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Attorneys for Plaintiffs

James Chakalos, as Personal Representative on behalf of the Estate of Janice Chakalos,

Plaintiff,

v.

Johnson & Johnson, Johnson & Johnson Consumer Companies, Inc., Imerys Talc America, Inc., f/k/a Luzenac America, Inc., Valeant Pharmaceuticals North America, Valeant Pharmaceuticals North America LLC, Valeant Pharmaceuticals International, Chattem, Inc., Sanofi US Services Inc., John Does/Jane Does 1-30 and Unknown Businesses and/or Corporations A-Z,

Defendants.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION, SOMERSET COUNTY

Civil Action No. L-1449-14

COMPLAINT AND JURY DEMAND

COMPLAINT
(Jury Trial Requested)

COMES NOW, the Plaintiff, by and through undersigned counsel, and files his Complaint against the Defendants, Johnson & Johnson, Johnson & Johnson Consumer Companies, Inc., Imerys Talc America, Inc., f/k/a Luzenac America, Inc., Valeant Pharmaceuticals North America, Valeant Pharmaceuticals North America LLC, Defendant Valeant Pharmaceuticals International, Chattem, Inc., Sanofi US Services 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, James Chakalos, is a resident of New York, currently residing at 171 Brehaut Avenue, Staten Island, New York 10307. Decedent, Janice Chakalos, was also a resident of New York when she used Defendants' products, when she was diagnosed with Ovarian Cancer and at the time of her death. Mr. Chakalos was married to Ms. Chakalos when she used Defendants' products, when she was diagnosed with Ovarian Cancer and at the time of her death. Mr. Chakalos is the personal representative for Ms. Chakalos estate.

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.

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, Office of the Corporate Secretary, One J&J Plaza, New Brunswick, New Jersey 08933.

4. The Defendant Imerys Talc America, Inc. f/k/a Luzenac America, Inc. is a Delaware corporation, with its principal place of business in the State of Georgia that conducts substantial business in this State. Imerys Talc America, Inc. may be served with process of this Court via service on its registered agent, Corporation Service Company, located at 830 Bear Tavern Road, West Trenton, New Jersey 08628.

5. Defendant Valeant Pharmaceuticals North America is a Delaware corporation, with its principal place of business. Valeant Pharmaceuticals North America may be served with process of this Court via service on its registered agent, The Corporation Trust Company, 820 Bear Tavern Road, West Trenton, New Jersey 08628.

6. Defendant Valeant Pharmaceuticals North America LLC is a foreign limited liability company registered in Delaware that is licensed and conducts substantial business in this state. Defendant can be served with process of this Court via service on its registered agent, The Corporation Trust Company, 820 Bear Tavern Road, West Trenton, New Jersey 08628.

7. Defendant Valeant Pharmaceuticals International is a Delaware corporation, with its principal place of business in the State of New Jersey. Valeant Pharmaceuticals International may be served with process of this Court via service on its registered agent, The Corporation Trust Company, 820 Bear Tavern Road, West Trenton, New Jersey 08628.

8. Chattem, Inc., a Sanofi Company is a Tennessee corporation. Chattem, Inc. may be served with process of this Court via service on its registered agent, Corporation service Company, 830 Bear Tavern Road, West Trenton, New Jersey, 08628. In the alternative, Chattem, Inc. may be served via Theordore K Whitfield Jr., 1715 W 38th Street, Chattanooga, TN 37409-1248.

9. Sanofi US Services Inc. f/k/a Sanofi-Aventis U.S. Inc. a/k/a Sanofi US is a Delaware corporation headquartered in Bridgewater, New Jeersey that is licensed and conducts substantial business in this State. Sanofi US can be served with process of this Court via service on its registered agent, Corporation Service Company, 830 Bear Tavern

Road, Trenton, New Jersey 08268.

10. 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.

11. 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 AND VENUE

12. This is an action for damages that exceeds the jurisdictional limits of this Court.

13. Venue in this action properly lies in New Jersey in that multiple defendants including Defendant Johnson & Johnson, Defendant Johnson & Johnson Consumer Companies, Inc., Defendant Valeant Pharmaceuticals International and Sanofi US Services Inc. are domestic corporations or have their principal place of business in New Jersey.

