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FILED U.S. DISTRICT COURT EASTERN DISTRICT ARKANSAS

IN THE UNITED STATES DISTRICT COURT JAMES W. MCCORMACK, CLERK FOR THE EASTERN DISTRICT OF ARKENSAS

JAMIE ENGEL,	)
Plaintiff,	2
	2
<b>v.</b>	
JOHNSON & JOHNSON,	
JOHNSON & JOHNSON CONSUMER	
INC., f/k/a JOHNSON & JOHNSON	
CONSUMER COMPANIES, INC., and	
IMERYS TALC AMERICA, INC.	
f/k/a LUZENAC AMERICA, INC.,	
, ,	
Defendants.	

CIVIL ACTION NO: 3, 17 CV86-JLH

This case assigned to District Judge\_Holmes and to Magistrate Judge \_\_\_\_\_Kearney\_\_\_\_ COMPLAINT AND JURY DEMAND

## **COMPLAINT AND JURY DEMAND**

COMES NOW Plaintiff Jamie Engel, and files her Original Complaint, against Johnson & Johnson, Johnson & Johnson Consumer Inc., f/k/a Johnson & Johnson Consumer Companies, Inc., and Imerys Talc America, Inc., f/k/a Luzenac America, Inc., and would respectfully show this Court as follows:

## **Parties**

1. Plaintiff Jamie Engle, is a citizen and resident of the County of Clay, State of Arkansas. At all times pertinent, including usage of Johnson's Baby Powder and Shower to Shower, as well as diagnosis and treatment of her ovarian cancer, the Plaintiff was a resident of the County of Clay, State of Arkansas.

2. Defendant Johnson & Johnson is a New Jersey corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. At all pertinent times, Johnson & Johnson did business in the State of Arkansas. Johnson & Johnson may be served

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with process of this Court via service on its registered agent, located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

3. Defendant Johnson & Johnson Consumer Inc., f/k/a Johnson & Johnson Consumer Companies, Inc., ("Johnson & Johnson Consumer"), is a New Jersey corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. At all pertinent times, Johnson & Johnson Consumer did business in the State of Arkansas. Johnson & Johnson Consumer may be served with process of this Court via service on its registered agent, One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

4. At all pertinent times, Johnson & Johnson Consumer<sup>1</sup> has been a wholly owned subsidiary of Johnson & Johnson under the complete dominion and control of Johnson & Johnson. Johnson & Johnson Consumer formulated, manufactured, marketed, tested, promoted, sold, and distributed Johnson's Baby Powder.

5. Unless otherwise specified, Johnson & Johnson and Johnson & Johnson Consumer shall be collectively referred to as the "Johnson & Johnson Defendants."

6. Defendant Imerys Talc America, Inc. f/k/a Luzenac America, Inc. ("Imerys"), is a Delaware corporation, with its principal place of business in the State of California at 1732 North First Street, Suite 450, San Jose, California 95112. At all pertinent times, Imerys did business in Arkansas. Imerys may be served with process of this Court via service on its registered agent, corporation Trust Company, 1209 Orange Street, Wilmington, DE 19801.

7. Hereinafter, when Johnson & Johnson Defendants and Imerys are referenced together they will collectively be called "Defendants."

<sup>1</sup> All allegations regarding Johnson & Johnson Consumer Inc. also include actions taken while that entity was known as Johnson & Johnson Consumer Companies, Inc.

### Jurisdiction and Venue

8. This Court has original jurisdiction pursuant to 28 U.S.C. §1332, because the matter in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs, and is between citizens of different states.

9. Venue in this Court is proper under 28 U.S.C. 1391(b)(2), as a substantial part of the events or omissions giving rise to the claim occurred in this judicial district.

### <u>Facts</u>

#### a. History of Talc Product for JOHNSON & JOHNSON DEFENDANTS

10. Talc, magnesium trisilicate, is an inorganic mineral mined from the earth.

11. Imerys 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.

12. Talc is the main substance in talcum powders, and talcum powders is the main ingredient in Johnson & Johnson Defendants' Johnson's Baby Powder, the product at issue in this case. Johnson's Baby Powder is composed almost entirely of talc.

13. At all pertinent times, Johnson & Johnson Defendants were engaged in the business of manufacturing, marketing, testing, promoting, selling, and/or distributing Johnson's Baby Powder.

14. Imerys has continuously advertised and marketed talc as safe for human use.

15. At all times pertinent, Imerys has supplied customers with Material Safety Data sheets ("MSDS") for talc. These material safety data sheets are intended to convey adequate health and warning information for its customers.

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

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babies and women.

17. Since Johnson's Baby Powder introduction, Johnson & Johnson 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.

18. For more than a century, Johnson's Baby Powder has been a symbol of freshness, cleanliness, and purity. Since the inception of Johnson's Baby Powder, Johnson & Johnson Defendants advertised and marketed the 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." Johnson & Johnson Defendants compelled women through advertisements to dust themselves with its product to mask odors. Throughout the history of Johnson's Baby Powder, the bottle has specifically targeted women: "[f]or you, use every day to help feel soft, fresh, and comfortable."

19. Although the label has changed over time, the message is the same: Johnson's Baby Powder is safe for use by women as well as babies. The Baby Powder label currently states that the product ". . . gently absorb[s] 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." Consumers are instructed to "[s]hake powder directly into your hand, away from the face, before smoothing on the skin."

20. Through other marketing, including on their website for Johnson's Baby Powder, Johnson & Johnson Defendants similarly encouraged women to use the product daily. Johnson & Johnson Defendants state that Johnson's Baby powder "keeps skin feeling soft, fresh and comfortable. Johnson's Baby Powder helps eliminate friction while keeping skin cool and

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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", "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," Johnson & Johnson Defendants recommend "[f]or baby use after every bath and diaper change," and "[f]or you, use anytime you want skin to feel soft, fresh, and comfortable."

21. Johnson & Johnson Defendants seek to convey an image of a safe and trusted family brand, by using language on their website for Johnson's Baby Powder, claiming the product is "[c]linically proven to be safe, gentle and mild."

22. Johnson & Johnson Defendants registered the term "Shower to Shower" as its trademark for talcum powder on March 28, 1966. Shower to Shower was test-marketed in New Orleans and Indianapolis in late 1966, and then 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).

23. Johnson & Johnson Defendants advertised and marketed Shower to Shower as safe for use by women "all over your body," as evidenced by the slogan "[a] sprinkle a day keeps odor away", and "[y]our 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." The Johnson & Johnson Defendants' website included the suggested use of the product "Shower to Shower" in the genital area with the following: "Soothe Your Skin: Sprinkle on problem areas to soothe skin that has been irritated from friction. Apply after a bikini wax to help reduce irritation and discomfort."

24. Johnson & Johnson Defendants also have a website,

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www.safetyandcarecommitment.com devoted to "Safety & Care commitment." The website has changed over time. Previously, Johnson & Johnson Defendants claimed "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", backed by a "Five-Level Safety Assurance Process." The "Five-Level Safety Assurance Process" stated that "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." Included on this page was Johnson & Johnson Defendants' so-called "Promise to Parents and their Babies" that "[w]hen you bring our baby care Johnson's Baby Powder into your home, you can be assured of our commitment to the safety of your family and families around the world."

25. Today, on Johnson & Johnson Defendants' www.safetyandcarecommitment.com, "safety is our priority", and "[o]ur goal is to exceed the safety standards in every country where our products are sold." Johnson & Johnson Defendants market their safety assurance process as "one of the most stringent in the world," purportedly "ensuring the safety and quality of every baby and beauty personal care product we make." Within this website, Johnson & Johnson Defendants devote an entire section to talc, as "decades of science have reaffirmed its safety" and "[b]ecause of its safety and effectiveness, we confidently include pharmaceutical grade talc in our products." Johnson & Johnson Defendants close by stating "[w]e take any questions about our product's safety seriously and as a result have dug deep into evidence and science on talc."

26. The www.safetyandcarecommitment.com also touts the safety of talc, "[w]e continue to use talc in our products because decades of science have reaffirmed its safety. Because of its safety and effectiveness, we confidently include the finest-grade talc in our products. Your trust in our products and your confidence using them every day is a huge responsibility—that's

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why we rely on scientific research to deliver the safest possible product. Science, research, clinical evidence and 30 years of studies by medical experts around the world continue to support the safety of cosmetic talc." Further, "[f]ew ingredients have demonstrated the same performance, mildness and safety profile as cosmetic talc." Nowhere do Johnson & Johnson Defendants warn of the increased risk of ovarian cancer linked to the use of Johnson's Baby Powder.

