside Satisfaction of Mortgage MSSS - Set Aside Sheriff's Sale MSET - Structured Settlement MTAX - Tax Ditches MREF - Tax Intercept MLAG - Tax Lagoons MVAC - Vacate Public Road MPOS - Writ of Possession MPRO - Writ of Prohibition</p> <p>MORTGAGES MCOM - Mortgage Commercial MMED - Mortgage Mediation MORT - Mortgage Non-Mediation (Res.)</p> <p>MECHANICS LIENS LIEN - Mechanics Lien</p>
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*** Not eFiled**

DUTY OF THE PLAINTIFF

Each plaintiff/counsel shall complete the attached Civil Case Information Statement (CIS) and file with the complaint.

DUTY OF THE DEFENDANT

Each defendant/counsel shall complete the attached Civil Case Information Statement (CIS) and file with the answer and/or first responsive pleading.



IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

Syrenthia Thrash)	
Plaintiff,)	
)	C.A. No.:
v.)	
)	Jury Trial Demanded
JOHNSON & JOHNSON; JOHNSON & JOHNSON)	
CONSUMER COMPANIES, INC.; IMERYS TALC)	
AMERICA, INC., F/K/A LUZENAC AMERICA,)	
INC.; IMERYS TALC DELAWARE, INC.; U.S.)	
BORAX, INC.; RIO TINTO MINERALS INC., RIO)	
TINTO MINERAL SERVICES INC.; AND)	
VALEANT PHARMACEUTICALS NORTH)	
AMERICA, LLC;)	
)	
Defendants.)	
)	
)	
)	

PLAINTIFF'S ANSWERS TO FORM 30 INTERROGATORIES

1. Give the name and present or last-known residential and employment address and telephone number of each eyewitness to the incident which is the subject of the litigation.

ANSWER:

To be supplemented, if applicable.

2. Give the name and present or last-known residential and employment address and telephone number of each person who has knowledge of the facts relating to the litigation.

ANSWER:

Plaintiff, who may be contacted only through the undersigned counsel. Plaintiff's treating physicians. The names and contact information of said treating physicians will be supplied by plaintiff. To be supplemented, if applicable.

3. Give the names of all persons who have been interviewed in connection with the above litigation, including the names and present or last-known residential and employment addresses and telephone numbers of the persons who made said interviews and the names

and present or last-known residential and employment addresses and telephone numbers of persons who have the original and copies of the interview.

ANSWER: None.

4. Identify all photographs, diagrams, or other representations made in connection with the matter in litigation, giving the name and present or last-known residential and employment address and telephone number of the person having the original and copies thereof. (In lieu thereof, a copy can be attached.)

ANSWER: None currently in possession.

5. Give the name, professional address, and telephone number of all expert witnesses presently retained by the party together with the dates of any written opinions prepared by said expert. If an expert is not presently retained, describe by type the experts whom the party expects to retain in connection with the litigation.

ANSWER: Experts in epidemiology, Experts in blood clotting, FDA Regulatory Experts, Causation Experts, Damages Experts and other experts will be retained.

6. Give a brief description of any insurance policy, including excess coverage, that is or may be applicable to the litigation, including:
 - a. The name and address of all companies insuring the risk;
 - b. The policy number(s);
 - c. The type of insurance;
 - d. The amounts of primary, secondary, and excess coverage.

ANSWER: Not Applicable

7. Give the name, professional address, and telephone number of all physicians, chiropractors, psychologists, and physical therapists who have examined or treated you at any time during the ten year period immediately prior to the date of the incident at issue in this litigation.

ANSWER: To be supplemented.

