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

DEANE BERG,	)	
	)	
PLAINTIFF	)	
	)	
VS.	)	**CIVIL ACTION NO.** 09-4179
	)	
JOHNSON & JOHNSON; JOHNSON & JOHNSON CONSUMER COMPANIES, INC.; LUZENAC AMERICA, INC.; RIO TINTO MINERALS INC.; JOHN DOES/JANE DOES 1-30; UNKNOWN BUSINESSES AND/OR CORPORATIONS A-Z,	)	**COMPLAINT**
	)	
DEFENDANTS.	)	

COMPLAINT
(Jury Trial Requested)

COMES NOW, the Plaintiff, by and through undersigned counsel, and files this her Complaint against the Defendants, Johnson & Johnson, Johnson & Johnson Consumer Companies, Inc., Luzenac America, Inc., Rio Tinto Minerals Inc., John Does/Jane Does 1-30, and Unknown Businesses and/or Corporations A-Z, and would show this Honorable Court the following in support thereof:

I. Parties

1. The Plaintiff is an adult resident citizen of Sioux Falls, South Dakota.

2. The Defendant, Johnson & Johnson, is a New Jersey corporation that is licensed and conducts substantial business in this State. Johnson & Johnson may be served with process of this Court via service on its registered agent, Steven M. Rosenberg, located at One Johnson & Johnson Plaza, New

Brunswick, New Jersey 08933. In the alternative, Johnson & Johnson may be served by process of this Court via United States Certified Mail pursuant to Rule 4 of the Federal Rules of Civil Procedure.

3. The Defendant, Johnson & Johnson Consumer Companies, Inc., is a New Jersey corporation that is licensed and conducts substantial business in this State. Johnson & Johnson Consumer Companies, Inc. may be served with process of this Court via service on its registered agent, Johnson & Johnson, located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933-0000. In the alternative, Johnson & Johnson Consumer Companies, Inc. may be served by process of this Court via United States Certified Mail pursuant to Rule 4 of the Federal Rules of Civil Procedure.

4. The Defendant Luzenac America, Inc. is a Delaware corporation that is licensed and conducts substantial business in this State. Luzenac America, Inc. may be served with process of this Court via service on its registered agent, Corporation Service Company, located at 2711 Centerville Road Suite 400, Wilmington, Delaware 19808. In the alternative, Luzenac America, Inc. may be served by process of this Court via United States Certified Mail pursuant to Rule 4 of the Federal Rules of Civil Procedure.

5. The Defendant Rio Tinto Minerals Inc. is a Delaware corporation that is licensed and conducts substantial business in this State. Rio Tinto Minerals Inc. may be served with process of this Court via service on its registered agent, Corporation Service Company, located at 2711 Centerville Road Suite 400, Wilmington, Delaware 19808. In the alternative, Rio Tinto Minerals Ins. may be

served by process of this Court via United States Certified Mail pursuant to Rule 4 of the Federal Rules of Civil Procedure.

6. Defendants John Does/Jane Does 1-30 are those persons, agents, employees, and/or representatives of Defendants whose conduct as described herein caused or contributed to the damages of the Plaintiff, all of whose names and legal identities are unknown to the Plaintiff at this time, but will be substituted by amendment when ascertained, individually and jointly.

7. Defendants Unknown Businesses and/or Corporations A-Z are unknown entities whose conduct as described herein caused or contributed to the damages of the Plaintiff, all of whose names and legal identities are unknown to the Plaintiff at this time, but will be substituted by amendment when ascertained, individually and jointly.

II. Jurisdiction

8. This Court has subject matter jurisdiction over this case pursuant to 28 U.S.C. § 1332 since there is complete diversity of the parties, and the amount in controversy exceeds seventy-five thousand dollars ($75,000.00).

9. This Court has personal jurisdiction over all Defendants in this case because the Defendants have done business in South Dakota, committed a tort in South Dakota, and have had continuous contacts with South Dakota. Specifically, these Defendants have manufactured, marketed, and sold a defective product in the State of South Dakota.

III. Venue

10. Venue is proper in this Court pursuant to 28 U.S.C. § 1332 because negligent acts of the Defendants took place in Sioux Falls, South Dakota.