27. Johnson & Johnson Defendants also have another website, "Facts About Talc", http://www.factsabouttalc.com/, dedicated to providing consumers with safety information: "[w]e want all the information we can get. We seek out the guidance of experts and we monitor the latest science to see if it impacts any of our products. We also listen to the people who use our products so we can take their experiences into account. Safety is a priority for all of our consumer products ... Safety is a value we all share." The website goes on to say "[w]e go beyond the findings of a single study because we must ensure we've assembled all of the available data from multiple scientific areas to reach conclusions based on evidence. One opinion or study can't outweigh decades of conclusive, scientific, evidence-based findings. As a scientist and, equally important, as a parent myself, I can tell you the science is clear: Cosmetic talc is, and has been, safe for use in consumer products."

28. Included on the "Facts About Talc" website is the Nurses' Health Study and the Women's Health Initiative Study, stating "the study data showed no increased risk of ovarian cancer in women... There was also no increase in risk among women who used powder for longer periods of time." Nowhere in the discussion of this study are the actual percentages of women who contracted ovarian cancer the study periods listed, and nowhere does the website list ovarian cancer as a possible side effect of continued talcum powder use.

29. On October 14, 2016, the Johnson & Johnson Defendants issued the following

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statement: "[a]t Johnson & Johnson, nothing is more important than ensuring our products are safe. Science, research, clinical evidence, and decades of studies by medical experts around the world continue to support the safety of the cosmetic talc used in Johnson's Baby Powder." *See* Press Release, Johnson & Johnson, *Talcum Powder: A Message About Safety* (Oct. 14, 2016) *available at* https://www.jnj.com/latest-news/tara-glasgow-statement-talcum-powder.

30. On the page where the October 14, 2016 press release is located, Johnson & Johnson Defendants include a video of Tara Glasgow, current Vice President of Research & Development at Johnson & Johnson Consumer, discussing the importance of safety at Johnson & Johnson. In particular, the video focuses on the "continuing safety" of Johnson's Baby Powder and its main ingredient, talcum powder. Nowhere do Johnson & Johnson Defendants warn of the increased risk of ovarian cancer linked to the use of Johnson's Baby Powder on a women's perineal and/or perineum area.

31. As detailed below, beginning in at least 1972, the Johnson & Johnson Defendants were aware of several studies demonstrating that use of talc-based powder in the genital area correlated to a significant increased risk of ovarian cancer. Since 1972, there have been at least twenty-one studies (including nineteen case-control studies, one cohort study, and one 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.

32. In light of the findings in these studies, Johnson & Johnson 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 Johnson's Baby Powder may be harmful to health, specifically the significant increased risk of ovarian cancer.

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## b. Scientific Literature Proves Link Between Talc Usage and Ovarian Cancer.

33. Research published in 1961 established that particles, like talc, can translocate from the exterior genital area to the ovaries in women. *See* G.E. Egli, and Michael Newton, *The Transport of Carbon Particles in the Human Female Reproductive Tract*, 12 FERT. STERIL. 2,151-155 (1961).

34. In 1971, the first study was conducted that suggested an association between talc and ovarian cancer. This study was conducted by W. J. Henderson in Cardiff, Wales. That study found talc particles "deeply embedded" in ten of thirteen ovarian tumors, twelve of twenty-one cervical tumors, one primary carcinoma of the endometrium and five of twelve "normal" ovaries from women with breast cancer. W. J. Henderson et al., *Talc and carcinoma of the ovary and cervix*, 78 J. OBSTET. GYNEACOL. BR. COMMW. 3, 266-272 (1971).

35. The scientific evidence linking talc use and ovarian cancer continued to build in the next decade. In 1982, the first epidemiologic study was led by Dr. Daniel Cramer on talc powder use in the female genital area. The National Institutes of Health ("NIH") funded a case-control study that found a statistically significant 92% increased risk in ovarian cancer with women who reported genital talc use. Additionally, it found that talc application directly to the genital area around the time of ovulation might lead to talc particles becoming deeply imbedded in the tissues 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. Daniel Cramer et al., *Ovarian cancer and talc: a case control study*, 50 CANCER 372-376 (1982).

36. In 1983, Patricia Hartge and Robert Hoover of the National Cancer Institute and Linda Lester and Larry McGowan of the George Washing University Medical Center, performed

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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 talc in the genital area. Patricia Hartge et al., *Talc and ovarian cancer*, 250 JAMA 1844 (1983) available at http://jamanetwork.com/journals/jama/article-abstract/1725023.

37. In 1988, a case control study of 188 women diagnosed with epithelial ovarian cancer and 539 controls found that 52% of the cancer patients habitually used talc 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. Alice Whittemore et al., *Personal and environmental characteristics related to epithelial ovarian cancer. II. Exposures talcum powder, tobacco, alcohol, and coffee*, 128 AM. J. EPIDEMIOL. 6, 1228-1240 (1988).

38. 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 talc powder use more than once per week. Margaret Booth et al., *Risk factors for ovarian cancer: a case-control study*, 60 BR. J. CANCER 4, 592-598 (1989).

39. Another case control study conducted in 1989 by Bernard Harlow 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 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 a positive dose-response relationship. Bernard Harlow and Neinke Weiss, *A case-control study of borderline ovarian tumors: the influence of perineal* 

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exposure to talc, 130 AM. J. EPIDEMIOL. 2, 390-394 (1989).

40. 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 compared to 239 controls, concluding 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." Bernard Harlow et al., *Perineal exposure to talc and ovarian cancer risk*, 80 OBSTET. GYNECOL. 1, 19-26 (1992).

41. Also in 1992, a case-control study was conducted by Karin Rosenblatt at 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), and a relative risk of 4.8 for ovarian cancer development from talc use on sanitary napkins. Karin Rosenblatt et al., *Mineral fiber exposure and the development of ovarian cancer*, 45 GYNECOL. ONCOL. 20-25 (1992).

42. Another 1992 case-control study conducted by Yong Chen with 112 diagnosed epithelial ovarian cancer cases and 224 age-matched community controls, found an elevated risk for ovarian cancer in 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*, 21 INT'L. J. EPIDEMIOL. 23-29 (1992).

43. In 1993, the United States National Toxicology Program published a study on the

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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 (Sept. 1993).

44. In 1995, a case control study conducted in Australia by David Purdie, involving over 1600 women found a statistically significant 27% increased risk in ovarian cancer for women who regularly use talc in the region of the abdomen or perineum. David Purdie et al., *Reproductive and other factors and risk of epithelial ovarian cancer: an Australian case-control study*, 62 INT'L. J. CANCER 6, 678-684 (1995).

45. 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 Asher Shushan et al., *Human menopausal gonadotropin and the risk of epithelial ovarian cancer*, 65 FERTIL. STERIL. 1, 13-18 (1995).

46. In 1997, a case-control study of 313 women with ovarian cancer and 422 controls found that the women with cancer were more likely to have applied talc powder to their external genitalia area. Women using these products had a statistically significant 50% to 90% higher risk of developing ovarian cancer. Linda Cook et al., *Perineal powder exposure and the risk of ovarian cancer*, 145 AM. J. EPIDEMIOL. 459-465 (1997).

47. In 1997, a case-control study 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 found a statistically significant increased risk for ovarian cancer for

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women who applied talc via sanitary napkins to their perineum. The study indicated that "[c]ommercial 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," concluding "[t]he results of this study appear to support the contention that talc exposure increases risk of ovarian carcinoma. Dusting with talcum powder is not an unusual practice for women, and, given the heterogeneity of the etiology and course of ovarian carcinoma, any possible harmful practices, particularly those with little benefit, should be deliberated." Stella Chang and Harvey Risch, *Perineal talc exposure and risk of ovarian carcinoma*, 79 CANCER 12, 2396-2401 (1997).

48. A 1998 case-control study conducted in Canada by Beatrice Godard found increased risk of ovarian cancer in women who used talc-based powders on their perineum. Beatrice Godard et al., *Risk factors for familial and sporadic ovarian cancer among French Canadians: a case-control study*, 179 AM. J. OBSTET. GYNCEOL. 2, 403-410 (1998).

49. In 1999, Dr. Cramer conducted a case-control study of 563 women newly diagnosed with epithelial ovarian cancer and 523 controls. The study found a statistically significant 60% increased risk of ovarian cancer in women that used talc-based body powders on their perineum: "[w]e 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"). Daniel Cramer et al., *Genital talc exposure and risk of ovarian cancer*, 81 INT'L. J. CANCER 3, 351-356 (1999).

50. In 2000, Roberta Ness, from University of Pennsylvania, led a case control study of over 2,000 women. This study found a statistically significant 50% increased risk of ovarian

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cancer from genital talc use in women. The study also found that talc causes inflammation, and that inflammation contributes to cancer cell development. Roberta Ness et al., *Factors Related to Inflammation of the Ovarian Epithelium and Risk of Ovarian Cancer*, 11 EPIDEMIOL. 2, 111-117 (2000).

51. Also in 2000, a prospective cohort study found a 40% increase in invasive serous cancers from women who applied talc to their perineum. Dorota Getrig et al., *Prospective Study* of Talc Use and Ovarian Cancer, 92 J. NAT'L. CANCER INST. 3, 249-252 (2000).