III. FACTS

14. Talc is a magnesium trisilicate and is mined from the earth. Talc is an inorganic mineral. The Defendant Imerys Talc America, Inc. f/k/a Luzenac America, Inc., mined the talc at issue in this case. Luzenac America, Inc was a subsidiary of the Rio Tinto group until 2011 when it was sold to Imerys Talc America, Inc.

15. Talc is the main substance in talcum powders. 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". Chattem, Inc manufactured "GoldBond". All of these products are composed of almost entirely talc.

Defendants Market Talc Products as Safe

16. In 1893, Defendants 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.

17. Johnson registered the term "Shower to Shower" as its trademark for talcum powder on March 28, 1966. After its first use of the "Shower to Shower" trademark, Johnson test-marketed its talcum powder in New Orleans and Indianapolis in late 1966. Marketing was extended to New England, the Middle and South Atlantic States and New York in May 1967. Since July 1967, distribution has been nationwide. *See Johnson & Johnson v. Colgate-Palmolive Co.*, 345 F.Supp 1216 (D. N.J. 1972).

18. Valeant Consumer Products, a division of Valeant Pharmaceuticals North America currently markets and sells "Shower to Shower" which is composed of almost entirely talc. Upon information and belief, Valeant Consumer Products acquired rights from Johnson and Johnson for "Shower to Shower" on September 28, 2012.

19. Chattem, Inc. manufacturers, markets and sells various "Gold Bond" body powders and advertises them as the "Powder with the Power." The main inactive ingredient in Gold Bond medicated powders is talc.

20. Sanofi f/k/a Sanofi-Aventis is the parent company of Chattem, Inc., the manufacturer and distributer of Gold Bond powders. Sanofi completed acquisition of Chattem, Inc. on March 11, 2010.

21. Chattem, Inc. is the U.S. consumer healthcare division of Sanofi.

22. At all times relevant herein, 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. In fact, Defendants Sanofi and Chattem Inc. sell talc-free Gold Bond formulas, yet continued to market talc containing powders as safe. Johnson's Baby Powder also comes in a cornstarch formula.

23. Imerys Talc f/k/a/ Luzenac America, Inc. has continually advertised and marketed talc as safe for human use.

24. Imerys Talc f/k/a/ Luzenac America, Inc. supplies 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.

25. Since Baby Powder's introduction, Defendants have consistently marketed it for use on women to maintain freshness and cleanliness. Historically, the Baby Powder label and advertising encouraged women to dust themselves with the Baby Powder daily to mask odors.

26. Traditionally, "Johnson's Baby Powder" has been a symbol of freshness, cleanliness, and purity. During the time in question, the Johnson & Johnson Defendants advertised and marketed 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 feel soft, fresh, and comfortable."

27. 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. The 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 on the skin."

28. 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 "keeps skin feeling soft, fresh and comfortable. It's a classic. 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 a 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 a 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."

29. Defendants seek to convey an image as safe and trusted family brand. For example, on their website for Johnson's Baby Powder, Defendants state the product is "Clinically proven to be safe, gentle and mild."

30. 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" includes 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."

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

32. On May 12, 2014, the Johnson & Johnson Defendants 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-pro-figure-skater.

33. During the time in question, the Johnson & Johnson Defendants 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."

34. During the time in question Defendant, Chattem, Inc. advertised and marketed its product "Gold Bond" as safe for use. Such advertising included "After shower, bath or exercise, simply apply Gold Bond Medicated Body Powder for lasting deodorant protection and that cool, refreshing feeling. You'll understand right away why people have trusted Gold Bond Powder to provide genuine medicated relief since 1908. Gold Bond Medicated Body Powder does what it says: Cools. Absorbs. Relieves. Works."