IV. Facts

11. Talc is a magnesium trisilicate and is mined from the earth. Talc is an inorganic mineral. The Defendants', Luzenac America, Inc., and Rio Tinto Minerals, Inc. mined the talc at issue in this case.

12. Talc is the main substance in talcum powders. The Defendants, Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc., manufactured products that are in issue in this case namely, "Johnson's Baby Powder" and "Shower to Shower". These products are composed of almost entirely talc.

13. At all time relevant herein, a feasible alternative to the Defendants' product has 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.

14. Luzenac America, Inc. and Rio Tinto Minerals Inc. have continually advertised and marketed talc as safe for human use.

15. Luzenac America, Inc. and Rio Tinto Minerals Inc. supply customers with material safety data sheets for talc. These material safety data sheets are supposed to convey adequate health and warning information to its customers.

16. Historically, "Johnson's Baby Powder" has been a symbol of freshness, cleanliness, and purity. During the time in question, the Defendants, Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc., 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 "clinically proven gentle and mild". The Defendants compelled women through advertisements to dust themselves with its product to mask odors. The bottle of "Johnson's Baby Powder" specifically targets women by stating, "For you, use every day to help fell soft, fresh, and comfortable."

17. During the time in question, the Defendants, Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc., 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."

18. The Plaintiff used the Defendants products to dust her perineum for feminine hygiene purposes from approximately 1975 to 2007. This was an intended and foreseeable use of the Defendants' products based on the advertising, marketing, and labeling of the products by the Defendants.

19. On or about December 26, 2006, the Plaintiff was diagnosed with ovarian cancer. At the time of her diagnosis the Plaintiff was forty-nine (49) years old and did not have any risks factors, genetic or otherwise, for the disease.

20. 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. Egi GE,

Newton M. "The transport of carbon particles in the human female reproductive tract." *Fertility Sterility* 12:151-155, 1961.

21. In 1968, a study concluded that "All 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 and unsuspected problem. Cralley LJ, Key MM, Groth DH, Lainhart WS, Ligo, RM. "Fibrous and mineral content of cosmetic talcum products." *Am Industrial Hygiene Assoc J.* 29:350-354, 1968.

22. In 1976, a follow-up to these findings whereby a study was conducted which examined 21 samples of consumer talcums and powders, including baby powders, between 1971 and 1975. The study concluded that "The 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, Langer AM, Selifoff IJ, Tordini A, Klimentidis R, Bowes DR, Skinner DL. "Consumer talcums and powders: mineral and chemical characterization." *J Toxicol Environ Health* 2:255-284, 1976.

23. A United States study conducted in 1982 suggested 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 DW, Welch WR, Scully RE, Wojciechowski CA. "Ovarian cancer and talc: a case control study." *Cancer* 50: 372-376, 1982.

24. The Defendants, Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc., publicly recognized the numerous 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.

25. From 1988 to 1992 cancer research in the United States found conclusively that frequent talcum powder application in the genital area increases a woman's risk of developing ovarian cancer. Hartage P, Hoover R, Lesher LP, McGowan L. "Talc and ovarian cancer." Letter JAMA 250: 1844, 1983; Whittemore AS, Wu ML, Paffenbarger, RS, Sarles DL, Kampert JB, Grosser S, Jung DEL, Ballon S, Hendrickson M. "Personal and environmental characteristics related to epithelial ovarian cancer. II. Exposures talcum powder, tobacco, alcohol, and coffee." *Am J Epidemiol* 1128:1228-1240, 1988; Rosenblatt KA, Szklo M, Rosenshein NB. "Mineral fiber exposure and the development of ovarian cancer." *Gynecol Oncol* 45:20-25, 1992; Harlow BL,

Cramer DW, Bell DA, Welch WR. "Perineal exposure to talc and ovarian cancer risk." *Obstet Gynecol* 80: 19-26, 1992.

26. Specifically, the 1992 Harlow study referenced above found that frequent talc use directly on the genital area during ovulation increased a woman's risk of ovarian cancer threefold. The study also found "The 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 was the most comprehensive study to date of talc use and ovarian cancer whereby 235 ovarian cancer cases were identified and compared to 239 controls. Through personal interviews with these women Harlow et al. found that nearly 17% of the control group reported frequent talc application to the perineum which provided support to the assumption that large numbers of women in the general population are using this cosmetic talc in the genital area without being warned of the risk of ovarian cancer from daily use. 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."