52. In 2003, a meta-analysis was conducted which re-analyzed data from 16 studies published prior to 2003, finding a 33% increase in ovarian cancer risk among talc users. Michael Huncharek 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. 2C, 1955-60 (2003).

53. In 2004, a case-control study of nearly 1400 women from twenty-two 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, compared with women using cornstarch powders as "[c]ornstarch is also not thought to exert the same toxicologic reaction in human tissue as does talc." This study concluded that "users should exercise prudence in reducing or eliminating use", and "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." Paul Mills et al., *Perineal talc exposure and epithelial ovarian cancer risk in the Central Valley* 

of California, 112 INT'L. J. CANCER 458-64 (2004).

54. In a 2007 study by Amber Buz'Zard, talc was found to increase proliferation, induce neoplastic transformation and increase reactive oxygen species ("ROS") generation timedependently in the ovarian cells. The study concluded that talc may contribute to ovarian carcinogenesis in humans because the mineral may contribute to ovarian neoplastic transformation, given that Pycnogenol was found to reduce the talc-induced transformation. Amber Buz'Zard et al., *Pycnogenal reduces talc-induced neoplastic transformation in human ovarian cell cultures*, 21 PHYTOTHERAPY RES. 6, 579-86 (2007).

In 2008, Margaret Gates performed a combined study of over 3,000 women from a 55. New England-based case-control study and a prospective Nurses' Health Study (the "Gates Study"). This study was funded by 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 noted a pronounced and positive dose-response relationship, increasing risk with increasing talc usage by women. These results "provide additional support for a main effect of genital talc exposure on epithelial ovarian cancer . . . the finding of highly significant trends between increasing frequency of use and risk 'strengthen[ing] the evidence of an association, because most previous studies have not observed a dose response." Notably, the study promoted an alternative to talc, cornstarch, which "has not been shown to increase ovarian cancer risk ....." The study concluded 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." Margaret Gates et al., Talc Use, Variants of the GSTM1, GSTT1, and NAT2

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Genes, and Risk of Epithelial Ovarian Cancer, 17 CANCER EPIDEMIOL., BIO. & PREV. 9, 2436-2444 (2008).

56. 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 confirmed by this study: "[t]here 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." Zosia Chustecka and Desiree Lie, *Talc Use in Genital Area Linked to Increased Risk for Ovarian Cancer*, Medscape Medical News (Oct. 8, 2008) available at http://www.medscape.com/viewarticle/581781.

57. In 2008, Melissa Merritt, from the Australian Cancer Study and Australian Ovarian Cancer Study Group, conducted a case-control study of over 3,000 women finding 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. Melissa Merritt et al., *Talcum powder, chronic pelvic inflammation and NSAIDs in relation to risk of epithelial ovarian cancer*, 122 INT'L. J. CANCER 1, 170-176 (2008).

58. In 2009, a case-control study of over 1,200 women found the risk of ovarian cancer increased significantly with 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

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duration and most frequent talc use. In conclusion the study stated, "that risk of ovarian cancer is significantly associated with talc use and with a history of endometriosis, as has been found in recent studies." Anna Wu et al., *Markers of inflammation and risk of ovarian cancer in Los Angeles County*, 124 INT'L. J. CANCER 6, 1409-1415 (2009).

59. In 2011, another case-control study of over 2,000 women found a 27% increased risk of ovarian cancer from genital talc use. Karin Rosenblatt et al., *Genital powder exposure and the risk of epithelial ovarian cancer*, 22 CANCER CAUSES & CONTROL 5,737-42 (2011).

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

61. In May 2015, Roberta Ness performed a meta-analysis of all accumulated epidemiologic evidence (23 case-control studies, 5 meta-analyses, and 3 analyses of a single cohort). Talc use was found to increase ovarian cancer by 30-60% in almost all well-designed studies. The results were published in the International Journal of Gynecological Cancer. Roberta Ness, *Does talc exposure cause ovarian cancer*?, 25 INT'L. J. CANCER 1, 51 (2015).

62. A 2016 study of African-American women found that that body powder had a statistically significant association with Epithelial Ovarian Cancer. Genital powder was associated with an increased risk of EOC (OR = 1.44; 95% CI, 1.11–1.86) and a dose–response relationship was found for duration of use and number of lifetime applications (P < 0.05). The study concluded that body powder is a modifiable risk factor for epithelial ovarian cancer among African-American

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women. Joellen Schildkraut et al., Association between Body Powder Use and Ovarian Cancer: the African American Cancer Epidemiology Study (AACES), 25 CANCER EPIDEMIOL., BIOMARKERS & PREV. 10, 1411 (2016).

63. A 2016 study examined 2,041 cases with epithelial ovarian cancer and 2,100 ageand-residence-matched controls. Overall, genital talc use was associated with an OR (95% CI) of 1.33 (1.16, 1.52), with a trend for increasing risk by talc-years. In addition, subtypes of ovarian cancer more likely to be associated with talc included invasive serous and endometrioid tumors and borderline serous and mucinous tumors. Premenopausal women and postmenopausal HT users with these subtypes who had accumulated greater than 24 talc-years had ORs (95% CI) of 2.33 (1.32, 4.12) and 2.57 (1.51, 4.36), respectively. Most women in the study reported using Johnson & Johnson's Baby Powder and Shower to Shower. Among epidemiologic variables, no confounders for the association were identified. Daniel Cramer et al., *The Association Between Talc Use and Ovarian Cancer: A Retrospective Case-Control Study in Two US States*, 27 EPIDEMIOL. 3, 334-346 (2016).

## c. Leading Authorities Agree on the Link Between Ovarian Cancer and Perineal Use of Talc Powder

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

65. On November 17, 1994, the Cancer Prevention Coalition ("CPC"), Chair and National Advisor of the Ovarian Cancer Early Detection and Prevention Foundation ("OCEDPF") and OCEDPF members filed a "Citizen Petition Seeking Carcinogenic Labeling

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on All Cosmetic Talc Products." The petition noted research dating back to 1961 establishing that cosmetic grade talc could translocate to the ovaries in women and increase the risk ovarian cancer development. This petition was submitted to the Commissioner of the Food and Drug Administration ("FDA") under the Federal Food, Drug, and Cosmetic Act. The petition requested the FDA: "[]mmediately require cosmetic talcum powder products to bear labels with a warning such as 'Talcum powder causes cancer in laboratory animals. Frequent talc application in the female genital area increases the risk of ovarian cancer.""

66. In February of 2006, the International Association for the Research of Cancer ("IARC") part of the World Health Organization published a paper classifying perineal use of talc-based body powder as a "Group 2B" human carcinogen. IARC found that between 16-52% of women in the world were using talc to dust their perineum. IARC, universally accepted as the international authority on cancer, concluded that studies from around the world consistently found an increased risk of ovarian cancer in women from perineal use of talc, ranging from 30-60%. IARC concluded "[p]erineal use of talc-based body powder is possibly carcinogenic to humans (Group 2B)."

67. In 2006, the Canadian government under The Hazardous Product Act and Controlled Product Regulations classified talc as a "D2A," "very toxic," "cancer causing" substance under its Workplace Hazardous Materials Information System ("WHMIS"). To compare, asbestos is also classified as "D2A."

68. In May 2008, the CPC, joined by its chairman, physicians and chairs of public health and medical associations, submitted a second citizen's petition "seeking a cancer warning on cosmetic talc products."2 The second petition asked that the FDA immediately require cosmetic

<sup>2</sup> The petition was submitted on behalf of: Samuel S. Epstein, M.D., Chairman, CPC, and Professor emeritus

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talcum powder products to bear labels with a prominent warning that frequent talc application in the female genital area is responsible for major risks of ovarian cancer. The FDA response to the two Citizen Petitions was filed on April 1, 2014.

69. In 2013, Cancer Prevention Research published a study that showed that women who used talcum powder in their groin area had a 20 to 30 percent greater risk of developing ovarian cancer than women who did not use talc products in that area.

70. The Gilda Radner Familial Ovarian Cancer Registry, Roswell Park Center Institute, and the Department of Gynecologic Oncology at University of Vermont publish a pamphlet entitled, "Myths & Facts about ovarian cancer: What you need to know." In this pamphlet, under "known" risk factors for ovarian cancer, it lists: "Use of Talc (Baby Powder) in the Genital Area."

71. Both the National Cancer Institute and American Cancer Society have listed genital talc use as a "risk factor" for ovarian cancer.

## d. Defendants Awareness of the Dangers of Talcum Powder.

72. 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.

73. 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

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.

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"Talcum Company Calls Study on Cancer Link Inconclusive", the Johnson & Johnson Defendants admitted being aware of the 1982 Cramer article that concluded women who apply talc daily to their genital areas were three times more likely to contract ovarian cancer.