Plaintiff Used Defendants' Products believing they were safe

35. Ms. Chakalos used "Johnson's Baby Powder", "Shower to Shower" and "GoldBond Powder" (hereinafter "the PRODUCTS") to dust her perineum for feminine hygiene purposes from her childhood until approximately 2011 as she believed they were safe. This was an intended and foreseeable use of the Defendants' products based on the advertising, marketing, and labeling of the products by the Defendants. Ms. Chakalos developed ovarian cancer and suffered effects attendant thereto, including her premature death, 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. As a direct and proximate result of these injuries, Ms. Chakalos incurred medical expenses, has endured pain and suffering and loss of enjoyment of life, and wrongful death. Additionally, Mr. Chakalos seeks damages for loss of consortium loss of decedent's value to her estate, and other damages as allowed by law.

36. In or around November 2010, Ms. Chakalos was diagnosed with ovarian cancer. At the time of her diagnosis Ms. Chakalos was sixty three (63) years old and did not have any risks factors, genetic or otherwise, for the disease.

37. After entering hospice care for ovarian cancer, Ms. Chakalos passed away on November 15, 2012.

Defendants Knew of the Increased Risk of Ovarian Cancer From Use of Talcum Powder in the genital area

38. 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. 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.

39. However, Defendants do not warn or inform consumers anywhere, including on the product labeling or in its 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

40. 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.

41. 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 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. In 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.

42. 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.

43. 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 Institutes of Health (NIH) funded case-control study found a statistically significant 92% increased risk in ovarian cancer with

women who reported genital talc use. Additinoally, 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 study." *Cancer* 50: 372-376, 1982.

44. In 1983, Partricia Hartge and Robert Hoover of the National Cancer Institute and Linda Lester and Larry McGowan of the George Washing 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 for women who use talcum powder in the genital area. Hartge P, et al. "Talc and ovarian cancer." Letter JAMA 250: 1844, 1983

45. 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 on their perineum had 1.45 times the risk of ovarian cancer then women that did not use talc daily, showing a positive dose-response relationship. *See* Whittemore 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.

46. 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.

47. 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 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. Epidemiol., 390-394 (1989).

48. 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.

49. Also in 1992, a case-control study was conducted by Karin Rosenblatt, et. al., from the Department of Epidemiology of John's Hopkins School of Hygiene and Public Health. 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, Rosenshein NB. "Mineral fiber exposure and the development of ovarian cancer." *Gynecol Onco/* 45:20-25, 1992.

50. Additionally, a another 1992 case-control study conducted by Yong Chen, et al., of 112 diagnosed epithelial ovarian cancer cases and 224 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).

51. 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 F344/N rats and B6C3F 1 mice (Inhalation studies)." *Technical Report Series No 421,* September 1993.

52. In 1995, a case control study was conducted in Australia by David Purdie, et al., involving 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).

53. In 1996, a case-control study similarly found a statistically significant increased risk of ovarian cancer in women who used talc-based powders in 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).

54. 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 News Service, January 10, 1996.

55. 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 signfiicant 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).

56. 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, "The 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).

57. 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. 403-410 (1998).

58. In 1999, Dr. Cramer conducted 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).

59. 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).

60. Also in 2000, a prospective cohort study, considered to be the most informative study to date, found a 40% increase in invasive serous 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.

61. 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).

62. 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 serous 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 toxicologic 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).

63. 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. *Id.*

64. 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 serous 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, GSTT1, and NAT2 Genes, and Risk of Epithelial Ovarian Cancer", 17 (9) Cancer Epidemiology, Biomarkers & Prev. 2436-2444 (2008).

65. 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. The main one is the use of oral contraceptives, which has been clearly established to lower the risk 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 Area Linked to Increased Risk for Ovarian Cancer", Medscape Medical News (2008).

66. 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 serous 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).

67. 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).

68. 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.L. 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

69. 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".

70. 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 "Overall evaluation" : "Perineal use of talc-based body powder is possibly carcinogenic to humans (Group 2B)."

71. 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".

72. 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.[1]" ***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.

73. 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

74. 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.