NAPOLI SHKOLNIK, LLC

By: /s/ James D. Heisman
James D. Heisman (#2746)
919 North Market Street, Suite 1801
Wilmington, DE 19801
(302) 330-8025
JHeisman@NapoliLaw.com
Attorney for Plaintiff

OF COUNSEL

Hunter Shkolnik
Napoli Shkolnik, PLLC
400 Broadhollow, Suite 305
Melville, NY 11747
(631) 224-1131
HShkolnik@Napolilaw.com
Attorney for Plaintiffs
(to be admitted Pro Hac Vice)

Dated: May 1, 2017



EXHIBIT 1 – SEPTEMBER 17TH
LETTER FROM ALFRED P. WEHNER

ALFRED P. WEHNER, D.M.D., Sc.D., CAND. MED.
DIPLOMATE, ACADEMY OF TOXICOLOGICAL SCIENCES
312 SAINT STREET
RICHLAND, WASHINGTON 99352

9/17/97

Mr. Michael R. Chudkowski
Manager, Preclinical Toxicology
J&J Consumer Products, Inc.
Skillman, NJ 08558-9418

Dear Mike:

There is a German saying which translates as follows:

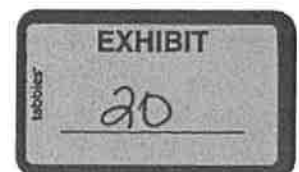
"A true friend is not he who beguiles you with flattery
but he who discloses to you your mistakes
before your enemies discover them."

In this spirit I would like to volunteer a critique of the three CTFA response statements which you faxed me on September 11. Some of the wording leaves CTFA wide open to counter-attack. The most harmless response statement of the three is the one dated July 1, 1992. It does not give the names of the authors and the title of the paper to which the response is being made. More important, I believe that different and/or additional more powerful statements along the lines of my critique faxed to Jerry McEwen, as far as applicable to the situation in 1992, would have put CTFA in a more advantageous tactical position. Several investigators have independently reported talc particles in ovarian tissue. Simply citing the Battelle study and stating that it "demonstrated that talc does not translate (sic!) through the cervix to the uterine cavity and beyond" does not address the problem, does not refute these findings, and therefore does not serve CTFA's best interest. All in all, in my opinion an inept response.

The problem with the response statement dated July 8, 1992, is more serious. The last sentence in the second paragraph states: "Finally, human studies on talc and cancer in industrial settings have shown that industrial exposure to talc, both by skin contact and inhalation, even at levels thousands of times higher than lifetime consumer exposure, presents no significant risk." This statement is outright false. All an Epstein, a Kennedy, or one of their aides knowledgeable in matters talc, would have to do at a hearing (or any occasion, at that) to demolish the credibility of the talc industry is to refer to the studies by Kleinfeld et al, Thomas, and Thomas and Stewart!

Referring in a 1992 statement to a 1977 editorial in defense of one's position is not a very persuasive argument. Much can happen in 15 years.

509/375-0873 FAX 509/375-5693



J&J-0115063

Here, too, I believe that more powerful and better defensible arguments could and should have been made on behalf of the industry.

The response statement dated November 17, 1994, is just as bad. The second sentence in the third paragraph reads: "The workshop concluded that, although some of these studies suggested a weak association might exist, when taken together the results of the studies are insufficient to demonstrate any real association." This statement is also inaccurate, to phrase it euphemistically. At that time there had been about 9 studies (more by now) published in the open literature that did show a statistically significant association between hygienic talc use and ovarian cancer. Anybody who denies this risks that the talc industry will be perceived by the public like it perceives the cigarette industry: denying the obvious in the face of all evidence to the contrary. This would be a particularly tragic misperception in view of the fact that the industry does have powerful, valid arguments to support its position.

The workshop did not conclude that "the results of the studies are insufficient to demonstrate any real association." As pointed out above, a "real" statistically significant association has been undeniably established independently by several investigators, which without doubt will be readily attested to by a number of reputable scientists/clinicians, including Bernard Harlow, Debra Novotny, Candace Sue Kasper, Debra Heller, and others. What the workshop panel did conclude was that (1) the results of the studies were ambiguous, inconsistent, contradictory and therefore inconclusive, (2) therefore hygienic use of cosmetic talc does not present a risk to the consumer. So why not use these powerful and irrefutable arguments (plus some of those along the lines of my fax to Rich) instead of questionable mush that leaves one vulnerable to counterattack? The following sentence states: "In addition there is no basis to conclude that talc is capable of migrating to the ovaries...". I submit that several reports, independently describing talc particles in/on ovarian tissue, along with other suggestive evidence (questionable as some of it might be) does provide a basis for just such a conclusion. My point is that such a complex and vexing issue cannot be credibly dismissed with one sweeping statement without any documenting references.