74. Upon information and belief, in response to the United States National Toxicology Program's 1993 study, the Cosmetic Toiletry and Fragrance Association ("CTFA"), now known as the Personal Care Products Council ("PCPC"), reconvened the Talc Interested Party Task Force ("TIPTF"). The TIPTF was originally formed by the CTFA in the 1980's to defend talc in response to the first epidemiologic studies that found an association between ovarian cancer and genital talc use. The Johnson & Johnson Defendants and Luzenac, now Imerys, were the primary actors and contributors to the TIPTF.

75. The stated purpose of the TIPTF was to pool financial resources of these companies in an effort to collectively defend talc use at all costs and to prevent regulation of any type over this industry. The TIPTF hired scientists to perform biased research regarding the safety of talc. Upon information and belief, the TIPTF lobbied various organizations, including the NTP, to prevent talc from being labeled as a carcinogen. Members of the TIPTF edited reports of the scientists hired by this group before they were submitted to governmental agencies and/or released to the consuming public. Members of the TIPTF knowingly released false information about the safety of talc to the consuming public, and used political and economic influence on regulatory bodies regarding talc. These activities were conducted by these companies and organizations, including the Johnson Defendants, PCPC and Imerys, over the past four (4) decades in an effort to prevent regulation of talc and to create confusion to the consuming public about the true hazards of talc relative to cancer.

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76. At all times relevant, PCPC coordinated the defense of talc and acted as a mouthpiece for the members of the TIPTF, including the Johnson & Johnson Defendants and IMERYS. Upon information and belief, PCPC was funded by the annual dues of its members including the Johnson & Johnson Defendants and Imerys.

77. Since approximately 1973, the Cosmetic Ingredient Review ("CIR") has reviewed the safety of ingredients used in the cosmetic and personal care products industry. Although Defendants have, at all relevant times, promoted CIR as an independent, regulatory body, CIR is an organization within and wholly funded by PCPC. In fact, CIR shares the same office space with PCPC and its employees are paid by PCPC.

78. Over the years, CIR has reviewed thousands of ingredients used in the cosmetics industry, but has only found 12 ingredients to be "unsafe for use in cosmetics." In contrast, CIR has deemed approximately 1800 ingredients to be "safe as used."

79. Even though PCPC knew of the safety concerns surrounding talc for almost three decades, the CIR did not begin to review talc until after the first lawsuit alleging a link between talc use and ovarian cancer was filed. Upon information and belief, during the CIR review process, Defendants influenced the scientists working on the review and ultimately edited the reviews in a biased manner. Not surprisingly, when CIR published its final report in 2015, it found talc to be safe as used in cosmetics.

80. On November 10, 1994, the CPC mailed a letter to then Johnson & Johnson CEO, Ralph Larson, informing Johnson & Johnson 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 as

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confirmation, quoting 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, as it is very difficult to detect with a low survival rate. The letter concluded by requesting that Johnson & Johnson Defendants withdraw talc products from the market because of the alternative of cornstarch powders, or at a minimum, place warning information on its talcbased body powders about the ovarian cancer risk they posed.

81. Upon information and belief around 1996, the FDA requested the condom industry to stop dusting condoms with talc due to health concerns linking talc to ovarian cancer. Subsequently, all U.S. manufacturers discontinued the use of talc in condom manufacturing, to reduce potential health hazards for women.

82. On September 17, 1997, Alfred Wehner a toxicology consultant retained by Johnson & Johnson Defendants, wrote a letter to Michael Chudkowski, manager of Pre-Clinical Toxicology at Johnson & Johnson Consumer Companies Inc., stating that on three separate occasions the TIPTF 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.

83. In 2002, Edward Kavanaugh, CTFA President, wrote a letter to Dr. Kenneth Olden, NTP Director, 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 acknowledged prior epidemiologic studies have concluded that talc increases the risk of ovarian cancer in women.

84. In 2006, IMERYS began placing an ovarian cancer warning on its talc MSDS, warning talc customers of the IARC classification, the Canadian Government's "D2A" classification of talc and "States Rights to Know." At the very least, Johnson & Johnson Defendants would have received these MSDS. The Johnson & Johnson Defendants never passed this warning information on to the consumers.

85. On September 26, 2012, Imerys' corporate representative testified in open court that his company exclusively supplied Johnson & Johnson Defendants with talc used in the latter's Baby Powder products, and that ovarian cancer is a potential hazard associated with a women's perineal use of talc-based body powders, like Johnson's Baby Powder.

86. On October 19, 2012, Johnson & Johnson Defendants' former in-house toxicologist and current consulting toxicologist, Dr. John Hopkins, testified on Johnson & Johnson Defendants' behalf that they "[are] and were aware of . . . all publications related to talc use and ovarian cancer."

## e. Defendants Failed to Warn Consumers and the Public about the Risks of Using Talcum Powder

87. The Johnson & Johnson Defendants had a duty to know and warn about the hazards associated with the use of Johnson's Baby Powder.

88. A Johnson & Johnson Technology Forecast, dated 1986, acknowledged that safety of cosmetic powders were a concern and that health professionals had decided that powders provide no health benefit. The document also acknowledged that "[r]etrospective studies have implicated talc use in the vaginal area with the incidence of ovarian cancer."

89. Despite the mounting scientific and medical evidence regarding talc use and ovarian cancer that has developed over the past several decades, none of Johnson & Johnson Defendants' warnings on the product label or in other marketing informed Plaintiff that use of the product in the genital area, as was encouraged by the Johnson & Johnson 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." Johnson & Johnson 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 from child's face to avoid inhalation, which can cause from child's face to avoid inhalation, which can cause breathing problems."

90. The Johnson & Johnson Defendants continue to represent on the labeling and other marketing that Johnson's Baby Powder is "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

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reviewed studies." The Johnson & Johnson Defendants also tout it as "clinically proven mildness."

91. Johnson & Johnson was also aware of the high rate of usage among African Americans (52%) and among Hispanics (37.6%). Despite its knowledge of the increased risk of ovarian cancer, Johnson & Johnson targeted these populations in its marketing efforts.

92. The Johnson & Johnson 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.

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

94. As a result of the Johnson & Johnson Defendants calculated and reprehensible conduct the Plaintiff was injured and suffered damages namely ovarian cancer which has required surgery and treatments.

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

96. At all pertinent times, a feasible alternative to the use of talcum powder use in Johnson's Baby Powder has existed. Cornstarch is an organic carbohydrate that is quickly broken down by the body with no known health effects. Cornstarch powders have been sold and marketed for the same uses with similar effectiveness as talcum powder.

97. Hereinafter, Johnson's Baby Powder and Shower to Shower will be referred to as the "Products."

## f. Ms. Jamie Engel's Talcum Powder Usage History

98. At all pertinent times alleged herein since approximately 1970 until 2014, Plaintiff purchased the Products and used them on a daily basis in and around her vaginal area. Plaintiff used them by applying the Products to her body in accordance with the instructions for use that accompanied the Products and in a reasonably foreseeable manner.

99. In April 2014, Plaintiff was diagnosed with ovarian cancer, and subsequently underwent an exploratory laparotomy, oophorectomy, hysterectomy, and treatments for said ovarian cancer. Plaintiff developed ovarian cancer, and suffered effects and sequelae therefrom, as a direct and proximate result of the unreasonably dangerous and defective nature of talcum powder, the main ingredients of Johnson's Baby Powder and Shower to Shower, and Johnson & Johnson Defendant, and Imerys' wrongful and negligent conduct in the research, development, testing, manufacture, production, promotion, distribution, marketing, and sale of the products.

## <u>COUNT I</u> Negligence as to Johnson & Johnson Defendants

100. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

101. Johnson & Johnson Defendants, at all pertinent times, had a duty of a reasonable manufacturer to foresee and appreciate risks of harm associated with the ordinary use of their Products, in light of the risks associated with the Products' usage in women's perineal region and perineum.

102. Johnson & Johnson Defendants, at all pertinent times, had a duty to properly design, manufacture, test, inspect, package, label, distribute, market, examine, maintain, supply, provide proper warnings and prepare for use of the Products.

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103. Johnson & Johnson Defendants, at all pertinent times, knew or in the exercise of reasonable care should have known, that the Products were of such a nature that they were not properly designed, manufactured, tested, inspected, packaged, labeled, distributed, marketed, examined, sold, supplied, prepared and/or provided with the proper warnings, and were unreasonably likely to injure users. Johnson & Johnson Defendants' actions

104. It was foreseeable that women's use of the Products' use in women's perineal and perineum areas including the use of powder on sanitary napkins could lead to an increased risk of ovarian cancer. Johnson & Johnson Defendants knew or in the exercise of reasonable care should have known the Products would cause serious injury, and they failed to disclose the known or knowable risks associated with the Products, including ovarian cancer. Johnson & Johnson Defendants willfully and deliberately failed to avoid those consequences, and in doing so, acted in conscious disregard of the safety of Plaintiff.

105. Johnson & Johnson Defendants owed a duty to Plaintiff to adequately warn her of the foreseeable risk of ovarian cancer associated with the Products, and the resulting harm it would cause.