75. 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

[1] The petition was submitted on behalf of: Samuel S. Epstein, M.D., Chairman, CPC, and Professor emeritus Occupational and Environmental Medicine, University of Illinois at Chicago School of Public Health; Peter Orris, M.D., Professor and Chief of Service, University of Illinois at Chicago Medical Center; Quentin Young, M.D., Chairman, Health and Medicine Policy Research Group, Chicago; Rosalie Bertell, Ph.D., International Association for Humanitarian Medicine, Scientific Advisor to the International Institute of Concern for Public Health, Toronto, and the International Science Oversight Board of the Organic Consumers Association, Washington, D.C.; and Ronnie Cummins, National Director of the Organic Consumers Association.

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.

76. 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 publication relations and talking points for press releases regarding the connection between talc and ovarian cancer. Defendants Johnson & Johnson, Luzenac and Sanofi 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 as a carcinogen.

77. On November 10, 1994, the Cancer Prevention Coalition ("CPC") mailed a letter to then J&J's CEO, Ralph Larson, informing Defendants 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 Defendants 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

78. On September 17, 1997, Alfred Wehner a toxicology consultant retained by Defendants, wrote a letter to Michael Chudkowski, 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, Luzenac and Sanofi, 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 Novotny, Candace Sue Kasper, Debra Heller, and others.

79. 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 an upcoming report. The NTP had already nominated 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 acknowledge and agreed that prior epidemiologic studies have concluded that talc increases the risk of ovarian cancer in women.

80. In 2006, Imerys began placing an ovarian cancer warning on its Material Safety Data Sheets (MSDS) it provides to its talc customers, including various Defendants. These MSDSs not only provided the warning information about the IARC classification but also included warning information regarding "States Rights to Know" and warning information about the Canadian Government's "D2A" classification of talc as well. At the very least, the Johnson & Johnson Defendants would have received these MSDSs. None of the Defendants passed 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 Defendants' Baby Powder.

81. 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

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

83. 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 by Defendants, could lead to an increased risk of ovarian cancer. For example, the only warnings on the Baby Powder label are to "Keep powder

away from child's face to avoid inhalation, which can cause breathing problems," and to "[a]void contact with eyes." The label also states: "SAFETY TIP: Keep out of reach of children. Do not use if quality seal is broken." Defendants provide similar warnings on their website: "For external use only. Keep out of reach of children. Close tightly after use. Do not use on broken skin. Avoid contact with eyes. Keep powder away from child's face to avoid inhalation, which can cause breathing problems."

84. The Johnson & Johnson Defendants continue to represent on the labeling and other marketing 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."

85. 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.

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

87. 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.

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

Causes of Action-Theories of Recovery

COUNT ONE - STRICT LIABILITY – FAILURE TO WARN
(All Defendants)

89. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

90. At all pertinent times, Imerys Talc f/k/a Luzenac America, Inc mined and sold talc to the Johnson & Johnson Defendants, which it knew was then packaging and selling 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.

91. At all pertinent times, Imerys Talc 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 in a women's perineal region, and it know or should have known that Johnson & Johnson was not warning its consumers of this danger.

92. At all pertinent times, the Johnson & Johnson Defendants, the Valeant Defendants, Sanofi and Chattem, Inc. were manufacturing, marketing, testing, promotion, selling and/or distributing the PRODUCTS in the regular course of business.

93. At all pertinent times, Ms. Chakalos used the PRODUCTS to powder her perineal area, which is a reasonably foreseeable use and in a manner normally intended by the Defendants.

94. 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.

95. At all pertinent times, including the time of sale and consumption, the PRODUCTS, when put to the aforementioned reasonably foreseeable use, 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 PRODUCTS by women to powder their perineal area. Defendants themselves failed to properly and adequately warn and instruct Plaintiffs as to the risks and benefits of the PRODUCTS given Plaintiffs need for this information. Had Ms. Chakalos received a warning that the use of the PRODUCTS in her genital area or on sanitary napkins would have significantly increased her risk of ovarian cancer, she would not have used the PRODUCTS in that manner. Her use of the 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 PRODUCTS, Plaintiffs have been injured catastrophically, and have been caused severe pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, economic damages and death.