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

carcinogenesis studies of talc (CAS No 14807-96-6) in F344/N rats and B6C3F 1 mice (Inhalation studies)." *Technical Report Series No 421*, September 1993.

28. On November 17, 1994, the Cancer Prevention Coalition joined by Chair and National Advisor of the Ovarian 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 agency action requested was that the FDA take the following action: "(1) Immediately 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".

29. 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 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* 1997; 145: 459-465.

30. In 2000, a prospective study was conducted, considered to this date the most informative study, found a 40% increase in invasive serous cancers from women who applied talcum powder to their perineum. Getrg DM, Hunter DJ,

Carmer DW, Coditz GA, Speizer FE, Willett WC, Hankinson SE. Prospective study of talc use and ovarian cancer. *J Natl Cancer Inst*; 2000: 92: 249-252.

31. The Defendants have been long-standing and active members and donors of the Cosmetic, Toiletry, and Fragrance Association (CTFA). 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 as a carcinogen in the upcoming 10th RoC Report. The NTP had already nominated cosmetic talc for this classification. In this letter the CTFA admitted that talc was "toxic", that "some talc particles . . . can reach the human ovaries", and acknowledge and agreed that prior epidemiologic studies have concluded that talc increases the risk of ovarian cancer in women.

32. 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, Geschwind JF, Kupelnick B. 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.* 2003; 23: 1955-60.

33. In 2004, a study of this subject found an overall 37% increased risk of ovarian cancer among talc users. Interestingly, this study 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. Mills PK, Riordan DG, Cress RD, Young HA. Perineal talc exposure and epithelial ovarian cancer risk in the Central Valley of California. *Int J Cancer*. 2004; 112: 458-64.

34. 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 increase risk in ovarian cancer in women from perineal use of talc. IARC found that between 16-52% of women in the world were using talc to dust their perineum and found increase risk of ovarian cancer in women talc users ranging from 30-60%. IARC concluded with this "Evaluation": "There is limited evidence in humans for the carcinogenicity of perineal use of talc-based body powder." IARC concluded with this "Overall evaluation": "Perineal use of talc-based body powder is possibly carcinogenic to humans (Group 2B)."

35. The Defendants had a duty to know and warn about the hazards associated with the use of its products.

36. The Defendants failed to inform its customers and end users of its products of a known catastrophic health hazard associated with the use of its products.

37. In addition, the Defendants procured and disseminated false, misleading, and biased information regarding the safety of its products to the public.

38. As a result of the Defendants calculated and reprehensible conduct the Plaintiff was injured and suffered damages namely ovarian cancer which has required multiple surgeries and treatments.

V. Causes of Action-Theories of Recovery

COUNT ONE – STRICT LIABILITY

39. The Defendants' products were defective because they failed to contain warnings and/or instructions, and breached express warranties and/or failed to conform to other express factual representation 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 Plaintiff, who could reasonably be expected to use and rely upon such products. 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.

40. The Defendants' products failed to contain, and continue to this day not to contain, warnings and/or instructions regarding the increased risk of ovarian cancer with the use of the products by women. The Defendants continue to market, advertise, and expressly represent to the general public that it is safe for women to use their product regardless of application. These Defendants continue with these marketing and advertising campaigns despite having 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.

COUNT TWO - NEGLIGENCE

41. The Defendants were negligent including, but not limited to, the following particulars, each of which was a proximate cause of Plaintiff's injuries and damages:

- In failing to warn Plaintiff of the hazards associated with the use of their product.
- In failing to properly test their products to determine adequacy and effectiveness or safety measures, if any, prior to releasing these products for consumer use;
- In failing to properly test their products to determine the increased risk of ovarian cancer during the normal and/or intended use of the products;
- In failing to inform ultimate users, such as Plaintiff as to the safe and proper methods of handling and using their products;
- In failing to remove their products from the market when the Defendants knew or should have known their products were defective;
- In failing to instruct the ultimate users, such as Plaintiff, as to the methods for reducing the type of exposure to the Defendants' products which caused increased risk in ovarian cancer;
- In failing to inform the public in general and the Plaintiff in particular of the known dangers of using the Defendants' products for dusting the perineum;
- In failing to advise users how to prevent or reduce exposure that caused increase risk for ovarian cancer;

- Marketing and labeling their product as safe for all uses despite knowledge to the contrary;

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.