106. At all pertinent times, the Johnson & Johnson Defendants knew or in the reasonable exercise of reasonable care should have known that the Products were unreasonably dangerous and defective when put to their reasonably anticipated uses.

107. Johnson & Johnson Defendants breached their duty by failing to comply with state and federal regulations concerning the study, testing, design, development, manufacture, inspection, production, advertisement, marketing, promotion, distribution, and/or sale of the Products, including, but not limited to the following ways, each of which is a proximate cause of Plaintiff's injuries:

a. Failing to warn Plaintiff of the hazards associated with the use of the Products, including the risk of ovarian cancer when used in the genital area and in the perineal area;

b. Failing to properly test the Products to determine adequacy and effectiveness or safety measures, if any, prior to releasing them for consumer use;

c. Failing to properly test the Products to determine the increased risk of ovarian cancer resulting from their normal and/or intended use;

d. Failing to inform ultimate users, such as Plaintiff as to the safe and proper methods of handling and using the Products;

e. Failing to remove the Products from the market or adding proper warnings when the Johnson & Johnson Defendants knew or in the exercise of reasonable care should have known the Products were defective;

f. Failing to instruct the ultimate user, such as Plaintiff, as to methods for reducing the type of exposure to the Products which led to increased risk of ovarian cancer;

g. Failing to inform the public in general, and Plaintiff in particular, of the known dangers of using the Products for dusting the perineal area and perineum;

h. Failing to advise users how to prevent or reduce exposure that caused an increase in ovarian cancer risk;

i. Marketing and labeling the Products as safe for all uses despite knowledge to the contrary; and

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

108. Johnson & Johnson Defendants so negligently and carelessly designed, manufactured, tested, failed to test, inspected, failed to inspect, packaged, labeled, distributed, recommended, displayed, sold, examined, failed to examine and supplied the Products, that it was

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dangerous and unsafe for the use and purpose for which it was intended.

109. But for, and as a natural and continuous result of Johnson & Johnson Defendants' negligence, Plaintiff purchased and used the Products that caused her to develop ovarian cancer, incur medical bills, conscious pain and suffering.

110. Johnson & Johnson Defendants conduct in continuing to manufacture, market, sell and distribute the Products after obtaining knowledge its application to the perineal and perineum areas causes an increased incidence of ovarian cancer in women, shows complete indifference to, or a conscious disregard for the safety of others justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter Johnson & Johnson Defendants and others from similar conduct in the future.

Wherefore, Plaintiff requests a judgment against Johnson & Johnson Defendants for damages in a sum to confer jurisdiction upon this Court together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

## <u>COUNT II</u> Negligence as to Imerys

111. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

112. At all pertinent times, Imerys had a duty of an ordinary, had a duty of a reasonable manufacturer to foresee and appreciate risks of harm associated with the ordinary use of their Product, in light of the risks associated with the Products' usage in women's perineal region and perineum.

113. At all pertinent times, Imerys had a duty to exercise reasonable care to consumers,

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including Plaintiff, to properly manufacture, design, develop, manufacture, test, inspect, package, promote, market, distribute, label, and provide proper warnings for talc use.

114. At all pertinent times, Imerys owed a duty to consumers, including Plaintiff, as foreseeable users of the Products, and the talc contained therein, would be reasonably safe for their intended uses and free from defects.

115. At all pertinent times, Imerys mined and sold talc to Johnson & Johnson Defendants, which it knew or in the exercise of reasonable care should have known was being packaged and sold to consumers in the Products. Further, Imerys knew or in the exercise of reasonable care should have known that it was foreseeable that the Products' consumers were using them to powder their perineal area and/or perineum.

116. At all pertinent times, Imerys knew or in the exercise of reasonable care should have known of the apparent of the talc powder-based Products in the perineal and/or perineum areas significantly increases the risk of ovarian cancer.

117. At all pertinent times, Imerys knew or in the exercise of reasonable care should have known that Johnson & Johnson Defendants were not providing warnings to consumers of the Products concerning the risk of ovarian cancer posed by talc.

118. Imerys breached its duty to Plaintiff when it knew or in the exercise of reasonable care failed to ensure the Products, containing talc it produced, included information on the carcinogenic properties of talc, like the increased risk of ovarian cancer.

119. But for, and as a natural and continuous result of Imerys' negligence, Plaintiff purchased and used the Products, causing her to develop ovarian cancer. Plaintiff also incurred medical bills, conscious pain and suffering.

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120. Imerys' conduct in continuing to manufacture, market, sell and distribute talc after obtaining knowledge that application of talc to the perineal and perineum areas and sanitary napkins causes an increased incidence of ovarian cancer in women, shows complete indifference to, or a conscious disregard for the safety of others justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter Imerys and others from similar conduct in the future.

Wherefore, Plaintiff requests a judgment against Imerys for damages in a sum to confer jurisdiction upon this Court together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

#### **COUNT III**

# Strict Product Liability – Defective Design as to Johnson & Johnson Defendants

121. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

122. Johnson & Johnson Defendants were in the business of designing, developing, manufacturing, assembling, marketing, testing, packaging, labeling, promoting, selling, supplying and distributing the Products in the regular course of business.

123. The Products are defective and unreasonably dangerous to consumers, as they are unsafe for reasonably foreseeable use and consumption, due to the increased risk of ovarian cancer when they are applied to women's perineal area or perineum.

124. The Products are defective in design as the Johnson & Johnson Defendants had reason to anticipate the dangers resulting from the Products' use in women's perineal area or perineum, increased risk of ovarian cancer, failed to give adequate warning of those dangers.

125. At all pertinent times, Johnson & Johnson Defendants knew or in the exercise of

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reasonable care should have known that the use of the talc powder-based Products in the perineal area significantly increases the risk of ovarian cancer, based upon scientific knowledge dating back to the 1960's.

126. At all pertinent times, Johnson & Johnson Defendants knew or in the exercise of reasonable care should have known that women were using the Products to powder their perineal area and/or perineum and/or on sanitary napkins.

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

a. Inadequate warning when the Products were first placed in the stream of commerce regarding the dangers associated with their use in the normally proscribed manner for consumers, like Plaintiff;

b. The Products contained unreasonably dangerous design defects when first placed into the stream of commerce and were not reasonably safe for intended uses, including dusting the perineal area or perineum, subjecting Plaintiff to risks that exceeded the benefits of use;

c. The Products were defective in design and formulation when placed in the stream of commerce, because it contained talc, making use more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with use of other non-talc options on the market;

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;

f. The Products were not accompanied by adequate instructions and/or warnings to fully apprise consumers, including Plaintiff, of the full nature and extent of the risks and side effects associated with their use, thereby rendering Johnson & Johnson Defendants liable; and

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g. Failure to provide any warning whatsoever against use of the Products in and around a woman's perineal and perineum areas or on sanitary napkins.

128. The Johnson & Johnson Defendants continue to market, advertise, and expressly represent to the general public that the Products are safe for women to use regardless of application. The Johnson & Johnson Defendants continued with marketing and advertising campaigns despite having scientific knowledge dating back to the 1960's that the Products increase the risk of ovarian cancer in women when used in the perineal area or perineum.

129. At all times pertinent, 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 Products. These safer alternative designs were economically and technologically feasible, and would have prevented and/or significantly reduced the risk of Plaintiff's injuries without substantially impairing utility.

130. At all pertinent times, the Products were substantially in the same condition as when they left the possession of Johnson & Johnson Defendants.

131. At all pertinent times, Plaintiff used the Products to powder her genital and perineum which are reasonably foreseeable and normally intended uses by the Johnson & Johnson Defendants, as they gave no warnings in opposition, but rather promoted use of the Products all over a woman's body.

132. The Products' defective designs proximately caused the Plaintiff's ovarian cancer. Plaintiff suffered severe and permanent physical injuries and significant pain and suffering. She incurred significant expenses for medical care and treatment.

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133. Johnson & Johnson Defendants conduct in continuing to manufacture, market, sell and distribute the Products after obtaining knowledge that their application to the perineal and perineum areas and sanitary napkins causes an increased incidence of ovarian cancer in women, shows complete indifference to, or a conscious disregard for the safety of others justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter Johnson & Johnson Defendants and others from similar conduct in the future.

Wherefore, Plaintiff requests a judgment against Johnson & Johnson Defendants for damages in a sum to confer jurisdiction upon this Court together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

## <u>COUNT IV</u> Breach of Express Warranty as to Johnson & Johnson Defendants

134. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

135. The Johnson & Johnson Defendants expressly warranted, through direct-toconsumer marketing, advertisements, and labels, that the Products were safe and effective for reasonably anticipated uses, including use by women on the perineal area and/or perineum. Plaintiff was a person whom Johnson & Johnson Defendants would reasonably have expected to use, consume, and/or be affected by the Products.

136. Plaintiff saw these advertisements, including television commercials, and believed the PRODUCT was safe and effective to use in her perineal area leading to her purchase of the product.