96. The development of ovarian cancer by the Plaintiffs was the direct and proximate result of the unreasonably dangerous and defective condition of the PRODUCTS at the time of sale and consumption, including their lack of warnings; Plaintiffs have suffered injuries and damages including but not limited to conscious pain and suffering of Plaintiffs, medical expenses and death.

97. The Defendants' 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 Plaintiffs 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.

98. Defendants' products failed to contain, and continue to this day not to contain adequate warnings and/or instructions regarding the increased risk of ovarian cancer with the use of their products by women. The 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. 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. 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.

99. Alternatively, if his honorable Court finds that the Defendants did not have a duty to warn when Ms. Chakalos began using the product or at each time she purchased thereafter, they had a post-sale duty to warn, perhaps through advertising or public announcements, as the science developed and the danger of ovarian cancer from using talc products became clear.

WHEREFORE, Plaintiffs pray for judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and such further and other relief as the Court deems just and appropriate.

COUNT TWO - STRICT LIABILITY – DEFECTIVE DESIGN
(Johnson & Johnson Defendants, Valeant Defendants, Sanofi and Chattem, Inc.)

100. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

101. At all pertinent times, the Johnson & Johnson Defendants, the Valeant Defendants, Sanofi and Chattem, Inc. were responsible for designing, developing, manufacturing, marketing, testing, packaging promoting, marketing, labeling, selling and/or distributing the

PRODUCTS in the regular course of business.

102. The PRODUCTS are defective and unreasonably dangerous to consumers as the utility of the PRODUCTS do not outweigh the danger of developing ovarian cancer.

103. The PRODUCTS are defective in their design or formulation in that 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.

104. At all pertinent times, Ms. Chakalos used the PRODUCTS to powder her perineal area and her sanitary napkins, which is a reasonably foreseeable use and in a manner normally intended by the Defendants.

105. 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.

106. At all pertinent times, the PRODUCTS were expected to reach, and did reach consumers in the State of New York, and throughout the United States, without substantial change in the condition in which it was sold.

107. At all times material to this action, the PRODUCTS were designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was 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 PRODCUTS contained unreasonably dangerous design defects and were not reasonably safe as intended to be used

including dusting the perineum, subjecting Plaintiffs to risks that exceeded the benefits of the subject product.

b. When placed in the stream of commerce, the PRODUCTS were defective in design and formulation, specifically that the PRODUCTS contained Talc, making the use the 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 product's design defects existed before it left the control of the Defendants;

d. The PRODUCTS were insufficiently tested;

e. The PRODUCTS caused harmful side effects including ovarian cancer that outweighed any potential utility of deodorizing, preventing chaffing or other possible benefits; and

f. The PRODUCTS were not accompanied by adequate instructions and/or warnings to fully apprise consumers, including Plaintiffs herein, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiffs.

108. 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.

109. 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.

110. In addition, at the time the subject product left the control of the Defendants, 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.

111. As a direct and proximate result of the PRODUCTS' defective design, Plaintiff suffered severe and permanent physical injuries including death. Plaintiff endured substantial pain and suffering. She incurred significant expenses for medical care and treatment. The Plaintiffs seek actual and punitive damages from the Defendants as alleged herein.

WHEREFORE, Plaintiffs pray for judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and such further and other relief as the Court deems just and appropriate.

COUNT THREE –NEGLIGENCE
(As to Imerys Talc)

112. The Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

113. At all pertinent times, Defendants had a duty to exercise reasonable care to consumers, including Plaintiffs herein, in the design, development, manufacture, testing, inspection, packaging, promotion, marketing, distribution, labeling and/or sale of the PRODUCTS.

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

115. At all pertinent times, Imerys Talc 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 1960s.

116. At all pertinent times, Imerys Talc knew or should have known that Johnson & Johnson was not providing warnings to consumers of the PRODUCTS of the risk of ovarian cancer posed by talc contained therein.