Nike, I realize that CTFA is not J&J. However, I believe that a defeat or embarrassment of CTFA also negatively affects J&J to some extent. As a consultant on a retainer I feel obligated to proactively act in the best interest of my client at all times, not only when I am approached with a specific assignment. This consideration alone motivated me to spend the time to bring my thoughts on this matter to your attention. I trust that in the process I did not step on anybody's toes.

Best regards

AL

J&J-0115054

JNJ 000040597



EXHIBIT 2 – MATERIAL SAFETY DATA SHEET



Distributed by:
Laguna Clay Company
14400 Lomitas Ave
City of Industry, CA 91746
1-800-4Laguna
info@lagunaclay.com
www.lagunaclay.com

Material Safety Data Sheet

Version: 1.0
Revision date: October 18, 2011

Section 1. Chemical Product and Company Identification

Product name:

Aquatal 303 Compacted	Mistron EG Powder	Nicron 402 Powder
Beaverwhite 325 Powder	Mistron FC 002 Powder	Nicron 403 Powder
Cimpact 699 Powder	Mistron Frost Powder	Nicron 503 Powder
EZ Flow 40 Powder	Mistron Monomix Powder	Nicron 504 Powder
EZ Flow MT Powder	Mistron Monomix TS-M	Nicron 554 Powder
EZ Flow RM Powder	Mistron RCS Powder	Nicron 604 Powder
Helicote MT Compacted	Mistron RCS AC Powder	Nicron 660 Powder
Mistrofil MT Compacted	Mistron RCS C Powder	Nicron 665 Powder
Mistrofil CP 3 Compacted	Mistron Superfrost Powder	Nicron 674 Powder
Mistrofil CP 5 Compacted	Mistron Ultramix Powder	Nicron 674DT
Mistron 100 Compacted	Mistron Vapor Powder	Silverline 002 Powder
Mistron 100 Powder	Mistron Vapor Compacted	Silverline 202 Powder
Mistron 100DT	Mistron Vapor 6 Powder	Silverline 202 GE Powder
Mistron 102 Compacted	Mistron Vapor RE Powder	Silverline 303 Powder
Mistron 002 Powder	Mistron Vapor RE Compacted	Silverline 403 Powder
Mistron 353 Powder	Mistron Vapor R Compacted	Silverline 503DT
Mistron 400C Powder	Mistron Vapor R Powder	Steasilk YC Compacted
Mistron 403 Powder	Mistron Vapor R Densified	Steawhite 2 Powder
Mistron 403B Powder	Nicron 002 Powder	Steawhite TS60 Powder
Mistron 554 Powder	Nicron 302 Powder	Talcoliva TF Powder
Mistron AB Powder	Nicron 303 Powder	Yellowstone Powder
Mistron CF5A-M Powder	Nicron 353 Powder	Yellowstone AC Powder
		Yellowstone C Powder

CAS Registry Number: 14807-96-6

Product use: Functional mineral for use in paper, paints, ceramics, plastics, personal care, etc.

Chemical Formula: $3\text{MgO}\cdot 4\text{SiO}_2\cdot \text{H}_2\text{O}$

Chemical Name: Hydrous magnesium silicate

Synonyms: Talc, Soapstone, Steatite

Chemical Family: Silicate

Manufacturer

Company name	Imerys Talc America, Inc.
Address	767 Old Yellowstone Trail Three Forks, MT 59752 USA
Tel:	+1 406-285-5300
Fax:	+1 406-285-3323
E-mail:	msds.talcamerica@imerys.com

Emergency telephone number: +1 303 623 5716

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Material Safety Data Sheet

Section 2. Composition / Information on ingredients

Talc is a natural association of talc, chlorite, dolomite and magnesite.