137. The Products did not conform to these express representations in violation of

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Arkansas common law, because the Products were unsafe for the reasonably foreseeable use and consumption of the Plaintiff, due to the increased risk of ovarian cancer when they are applied to women's perineal area or perineum.

138. As a direct and proximate result of Johnson & Johnson Defendants' breach of express warranty, Plaintiff purchased and used the Products, causing her to develop ovarian cancer.

Wherefore, Plaintiff requests a judgment against Johnson & Johnson Defendants for damages in a sum to confer jurisdiction upon this Court together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

## <u>COUNT V</u> Breach of Implied Warranty as to Johnson & Johnson Defendants

139. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

140. The Johnson & Johnson Defendants are merchants with respect to goods like the Products

141. Johnson & Johnson Defendants sold the Products which Plaintiff regularly used to powder her perineal area and perineum. Johnson & Johnson Defendants impliedly warranted to Plaintiff, and those similarly situated that the Products were of merchantable quality and safe for its intended use.

142. Johnson & Johnson Defendants knew or in the exercise of reasonable care should have known the uses for which the Products were intended, including use by women in the perineal and perineum area, and impliedly warranted the Products to be of merchantable quality and safe for such use.

143. The Products were defective in design and manufacture and design and were therefore not fit for their intended uses and were not designed, manufactured, or sold in accordance with good design, manufacturing, or industry standards. The Products were not fit for the common, ordinary and intended uses, including usage by women in the perineal and perineum areas. Therefore, the Johnson & Johnson Defendants have breached the implied warranty of merchantability as well as the implied warranty of fitness for a particular purpose. Such breaches by the Johnson & Johnson Defendants were a proximate cause of the injuries and damages sustained by Plaintiff.

144. When the Products were distributed into the stream of commerce and sold by Johnson & Johnson Defendants, they was unsafe for its intended use, and not of merchantable quality, as warranted by Johnson & Johnson Defendants as use of the Products by women in the perineal and perineum areas causes ovarian cancer.

145. At all times pertinent, 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 Products. These safer alternative designs were economically and technologically feasible, and would have prevented and/or significantly reduced the risk of Plaintiff's injuries without substantially impairing utility.

146. The Johnson & Johnson Defendants knew or should have known of the particular purpose for which the Products were being used, the powdering of women's perineal area and/or perineum, as they encouraged women to apply the Products "all over a women's body." The

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Johnson & Johnson Defendants knew or should have known that the Plaintiff, and consumers generally, relied on their skill and expertise as they were in a position to know the risks and benefits of the Products.

147. As a direct and proximate result of Johnson & Johnson Defendants' breach of implied warranty, Plaintiff relied on them and purchased and used the Products that caused her to develop ovarian cancer; she incurred medical bills, conscious pain and suffering.

Wherefore, Plaintiff requests a judgment against Johnson & Johnson Defendants for damages in a sum to confer jurisdiction upon this Court together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

# <u>COUNT VII</u> Strict Liability - as to IMERYS

148. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

149. At all pertinent times, Imerys mined, milled, and silled talc for Johnson & Johnson Defendants for use in the Products.

150. At all pertinent times, Imerys knew the talc they mined, milled, and silled for Johnson & Johnson Defendants was defective.

151. At all pertinent times, Imerys mined, milled, and silled talc to the precise specifications dictated by the Johnson & Johnson Defendants for use in the Products.

152. At all pertinent times Imerys' talc produced for use in Johnson & Johnson Defendants' Products constituted the primary ingredient in the Products.

153. At all pertinent times Imerys' knew the talc produced for Johnson & Johnson

Defendants' was used in the Products.

154. At all pertinent times Imerys substantially participated in the integration of the talcum powder it mined, milled, and silled into the final product, Johnson's Baby Powder, for Johnson & Johnson Defendants. Imerys substantially participated in the production of the final products, Johnson's Baby Powder, in ways which include but are not limited to the following:

a. Upon information and belief, mining talc to the precise Johnson & Johnson Defendants' specifications for production of the Products;

b. Upon information and belief milling and silling the mined talc to the Johnson & Johnson Defendants' specifications

c. Coordinating talc production efforts with the Johnson & Johnson Defendants, as a significant portion of the products' manufacture and production; and

d. Contributing the most significant ingredient to the products' composition.

155. At all pertinent times Imerys knew or in the exercise of reasonable care should have known that the use of talc-based Products in the perineal area significantly increases a woman's risk of ovarian cancer, based upon scientific knowledge dating back to the 1960s.

156. At all pertinent times, Imerys knew or in the exercise of reasonable care should have known that Johnson & Johnson Defendants were not providing any warnings to the products' consumers regarding the risk of ovarian cancer posed by talc.

157. At all pertinent times, Imerys knew or in the exercise of reasonable care should have known that Johnson & Johnson Defendants were not providing warnings to consumers of the Products concerning the risk of ovarian cancer posed by talc. Thus, it was unreasonable for Imerys to rely upon the Johnson & Johnson Defendants to warn the end consumer of the dangers

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associated with the use of the Products.

158. At all pertinent times, Imerys breached its duty to Plaintiff and those similarly situated in providing talc to the Johnson & Johnson Defendants, when it knew or in the exercise of reasonable care should have known that its talc would be used in the Products, and failing to adequately take steps to ensure that ultimate consumers of the Products, like Plaintiff, received the information that Imerys possessed on the carcinogenic properties of talc, including its risk of causing ovarian cancer.

159. As a direct and proximate result of Imerys' negligence, Plaintiff purchased and used the Products, causing her to develop ovarian cancer; Plaintiff also incurred medical bills, conscious pain and suffering.

160. Imerys' conduct in continuing to manufacture, market, sell and distribute the talc after obtaining knowledge that application of talc to the perineal and perineum areas increases the risk of ovarian cancer in women, shows complete indifference to, or a conscious disregard for the safety of others justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter Imerys and others from similar conduct in the future.

Wherefore, Plaintiff requests a judgment against Imerys for damages in a sum to confer jurisdiction upon this Court together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

# <u>COUNT VIII</u> Concert of Action as to all DEFENDANTS

161. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

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162. Johnson & Johnson Defendants and Imerys and/or their predecessors-in-interest knowingly agreed, contrived, combined, confederated and conspired among themselves to cause injuries, diseases, and/or illnesses by exposing Plaintiff to the h armful and dangerous products. Johnson & Johnson Defendants and Imerys further knowingly agreed, contrived, confederated and conspired to deprive Plaintiff of the opportunity of informed free choice as to whether to use the products, or to expose herself to the associated dangers. Johnson & Johnson Defendants and Imerys committed the above described torts by willfully misrepresenting and suppressing the truth as to the risks and dangers associated with the use of the products in pursuit of a common design and/ or plan.

163. In furtherance of said conspiracies, Johnson & Johnson Defendants and Imerys, acting in concert with one another or pursuant to a common design, performed the following overt acts:

a. For decades, Johnson & Johnson Defendants and Imerys, 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 ordinary and foreseeable use of their Products by women is 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 Johnson & Johnson Defendants and Imerys, these parties individually, jointly, and in conspiracy with each other, fraudulently, willfully and maliciously:

i. Withheld, concealed and suppressed medical information regarding the increased risk of ovarian cancer (as set out in the "Facts" section of this pleading). In addition, on July 27, 2005 the Johnson & 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. Through the TIPTF and PCPC, Johnson & Johnson 41

Defendants instituted a "defense strategy" to defend talc at all costs. Through the TIPTF, Johnson & Johnson Defendants and Imerys used their influence over the NTP subcommittee, and the threat of litigation against NTP to prevent NTP from classifying talc as a carcinogen on its 10<sup>th</sup> Report on Carcinogens ("RoC"). According to the Johnson & Johnson Defendants and Imerys, "... we believe these strategies paid off"; and

iii. Caused to be released, published and disseminated medical and scientific data, literature, and test reports containing information and statements regarding the risks of ovarian cancer which Johnson & Johnson Defendants and Imerys knew were incorrect, incomplete, outdated, and misleading. Specifically, through the TIPTF and PCPC, the Johnson & Johnson Defendants and Imerys 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 Johnson & Johnson Defendants and Imerys were criticized by their own Toxicologist consultant for releasing this false information to the public, yet nothing was done by the Johnson & Johnson Defendants and IMERYS to correct or redact this public release of knowingly false information.

c. By these false and fraudulent representations, omissions, and concealments, Johnson & Johnson Defendants and Imerys intended to induce Plaintiff and others to rely upon false and fraudulent representations, omissions and concealments, and to continue to expose herself to the dangers inherent in the use and exposure to the Products.

164. Individually and in concert with each other, Johnson & Johnson Defendants and Imerys participated in a common plan to commit the torts alleged herein, and each acted tortuously in pursuance of the common plan to protect and promote the health and safety of talc use, to the known detriment of the public, including Plaintiff.

165. Plaintiff reasonably and in good faith relied upon false and fraudulent representations, omissions, and concealments made by Johnson & Johnson Defendants and Imerys regarding the nature of the Products.