COUNT THREE - BREACH OF WARRANTEES

42. The Defendants designed, manufactured, assembled, fabricated and/or distributed the products in question in a defective condition and therefore breached an implied warranty of fitness and an implied warranty of merchantability, in addition to various express warranties. The Defendants, as sellers, were merchants with respect to the products which they sold. In addition, these products were not fit for the ordinary purposes for which such goods are used. The Defendants also had reason to know of the particular purpose for which these products would be used, as well as the knowledge that persons such as Plaintiff would rely on the seller's skill to furnish suitable products.

43. Therefore. the Defendants have breached the implied warranty of merchantability as well as the implied warranty of fitness for a particular purpose, in addition to various express warranties. Such breach or breaches of implied and express warranties by the Defendants was a proximate cause of the injuries and damages sustained by Plaintiff.

COUNT FOUR – CIVIL CONSPIRACY

44. All of the allegations contained in the previous paragraphs are re-alleged herein. Plaintiff further alleges that Defendants and/or their predecessors-in-

interest knowingly agreed, contrived, combined, confederated and conspired among themselves to cause Plaintiff 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 her 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.

45. 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 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:

1. withheld, concealed and suppressed said medical information regarding the increased risk of ovarian cancer from Plaintiff (as set out in the "Facts" section of this pleading)
2. 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.

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.

46. Plaintiff reasonably and in good faith relied upon false and fraudulent representations, omissions, and concealments made by Defendants regarding the nature of their products. As a direct and proximate result of Plaintiff's reliance, Plaintiff has sustained damages including injuries, illnesses and disabilities and has been deprived of the opportunity of informed free choice in connection with the use of exposure to Defendants' products.

COUNT FIVE - ACTING IN CONCERT

47. Additionally and/or alternatively, the Defendants aided and abetted each other in the negligence, gross 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 SIX- GROSS NEGLIGENCE

48. 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.

49. The Defendants, Johnson & Johnson, and Johnson & Johnson Consumer Companies, Inc. 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 placed 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 profits over the health and well being of its customers as evidence in the Propulsid litigation, Ortho Evra litigation, 2006 Pennsylvania Tylenol litigation, 2006 TMAP investigation, and 2007 violation of the Foreign Corrupt Practices Act.

50. The above listed evidence indicates a pattern and practice of the Defendants, Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc., to place corporate profits over 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".

51. All of the Defendants 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.

VI. Damages

52. 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:

1. Severe impairment to her ovaries and reproductive system;
2 Medical Expenses, past and future;

3. Pain and Suffering, past and future;
4. Mental Anguish, Anxiety, and Discomfort, past and future;
5. Lost wages and income, past and future;
6. Fear of Cancer or other related diseases, past and future;
7. Physical Impairment;
8. Physical Disfigurement;
9. Loss of Enjoyment of Life;
10. Pre and post judgment interest;
11. Exemplary and Punitive Damages;
12. Treble damages;
13. Reasonable and necessary attorneys fees; and
14. Such other relief to which Plaintiff may be justly entitled.

VII. Discovery Rule

53. Plaintiff has suffered an illness which has a latency period and does not arise until many years after exposure. Plaintiff's illness did not distinctly manifest itself until she was made aware that her ovarian cancer could be caused by her use of the Defendants products. Consequently, the discovery rule applies to this case and the statute of limitations has been tolled until the day that Plaintiff knew or had reason to know that her ovarian cancer was linked to her use of the Defendants' products.

VIII. Conditions Precedent

54. All conditions precedent have been performed or have occurred as required by the Federal Rules of Civil Procedure.

WHEREFORE, PREMISES CONSIDERED, the Plaintiff demands judgment of and from the Defendants in an amount within the jurisdictional limits of this Honorable Court for compensatory damages against all Defendants, actual damages; consequential damages; exemplary damages, jointly and severally against all Defendants; interest on damages (pre-and post-judgment) in

accordance with the law; Plaintiff's reasonable attorney's fees, as well as costs of court and all other costs incurred; and such other and further relief as the Court may deem just and proper.

RESPECTFULLY SUBMITTED, this the 4th day of December, 2009.

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