Main constituents	EINECS	CAS.	Amount (%)
Talc	238-877-9	14807-96-6	>96
Chlorite	215-285-9	1318-59-8	<2
Dolomite	240-444-2	16389-88-1	<2
Magnesite	208-915-9	546-93-0	<2

Section 3. Hazard Identification

Emergency Overview: Under normal conditions of use, this product is not expected to create any unusual emergency hazard. This product is NOT flammable, NOT reactive, NOT explosive, has No flash point, and poses no special hazards in the presence of fire.

Potential Health Effects

Route of Exposure: Inhalation is the primary route of exposure

Inhalation:

Acute: Exposure to a large concentration of air-borne dust of this material may cause mechanical irritation of the mucous membranes and respiratory tract.

Chronic: Repeated and prolonged exposure to large amount of talc dust might induce a mild pneumoconiosis. This is caused by lung overload exposure, a non specific particle effect, rather than a specific intrinsic fibrogenic activity of talc.

Skin Contact:

Acute: Direct contact may cause dryness or mild irritation if an allergic predisposition exists

Chronic: Prolonged contact may cause dryness of skin or mild irritation if an allergic predisposition exists

Eye Contact:

Acute: Direct contact with dust may cause mechanical irritation of the eyes

Chronic: Repeated exposure may cause conjunctive inflammation

Ingestion:

Acute: This material is considered to be harmless and inert when ingested.

Chronic: Repeated ingestion of large doses of talc for 13 and 10 successive days by rabbits and mice revealed negative teratogenic and carcinogenic results.

Section 4. First-aid Measures

Eye contact: Rinse with copious quantities of water for at least 15 minutes and seek medical attention if irritation persists.

Skin contact: No special first aid measures necessary.

Inhalation: No special first aid measures. Remove to fresh air and get medical attention in case of serious respiratory problems.

Ingestion: No first aid measures required.

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Material Safety Data Sheet

Section 5. Fire-fighting Measures

Extinguishing media: All extinguishing media can be used.

Special hazards arising from the substance or mixture: The product is not flammable, combustible or explosive. No hazardous thermal decomposition.

Advice for fire-fighters: No specific fire-fighting protection is required. Use an extinguishing agent suitable for the surrounding fire.

Section 6. Accidental Release Measures

Personal precautions, protective equipment and emergency procedures: Avoid airborne dust generation. If the generation of dust is likely, personal protective equipment should be worn in compliance with national legislation.

Environmental precautions: No special requirements. Contain spillage and clean up as indicated below.

Methods and material for containment and cleaning up: Dry product should be cleaned with a shovel or vacuum cleaner while wearing personal protective equipment in compliance with national legislation. Washing the floor with water is not recommended since it may cause the floor to become slippery. However, if talc is already wet, and only in this case, the floor should be thoroughly flushed with water to remove all slipperiness. Talc is not considered a hazardous waste as defined by the US EPA RCRA (40 CFR 261) regulations. Observe all applicable federal, state and local regulations when handling, storing or disposing of this substance.

Section 7. Handling and Storage

Precautions for safe handling: Avoid airborne dust generation. Provide appropriate exhaust ventilation at places where airborne dust is generated. In case of insufficient ventilation, wear suitable respiratory protective equipment. Handle packaged products carefully to prevent accidental bursting. If you require advice on safe handling techniques, please contact your supplier.

Conditions for safe storage: Keep the product dry and in closed containers.

Section 8. Exposure Controls / Personal Protection

Control parameters: Follow workplace regulatory exposure limits for all types of airborne dust (e.g. total dust, respirable dust, and respirable crystalline silica dust). In the U.S., the Occupational Exposure Limit (OEL) for talc containing no asbestos fibers and less than 1% crystalline silica is 2 mg/m³ respirable fraction (ACGIH) measured as an 8 hours TWA (Time Weighted Average). The OSHA exposure limit for talc is 20 mppcf Permissible Exposure Limit (PEL) TWA. For the equivalent limits in other countries, please consult a competent occupational hygienist or the local regulatory authority.

Engineering controls: Minimise airborne dust generation. Use process enclosures, local exhaust ventilation or other engineering controls to keep airborne levels below specified exposure limits. If user operations generate dust, use ventilation to keep exposure to airborne particles below the exposure limit. Apply organisational measures, e.g. by isolating personnel from dusty areas. Remove and wash soiled clothing.