166. As a direct and proximate result of Plaintiff's reliance, she sustained damages

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including injuries, and illnesses and was deprived of the opportunity of informed free choice in connection with the use of exposure to the Products. Plaintiff incurred medical bills, conscious pain and suffering.

Wherefore, Plaintiff requests a judgment against Johnson & Johnson Defendants and Imerys for damages in a sum to confer jurisdiction upon this Court together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

#### <u>COUNT IX</u> Civil Conspiracy as to all DEFENDANTS

167. Plaintiff re-alleges and reincorporates by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

168. Johnson & Johnson Defendants and Imerys and/or their predecessors-in-interest knowingly agreed, contrived, combined, confederated and conspired among themselves to cause Plaintiff's injuries, diseases, and/or illnesses by exposing her to a harmful and dangerous Products without providing warnings for that danger. Johnson & Johnson Defendants and Imerys further knowingly agreed, contrived, confederated and conspired to deprive Plaintiff the opportunity of informed free choice as to whether to use the Products or to expose herself to the associated dangers. Johnson & Johnson Defendants and Imerys committed the wrongs as described herein by willfully misrepresenting and suppressing the truth as to the risks and dangers associated with the use of and exposure to the Products.

169. Johnson & Johnson Defendants and Imerys are foreign corporations authorized to do business in the United States including the State of Arkansas. Johnson & Johnson Defendants

and Imerys have derived substantial revenue from the production, marketing, distribution, and sale

of the Products in intrastate and interstate commerce. Johnson & Johnson Defendants and Imerys

should have expected their acts and business activities to have consequences within the State of

Arkansas.

170. In furtherance of said conspiracies, Johnson & Johnson Defendants and Imerys

performed the following overt acts in the United States including the State of Arkansas:

a. For decades, Johnson & Johnson Defendants and Imerys, individually, jointly, and in conspiracy with each other, have been in possession of medical and scientific data, literature and test reports that clearly indicated that ordinary and foreseeable use of the Products by women are unreasonably 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 Johnson & Johnson Defendants and Imerys, they individually, jointly, and in conspiracy with each other, fraudulently, willfully and maliciously:

i. Withheld, concealed and suppressed medical information regarding the increased risk of ovarian cancer for Plaintiff, as described above. In addition, on July 27, 2005, Johnson & Johnson Defendants and Imerys through the TIPTF, corresponded about 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. Instituted a "defense strategy" through the TIPTF to defend talc at all costs. In furtherance of this defense strategy, Johnson & Johnson Defendants and Imerys, 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;

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 Johnson & Johnson Defendants and Imerys knew were incorrect, incomplete, outdated, and misleading. Specifically, Johnson & Johnson Defendants and Imerys, 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 Johnson & Johnson Defendants was criticized by their own toxicologist consultant for releasing this false information to the public, yet nothing was done by the Johnson & Johnson Defendants to correct or redact this public release of knowingly false information.

c. By these false and fraudulent representations, omissions, and concealments, Johnson & Johnson Defendants and Imerys intended to induce, and did induce Plaintiff to rely upon these false and fraudulent representations, omissions and concealments, and to continually expose herself to the dangers inherent in the use and exposure to the Products.

171. Johnson & Johnson Defendants and Imerys knew or in the exercise of reasonable care should have known that the actions alleged above constituted a willful breach of a duty owed to Plaintiff and others similarly situated, that the Products were of safe and marketable use for its intended purpose, and free of unreasonable dangers to health and safety.

172. Johnson & Johnson Defendants and Imerys ratified and adopted each of the foregoing acts and omissions in furtherance of the conspiracy.

173. Plaintiff reasonably and in good faith relied upon the fraudulent representations, omissions, and concealments made by Johnson & Johnson Defendants and Imerys regarding the nature of the Products.

174. As a direct, foreseeable and proximate result of the Johnson & Johnson Defendants and Imerys' conspiracy, Plaintiff purchased and used the Products in her perineal and perineum areas, which caused each her to develop ovarian cancer.

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

Plaintiff incurred medical bills, conscious pain and suffering.

Wherefore, Plaintiff requests a judgment against Johnson & Johnson Defendants and Imerys for damages in a sum to confer jurisdiction upon this Court together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

## <u>Count X</u> Fraud as to all DEFENDANTS

176. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

177. In the course of business, Johnson & Johnson Defendants and Imerys designed, manufactured and sold the Products, knowing it was reasonable and foreseeable that women would use the Products to powder their perineal and perineum areas.

178. At all relevant times, the Johnson & Johnson Defendants and Imerys intentionally, willfully, and/or recklessly, with the intent to deceive, misrepresented and/or concealed material facts to consumers and users, including Plaintiff.

179. At all relevant times, the Johnson & Johnson Defendants and Imerys misrepresented and/or concealed material facts concerning the Products to consumers, including Plaintiff, with knowledge of the falsity of their misrepresentations.

180. Johnson & Johnson Defendants and Imerys were aware of the dangerous and defective condition of the Products and intentionally withheld this information from Plaintiff, the healthcare field, and the general public even though these significant dangers were not readily obvious to ordinary users.

181. At all pertinent times and upon information and belief, the misrepresentations and

concealments made by the Johnson & Johnson Defendants and Imerys concerning the Products

include, but are not limited to the following:

a. Falsely labeling and advertising the Products: "[f]ew ingredients have demonstrated the same performance, mildness and safety profile as cosmetic talc"; "[w]e continue to use talc in our products because decades of science have reaffirmed its safety"; "[s]cience, research, clinical evidence, and decades of studies by medical experts around the world continue to support the safety of the cosmetic talc used in Johnson's Baby Powder";

b. Knowingly misrepresenting to Plaintiff and the public, through the advertisements described above, that the Products are safe for use all over the body, including the perineal and perineum areas;

c. Intentionally failing to disclose that the Products, when used in the perineal area, increases the risk of ovarian cancer due to the talc;

d. Intentionally failing to include adequate warnings with the Products regarding the potential and actual risks of using it in the perineal area of women, and the nature, scope, severity, and duration of any serious resulting injuries, including ovarian cancer; and

e. Despite knowledge regarding the carcinogenic nature of talc and its likelihood to increase the risk of ovarian cancer in women, the Johnson & Johnson Defendants and Imerys falsely marketed, advertised, labeled and sold the Products as safe for public consumption and usage, including for use by women to powder their perineal areas.

182. Plaintiff justifiably relied upon the aforementioned misrepresentations and concealments made by the Johnson & Johnson Defendants and Imerys and used the Products as described herein for many years.

183. As a direct and proximate result of Plaintiff's reliance on Johnson & Johnson

Defendants and Imerys' fraudulent misrepresentations and concealments, she was seriously and

permanently injured.

184. As a direct and proximate result of Plaintiff's reliance, she sustained damages

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including injuries, and illnesses, and was deprived of the opportunity of informed free choice in connection with the use of and exposure to Johnson & Johnson Defendants and Imerys' Products. As a direct and proximate result of Plaintiff's use of the Products, she incurred medical bills, conscious pain and suffering.

185. The conduct of Johnson & Johnson Defendants and Imerys in continuing to market, promote, sell and distribute the Products while fraudulently concealing knowledge that the products were failing and not performing as represented and intended, shows a complete indifference to, or conscious disregard for the safety of others justifying an award in such sum which will serve to deter Johnson & Johnson Defendants and Imerys and others from similar conduct.

Wherefore, Plaintiff requests a judgment against Johnson & Johnson Defendants and Imerys for damages in a sum to confer jurisdiction upon this Court together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

# COUNT XI CONSTRUCTIVE FRAUD as to all DEFENDANTS

186. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs as though fully set forth therein.

187. Johnson & Johnson Defendants and Imerys had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff and the public that the Products had been tested and found to be safe and effective for use in the perineal area. However, the representations made by Johnson & Johnson Defendants and Imerys, in fact, were false.

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188. Johnson & Johnson Defendants and Imerys failed to exercise reasonable care in the representations concerning the Products while they were involved in the manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants committed fraud in the law when they made misrepresentations regarding the Products' safety without mention of the high risk of unreasonable, dangerous and adverse side effects.

189. Johnson & Johnson Defendants and Imerys breached their duty in representing that the Products have no serious side effects, and were safe for use in the perineal and perineum areas.

190. As a foreseeable, direct and proximate result of the constructive fraud of Johnson & Johnson Defendants and Imerys as set forth herein, Johnson & Johnson Defendants and Imerys knew and had reason to know, that the Products had been insufficiently tested, or had not been tested at all, and that the Products lacked adequate and accurate warnings, created a high risk and/or higher than acceptable risk, and/or higher than reported and represented risk, of adverse side effects like ovarian cancer.