117. At all pertinent times, Imerys Talc was negligent in providing talc to the Johnson & Johnson Defendants, when it knew or should have known that the talc would be used in the PRODUCTS, without adequately taking steps to ensure that ultimate consumers of the PRODUCTS, including Decedent, received the information that Imerys Talc possessed on the carcinogenic properties of talc, including its risk of causing ovarian cancer.

118. As a direct and proximate result of Imery's Talc's negligence Plaintiff purchased and used the PRODUCTS that caused Plaintiff to develop ovarian cancer; Plaintiff incurred medical bills, conscious pain and suffering, and death; Plaintiffs were caused to sustain damages as a direct and proximate result including untimely death, funeral and burial costs, as well as the loss of his wife's services, companionship, comfort, instruction, guidance, counsel, training and support.

WHEREFORE, Plaintiffs pray for judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and such further and other relief as the Court deems just and appropriate.

COUNT FOUR – NEGLIGENCE
(Johnson & Johnson Defendants, Valeant Defendants, Sanofi and Chattem, Inc.)

119. Plaintiffs hereby incorporate by reference each of the preceding paragraphs as if fully set forth herein.

120. The Johnson & Johnson Defendants, the Valeant Defendants, Sanofi and Chattem, Inc. were negligent in marketing, designing, manufacturing, packaging, labeling, supplying, inspecting, testing selling and/or distributing the 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 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 products;

d. In failing to inform ultimate users, such as Plaintiff as to the safe and proper methods of handling and using their products;

e. In failing to remove their products from the market or adding proper warnings when the Defendants knew or should have known their 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' 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' 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 uses despite knowledge to the contrary;

j. In failing to act like a reasonably prudent company under similar circumstances

121. 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.

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

123. As a direct and proximate result of Defendants' negligence Plaintiff purchased and used the PRODUCTS that caused Plaintiff to develop ovarian cancer; Plaintiff incurred medical bills, conscious pain and suffering, and death; Plaintiffs were caused to sustain damages as a direct and proximate result including untimely death, funeral and burial costs, as well as the loss of his wife's services, companionship, comfort, instruction, guidance, counsel, training and support.

WHEREFORE, Plaintiffs pray for judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and such further and other relief as the Court deems just and appropriate.

COUNT FIVE - BREACH OF EXPRESS WARRANTY
(Johnson & Johnson Defendants, Valeant Defendants, Sanofi and Chattem, Inc.)

124. Plaintiffs hereby incorporate by reference each of the preceding paragraphs as if fully set forth herein.

125. The Johnson & Johnson Defendants, the Valeant Defendants, Sanofi and Chattem, Inc. expressly warranted, through direct-to-consumer marketing, advertisements, and labels, that the PRODUCTS were safe and effective for reasonably anticipated uses, including use by women in the perineal area and on sanitary napkins.

126. Ms. Chakalos saw these advertisements, including television commercials, and believed the product was safe and effective to use in her perineal area.

127. The PRODUCTS did not conform to these express representations in violation of N.Y. U.C.C. Law 2-313, *et seq.* and New York 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 PRODUCTS were sold.

128. As a direct and proximate result of Defendants' breach of warranty, Plaintiff purchased and used, as aforesaid, the PRODUCTS that directly and proximately caused Plaintiff to develop ovarian cancer.

WHEREFORE, Plaintiffs pray for judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and such further and other relief as the Court deems just and appropriate.

COUNT SIX - BREACH OF IMPLIED WARRANTY
(Johnson & Johnson Defendants, Valeant Defendants, Sanofi and Chattem, Inc.)

129. Plaintiffs hereby incorporate by reference each of the preceding paragraphs as if fully set forth herein.

130. At the time the Johnson & Johnson Defendants, the Valeant Defendants, Sanofi and Chattem, Inc. designed, manufactured, assembled, fabricated, labeled, packaged, sold and/or distributed the PRODUCTS, the Defendants knew of the uses for which the PRODUCTS were intended, including use by women in the perineal area, and impliedly warranted the PRODUCTS to be of merchantable quality and safe for such use.