Personal protection:

Eye protection: Wear safety glasses with side-shields in circumstances where there is a risk of dust generation which could lead to mechanical irritation of the eye.

Skin protection: No specific requirement. For hands, see below

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Hand protection: Protective gloves are not necessary but recommended for those prone to skin irritation or dryness.

Respiratory protection: In case of overexposure to airborne dust concentrations, wear respiratory protective equipment that complies with the requirements of national legislation.

Section 9. Physical and Chemical Properties

Information on basic physical and chemical properties

Appearance: White, off white to light grey powder.

Odour: Odourless

pH: 9 - 9.5 (10% slurry in water)

Melting point: >1300°C

Flammability (solid, gas): Not flammable.

Relative density: 2.7 - 2.8 g/cm³

Solubility:

Solubility in water: Negligible

Solubility in hydrofluoric acid: Yes

Decomposition temperature: >1000°C

Explosivity: Not explosive

Section 10. Stability and Reactivity

Reactivity: Inert, not reactive

Chemical stability: Chemically stable.

Possibility of hazardous reactions: No hazardous reaction.

Conditions to avoid: None.

Incompatible materials: None known.

Hazardous decomposition products: None.

Section 11. Toxicological Information

NIOSH registry number: WW2710000

SAX toxicity evaluation: THR: Not available

Carcinogenic Status:

IARC: In 2006, IARC concluded that inhaled talc not containing asbestos or asbestiform fibers is not classifiable as a human carcinogen (Group 3).

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IARC: In 2006, IARC ruled that there is limited evidence that the use of talc-based body powder for perineal dusting is a possible risk factor for ovarian cancer (Group 2B). This is not a route of exposure relevant to workers and applies only to one specific use of talc.

OSHA: Not listed

ACGIH: A4 – not classified as a human carcinogen

WHMIS: Class D-2A

NTP: Not listed. A 2-year inhalation study demonstrated clear evidence of carcinogenic activity in female rats at exposure levels of 18 mg/m³. Some evidence of carcinogenic activity was observed in male rats at the same level. No evidence of carcinogenic activity was found in mice (NTP TR-421).

Tumorigenic Data

TCLo: ihl-rat 11 mg/m³/1Y-1

TDLo: imp-rat 200 mg/kg

Other Toxicity Data: Skin and eye irritation data: skn-hmn 300 ug/3D-I MLD

Teratogenicity (reproductive effects data): Repeated ingestion of large doses of talc for 13 and 10 successive days by rabbits and mice revealed negative teratogenic and carcinogenic results

Mutation Data: Not available

Section 12. Ecological Information

Toxicity: No data are available on this product. No specific adverse effects known.

Persistence and degradability: No data are available on this product. Product is an inorganic substance and therefore is not considered biodegradable.

Other adverse effects: No specific adverse effects known.

Section 13. Disposal Considerations

Waste disposal information: Talc is not considered a hazardous waste as defined by the US EPA RCRA (40 CFR 261) regulations. Observe all applicable federal, state and local regulations when handling, storing or disposing of this substance.

Disposal guidelines: Where possible, recycling is preferable to disposal. Recycling and disposal of packaging should be carried out by an authorized waste management company. Recycling and disposal of packaging should be carried out in compliance with local regulations. Responsibility for proper waste disposal lies with the owner of the waste.

Section 14. Transport Information

US Department of Transportation (DOT): No classification assigned

Canadian Transportation of Dangerous Goods: No classification assigned

Land Transport – ADR/RID: No classification assigned

Air Transport – IATA/ICAO: No classification assigned

Maritime Transport – IMDG: No classification assigned

Harmonized Tariff Code: Talc – crushed or powdered. 2526.20.00 (stat suffix 00)

EPA TSCA 12(B) Export Notification: Not listed

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Material Safety Data Sheet

Section 15. Regulatory Information

Chemical Inventories: The following inventories have been investigated as to the publicly available portion of the lists:

MINERAL	CAS No.	EINECS (EU)	AICS (Australia)	CEPA (DSL/NDSL) (Canada)	KECI Korean Gazette No. (Korea)	ENCS/ISHL/MITI (Japan)
Talc	14807-96-6	238-877-9	Yes	Yes (DSL)	KE-32773	Yes*
Chlorite	1318-59-8	215-285-9	No	Yes* (DSL)	KE-05489	Yes*
Dolomite	16389-88-1	240-440-2	Yes	Yes (DSL)	KE-13036	Yes*
Magnesite	546-93-0	208-915-9	Yes	Yes (DSL)	KE-22686	Yes

MINERAL	IECSC (China)	PICCS (Philippines)	TSCA (USA)	Swiss ID No. (Switzerland)	NZIoC (New Zealand)
Talc	Yes	Yes	Yes	G-6939	Yes
Chlorite	Yes	Yes	Yes*	Not listed	Yes
Dolomite	Yes	Yes	Yes	G-8431	Yes
Magnesite	Yes	Yes	Yes	G-7477	Yes

Yes*: There exists a broad category for naturally occurring chemicals, so these minerals are covered by definition, but not specifically listed.

Other Pertinent Classifications/Regulations:

California PROP 65 Status: talc not listed

State Right-To-Know: Talc listed in IL, MA, NJ, PA, FL

Clean Air Act – Ozone depleting chemicals (ODC): None

CONEG Approved Packaging: Yes

National Fire Protection Association (NFPA) Ratings (0-4 scale):

Health = 0

Fire = 0

Reactivity = 0

National Paint and Coating Association (NPCA) – Hazardous Material Identification System (HMIS)

Health: 1* (chronic potential)

Flammability: 0

Physical: 0

Personal protection: dust respirator, gasses or goggles, gloves

Section 16. Other Information

References and sources:

1. Baan, R, Straif K, Secretan B, Ghissassi FE and Coglianov V. (2006), On behalf of the WHO International Agency for Research on cancer Monograph Working Group. Carcinogenicity of carbon black, titanium dioxide and talc. The Lancet Oncology. 7:295-296.
2. Wild, P.; "Lung cancer risk and talc not containing asbestiform fibers: a review of the epidemiological evidence". Occup. Environ. Med. 2006; 63, 4-9.
3. Cohrssen, B. and Powell C.H. (2001). Talc. In Patty's Toxicology, 5th ed., Bingham, E., Cohrssen, B., and Powell, C.H., eds., John Wiley & Sons, Inc. NY. pp. 519-538.

Material Safety Data Sheet

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Glossary

ACGIH – American Conference of Governmental Industrial Hygienists

IARC – International Agency for Research on Cancer

IATA – International Air Transport Association

ICAO – International Civil Aviation Organisation

IMDG – International Maritime Dangerous Goods

NIOSH - National Institute of Occupational Safety and Health

NTP – National Toxicological Program

OSHA – Occupational Safety and Health Association

OEL – Occupational Exposure Limit

PEL – Permissible Exposure Limit

RID/ADR – The European Agreements Concerning the International Carriage of Dangerous Goods by Rail (RID) and by Road (ADR)

TLV – Threshold Limit Value

TWA – Time Weighted Average

WHMIS – Workplace Hazardous Materials Information System (Canada)

Revisions

- Changed company name

Notice to reader

This material safety data sheet complements the technical data sheets but does not replace them. The information it contains is based on our present knowledge of the product on the date indicated. It is given in good faith. Users should be warned about the risks associated with using the product for a different purpose than that for which it was developed, and particularly for uses for which we are not qualified to give advice.

These regulatory prescriptions are provided with a view to helping users meet their obligations when using this product. This list should not be considered exhaustive and does not exempt users from ensuring that they are not required to comply with any further prescriptions other than those mentioned above concerning product possession and handling for which they are solely responsible.

Only the original English version is authoritative.



Distributed by:
Laguna Clay Company
14400 Lomas Ave
City of Industry, CA 91746
1-800-4Laguna
info@lagunaclay.com
www.lagunaclay.com



IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

Syrenthia Thrash)	
)	
Plaintiff,)	C.A. No.:
)	
v.)	Jury Trial Demanded
)	
JOHNSON & JOHNSON; JOHNSON & JOHNSON)	
CONSUMER COMPANIES, INC.; IMERYS TALC)	
AMERICA, INC., F/K/A LUZENAC AMERICA,)	
INC.; IMERYS TALC DELAWARE, INC.; U.S.)	
BORAX, INC.; RIO TINTO MINERALS INC.; RIO)	
TINTO MINERAL SERVICES INC.; AND)	
VALEANT PHARMACEUTICALS NORTH)	
AMERICA, LLC.;)	
)	
Defendants.)	
)	
)	
)	
)	

PRAECIPE

PLEASE ISSUE Summons and Complaint through the Sheriff of New Castle County to the defendants at the addresses indicated herein:

IMERYS TALC AMERICA, INC.
c/o The Corporation Trust Company
Corporation Trust Center
1209 Orange Street
Wilmington, DE 19801

IMERYS TALC DELAWARE, INC.
c/o The Corporation Trust Company
Corporation Trust Center
1209 Orange Street
Wilmington, DE 19801

JOHNSON & JOHNSON CONSUMER COMPANIES, INC.
c/o The Corporation Trust Company
Corporation Trust Center
1209 Orange Street

Wilmington, DE 19801

RIO TINTO MINERALS, INC.

c/o The Corporation Service Company
2711 Centerville Road
Suite 400
Wilmington, DE 19808

RIO TINTO MINERAL SERVICES, INC.

c/o The Corporation Service Company
2711 Centerville Road
Suite 400
Wilmington, DE 19808

U.S. BORAX, INC.

c/o The Corporation Service Company
2711 Centerville Road
Suite 400
Wilmington, DE 19808

VALEANT PHARMACEUTICALS NORTH AMERICA, LLC

c/o The Corporation Trust Company
Corporation Trust Center
1209 Orange Street
Wilmington, DE 19801

PLEASE ISSUE Summons and Complaint through Plaintiffs' Attorneys to the defendants listed below at the addresses indicated herein pursuant to 10 Del. C. § 3104.

JOHNSON & JOHNSON

One Johnson & Johnson Plaza
New Brunswick, NJ 08933

NAPOLI SHKOLNIK, LLC

By: /s/ James D. Heisman

James D. Heisman (#2746)
919 North Market Street, Suite 1801
Wilmington, DE 19801
(302) 330-8025
JHeisman@NapoliLaw.com
Attorney for Plaintiff(s)

OF COUNSEL

Hunter Shkolnik
Napoli Shkolnik, PLLC
400 Broadhollow, Suite 305
Melville, NY 11747
(631) 224-1131
HShkolnik@Napolilaw.com
Attorney for Plaintiffs
(to be admitted Pro Hac Vice)

Dated: May 1, 2017

To serve upon defendant a copy hereof and of the complaint (and of the affidavit of demand if any has been filed by plaintiff).

Dated:

SUSAN A. HEARN

Prothonotary

Per Deputy

TO THE ABOVE-NAMED DEFENDANTS:

In case of your failure, within 20 days after service hereof upon you, exclusive of the day of service, to serve on plaintiff's attorney named above an answer to the complaint (and, if an affidavit of demand has been filed, an affidavit of defense), judgment by default will be rendered against you for the relief demanded in the complaint (or in the affidavit of demand, if any).

SUSAN A. HEARN

Prothonotary

Per Deputy

To serve upon defendant a copy hereof and of the complaint (and of the affidavit of demand if any has been filed by plaintiff).

Dated:

SUSAN A. HEARN
Prothonotary

Per Deputy

TO THE ABOVE-NAMED DEFENDANTS:

In case of your failure, within 20 days after service hereof upon you, exclusive of the day of service, to serve on plaintiff's attorney named above an answer to the complaint (and, if an affidavit of demand has been filed, an affidavit of defense), judgment by default will be rendered against you for the relief demanded in the complaint (or in the affidavit of demand, if any).

SUSAN A. HEARN
Prothonotary

Per Deputy