131. The Defendants, as sellers, were merchants with respect to the products which they sold.

132. Defendants sold these 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 PRODUCTS sold to Plaintiff because the PRODUCTS were not fit for their common, ordinary and intended uses, included use by women in the perineal area.

133. Therefore the Defendants have breached the implied warranty of merchantability as well as the implied warranty of fitness for a particular purpose as stated N.Y. U.C.C. Law §§ 2-314, *et seq.* under New York common law. Such breach by the Defendants was a proximate cause of the injuries and damages sustained by Plaintiff.

134. As a direct and proximate result of Defendants' breach of implied warranty, Plaintiff purchased and used the PRODUCTS that caused Plaintiff to develop ovarian cancer; Plaintiff incurred medical bills, conscious pain and suffering, and death; Plaintiffs were caused to sustain damages as a direct and proximate result including untimely death,

funeral and burial costs, as well as the loss of his wife's services, companionship, comfort, instruction, guidance, counsel, training and support.

WHEREFORE, Plaintiffs pray for judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and such further and other relief as the Court deems just and appropriate.

COUNT SEVEN - CIVIL CONSPIRACY
(All Defendants)

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

136. 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.

137. 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:

i. 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); 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";

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.

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

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

WHEREFORE, Plaintiffs pray for judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and such further and other relief as the Court deems just and appropriate.

COUNT EIGHT – CONCERT OF ACTION
(All Defendants)

140. Plaintiffs hereby incorporate by reference each of the preceding paragraphs as if fully set forth herein.

141. At all pertinent times, Defendants, and the Personal care and Products Council (PCPC) knew that the PRODUCTS should contain warnings on the risk of ovarian cancer posed by women using the product to powder the perineal region, but purposefully sought to

suppress such information and omit from talc based products so as not to negatively affect sales and maintain the profits of the Defendants.

142. 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.

WHEREFORE, Plaintiffs pray for judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and such further and other relief as the Court deems just and appropriate.

COUNT NINE- GROSS NEGLIGENCE
(All Defendants)

143. Plaintiffs hereby incorporate by reference each of the preceding paragraphs as if fully set forth herein.

144. 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.

145. The Johnson and 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 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.

146. The above listed evidence indicates a pattern and practice of Johnson & Johnson Defendants 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".

WHEREFORE, Plaintiffs pray for judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and such further and other relief as the Court deems just and appropriate.

COUNT TEN – NEGLIGENT MISREPRESENTATION
(All Defendants)

147. Plaintiffs hereby incorporate by reference each of the preceding paragraphs as if fully set forth herein.

148. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiffs and the public that the products 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.

149. Defendants failed to exercise ordinary care in the representations concerning the PRODUCTS while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants

negligently misrepresented the PRODUCTS' high risk of unreasonable, dangerous, adverse side effects, including the risk of ovarian cancer.

150. Defendants breached their duty in representing that the PRODUCTS have no serious side effects.

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

152. As a direct and proximate result of Defendants' conduct, Plaintiffs have been injured and sustained severe pain, suffering, loss of enjoyment of life, loss of care and comfort, economic damages and death.

WHEREFORE, Plaintiffs pray for judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and such further and other relief as the Court deems just and appropriate.

COUNT ELEVEN – WRONGFUL DEATH
(All Defendants)

153. Plaintiff repeats, reiterates, and realleges each and every allegation contained in paragraphs "1" through "26", inclusive, with the same force and effect as if fully and completely set forth herein.

154. As a result of the negligence, carelessness, and recklessness of the defendants, their servants, agents, and/or employees, in the medical services rendered, and lack of informed consent to the plaintiff's decedent, Janice Chakolas, said plaintiff's decedent sustained grievous personal injuries which resulted in her death.

155. Defendants were otherwise negligent.

156. Plaintiff's decedent, Janice Chakolas, is survived by her husband, plaintiff James Chakolas, and children, Frank C. Wolsky next of kin.

157. In connection with the injuries sustained by the plaintiff's decedent, and her resulting death, plaintiff's decedent's next of kin and plaintiff's decedent's estate have necessarily incurred, or become obligated to pay various medical and funeral and related expenses in connection with the medical treatment and the funeral of the plaintiff's decedent, and have and will necessarily incur expenses in the settlement of the estate of the plaintiff's decedent, in various amounts.

158. As a result of the negligent acts of the defendants resulting in the wrongful death of the plaintiff's decedent, decedent's next of kin have been deprived of the support, maintenance, services, guidance, communion, protection, and intellectual, moral, spiritual and physical training of the plaintiff's decedent, Janice Chakolas, amongst other losses.

159. That by reason of the foregoing, the plaintiff's decedent's next of kin have been damaged in an amount to be determined.

WHEREFORE, Plaintiffs pray for judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and such further and other relief as the Court deems just and appropriate.

COUNT TWELVE – LOSS OF CONSORTIUM
(All Defendants)

160. Plaintiffs hereby incorporate by reference each of the preceding paragraphs as if fully set forth herein.

161. Plaintiff, James D. Chakalos, has been at all times relevant to this complaint, and until her death, the husband of Plaintiff Janice Chakalos.

162. As a result of the injuries suffered by his wife, including but not limited to ovarian cancer and death, Plaintiff, has and will in the future suffer the loss of the usual services and consortium of his wife.

WHEREFORE, Plaintiffs pray for judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees and such further and other relief as the Court deems just and appropriate.

COUNT THIRTEEN – PUNITIVE DAMAGES
(all Defendants)

163. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

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

165. in one or more of the following ways:

a. Defendants knew of the unreasonably high risk of ovarian cancer posed by the PRODUCTS before manufacturing, marketing, distributing and/or selling the PRODUCTS, yet purposefully proceeded with such action;

b. Despite their knowledge of the high risk of ovarian cancer associated with the PRODUCTS, Defendants affirmatively minimized this risk through marketing and promotional efforts and product labeling;

c. Through the actions outlined above, Defendants expressed a reckless indifference to the safety of users of the PRODUCTS, including Plaintiffs, Defendants' conduct, as described herein, knowing the dangers and risks of the PRODUCTS, yet concealing and/or omitting this information, in furtherance of their conspiracy and concerted action was outrageous because of Defendants' evil motive or a reckless indifference to the safety of users of the PRODUCTS.

166. As a direct and proximate result of the willful, wanton, evilly motivated and/or reckless conduct of the Defendants, the Plaintiffs have sustained damages as set forth above.

167. 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 1n 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.

WHEREFORE, Plaintiff prays for a judgment for punitive damages against all Defendants in a fair and reasonable amount sufficient to punish Defendants and deter them and others from engaging in similar conduct in the future, costs expended herein, and such further and other relief as the Court deems just and appropriate.

Damages

168. Plaintiffs 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 of Ms. Chakalos;

d. Physical Impairment;

e. Loss of Enjoyment of Life;

f. Pre and post judgment interest;

g. Wrongful death

h. Loss of consortium

i. Exemplary and Punitive Damages;

j. Treble damages;

k. Reasonable and necessary attorneys fees; and

l. Such other relief to which Plaintiff may be justly entitled.

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.

DEMAND FOR JURY TRIAL

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

Date: October 31, 2014

Respectfully submitted,

KUHARSKI, LEVITZ & GIOVINAZZO

By: _____
MICHAEL J. KUHARSKI
For the Firm

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*Application for admission *pro hac vice* to be filed

Attorneys for Plaintiffs

CERTIFICATION PURSUANT TO LOCAL RULE 11.2

The undersigned attorney for Plaintiffs certifies that the matter in controversy is not the subject of any other action pending in any Court or of a pending arbitration or administrative proceeding.

I certify that the foregoing statement made by me is true to the best of my knowledge, information and belief. I am aware that if the foregoing statement made by me is willfully false, I am subject to punishment.

Date: October 31, 2014

Respectfully submitted,

KUHARSKI, LEVITZ & GIOVINAZZO

By: _____
MICHAEL J. KUHARSKI
For the Firm
Attorneys for Plaintiffs