191. At all pertinent times the misrepresentations, omissions and concealments concerning the Products made by the Johnson & Johnson Defendants and Imerys include, but are not limited to the following:

a. Failing to disclose to Plaintiff, and those similarly situated, through adequate warnings, representations, labeling or otherwise, that the Products are inherently dangerous and carcinogenic in nature, posing serious health risks to consumers;

b. Failing to disclose to Plaintiff, and those similarly situated, through adequate warnings, representations, labeling or otherwise the material fact that the use of the Products in the perineal area creates a significantly increased risk of ovarian cancer; and

c. Falsely marketing, advertising, labeling and selling the Products as safe for public consumption and usage, including for use by women to

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powder their perineal areas, despite knowledge of the carcinogenic nature of talc and its likelihood to increase the risk of ovarian cancer in women.

192. At all pertinent times, Johnson & Johnson Defendants and Imerys failed to exercise reasonable care in ascertaining or sharing information regarding the safe use of the Products, failed to disclose facts indicating that the Products were inherently dangerous and carcinogenic in nature, and otherwise failed to exercise reasonable care in communicating the information concerning the Products to Plaintiff, and/or concealed relevant facts that were known to them.

193. At all pertinent times, Plaintiff was neither aware of the falsity of the foregoing misrepresentations, nor that material facts concerning talc and the Products had been concealed or omitted. In reasonable reliance upon the Johnson & Johnson Defendants and Imerys' misrepresentations and/or omissions, Plaintiff was induced to and did purchase the Products and used them on her perineal area and perineum. If the Johnson & Johnson Defendants and Imerys had disclosed true and accurate material facts concerning the risks of the use of the Products, in particular the risk of developing ovarian cancer from using the Products in the perineal area and perineum. Plaintiff would not have purchased and/or received the Products and/or used the Products in that manner.

194. Plaintiff's reliance upon the Johnson & Johnson Defendants and Imerys misrepresentations and omissions was justified and reasonable because, among other reasons, those misrepresentations and omissions were made by individuals and entities who were in a position to know the material facts concerning the Products and the association between the Products and the incidence of ovarian cancer, while Plaintiff was not in a position to know these material facts. Johnson & Johnson Defendants and Imerys failed to warn or otherwise provide

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notice to the consuming public as Products' risks, thereby inducing Plaintiff to use it in lieu of safer alternatives, and in ways that created unreasonably dangerous risks to her health. At all relevant times, the Johnson & Johnson Defendants and Imerys' corporate officers, directors, and/or managing agents knew of and ratified the acts, as alleged herein.

195. As a direct, foreseeable and proximate result of the Johnson & Johnson Defendants and Imerys fraudulent conduct, Plaintiff purchased and used the Products in her perineal area and perineum.

196. As a direct and proximate result of such use, Plaintiff developed ovarian cancer, and was caused to incur medical bills, lost wages, and conscious pain and suffering.

Wherefore, Plaintiff requests a judgment against Johnson & Johnson Defendants and Imerys for damages in a sum to confer jurisdiction upon this Court together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

# **<u>COUNT VII</u>** Failure to Warn as to all DEFENDANTS

197. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

198. At all pertinent times, Imerys mined, milled, and silled talc for Johnson & Johnson Defendants.

199. At all pertinent times, Imerys knew or in the exercise of reasonable care should have known that Johnson & Johnson Defendants were packaging and selling talc to consumers as Johnson's Baby Powder, and it knew or in the exercise of reasonable care should have known that

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consumers were using the products to powder their perineal and perineum regions.

200. At all pertinent times, Imerys knew or in the exercise of reasonable care should have known or anticipated the unreasonably dangerous and carcinogenic nature of the talc it sold to Johnson & Johnson Defendants, especially when used in a women's perineal region. Further, Imerys knew or in the exercise of reasonable care should have known that Johnson & Johnson Defendants were not warning consumers of this danger.

201. At all pertinent times, Imerys knew the talc mined, milled, and silled was defective at distribution and sale to Johnson & Johnson Defendants. Upon information and belief, the talc Imerys mined, milled, and silled for Johnson & Johnson Defendants was created to the specifications mandated by contract with the Johnson & Johnson Defendants.

202. At all pertinent times, the Johnson & Johnson Defendants were engaged in the manufacturing, marketing, testing, promotion, selling and/or distributing the Products in the regular course of business.

203. At all pertinent times, the Johnson & Johnson Defendants knew or in the exercise of reasonable care should have known or anticipated that the use of a talc-based Products in the perineal and/or perineum area significantly increases the risk of ovarian cancer based upon scientific knowledge dating back to the 1960's.

204. At all pertinent times, including the time of sale and consumption, the Products were unreasonably dangerous and defective condition, given the Defendants' knowledge that Johnson Baby Powder was carcinogenic and could lead to an increased risk of ovarian cancer when applied to the perineal area, a reasonably foreseeable use of the Products, Defendants failed to provide adequate warnings or instruction to consumers, including Plaintiff, regarding the increased

risk of ovarian cancer associated with the use of the Products in the perineal or perineum areas.

Defendants failed to properly and adequately warn and instruct Plaintiff as to the risks and benefits

of the Products.

205. The Defendants' Products were defective in:

a. Failing to contain clear and concise warnings and/or instructions on the Products' packaging regarding the risk of application to the perineal area;

b. Failing to include clear and concise warnings and/or instructions in the Products' advertisements, including those in print, on the web, on the radio, or televised, regarding the potential harmful effects, including the increased risk of ovarian cancer, associated with its use;

c. Failing to alert the Public to the specific dangers of talc use, including the increased risk of development of cancers including ovarian cancer;

d. Breaching express warranties and/or failing to conform to express factual representations upon which Plaintiff justifiably relied in electing to use the Products; and

e. Breaching implied warranties of merchantability as the Products were defectively designed with an available safer alternative and the Defendants failed to warn of the increased risk of ovarian cancer.

206. The dangerous and defective conditions in the Products existed at the time they were delivered by the manufacturer to the distributor. At all pertinent times in which Plaintiff used the Products to powder her perineal area, the Products were in the same condition as when they were manufactured, distributed and sold.

207. Plaintiff was unaware at all pertinent times, of the dangers associated with use of

the Products in her perineal area and perineum. Plaintiff used the Products to powder her perineal

area, which is a reasonably foreseeable use and in a manner normally intended by the Defendants.

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208. Had Plaintiff received a warning that the use of the Products in her perineal area would significantly increase her risk of ovarian cancer, she would not have used the Products in that manner. Her use of the Products caused her development of ovarian cancer.

209. As a direct and proximate result of the unreasonably dangerous and defective condition of the Products at the time of sale and consumption, Plaintiff developed ovarian cancer. Plaintiff suffered injuries and damages including but not limited to conscious pain and suffering, and medical expenses.

210. The conduct of Defendants in continuing to market, promote, sell and distribute the Products after obtaining knowledge that talcum powder was significantly linked to causing ovarian cancer in women who used the Products in their perineal and/or perineum areas, shows a complete indifference to, or conscious disregard for the safety of others justifying an award in such sum which will serve to deter Defendants and others from similar conduct.

Wherefore, Plaintiff requests a judgment against Defendants for damages in a sum to confer jurisdiction upon this Court together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

# <u>COUNT XV</u> Arkansas Deceptive Trade Practices as to all DEFENDANTS

211. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

212. At all pertinent times, Defendants engaged in deceptive trade practices, in violation of the Arkansas Deceptive Trade Practice Act, Ark. Code Ann. § 4-88-101 *et. seq.* in the manufacturing, distributing, marketing, promoting, and sale of the Products in the following ways:

a. Representing that the Products have uses, benefits or qualities, like maintaining "softness" or "dryness" of the skin when applied directly, when the benefits of such usage is disproportionately outweighed by the significant increase in the likelihood of ovarian cancer when applied in the perineal or perineum regions;

b. Representing that the Products are of a particular standard or quality, purportedly safe for use by women in the perineal and/or perineum areas, when Defendants knew or in the exercise of reasonable care should have known that such use would lead to significant increased likelihood of ovarian cancer;

c. Continuing to advertise the Products as safe and effective for use all over the body, when Defendants have known from at the least the 1970's that such usage leads to a significant increase in the likelihood of ovarian cancer when it is applied to the perineal and/or perineum areas;

d. Consistently engaging in advertising campaigns in the print, radio, web, and cable advertisements promoting the safety of the products when applied to a women's perineal and/or perineum areas, promoting confusion as mounting scientific literature and evidence says otherwise;

e. Johnson & Johnson Defendants and Imerys consciously choosing to release false information to the public regarding the safety of talc, leading to confusion and misunderstanding of the dangers surrounding talc use on a women's perineal and/or perineum areas; and

f. Otherwise engaging in practices that are unfair and/or deceptive to consumers, including Plaintiff.

213. As a direct and proximate result of Defendants deceptive trade practices in the

marketing, promoting, selling, distributing, advertising, and offering for sale the Products to

consumers in the State of Arkansas, Plaintiff was harmed. Had Plaintiff received a warning that

the use of the Products in her perineal area, would significantly increase her risk of ovarian cancer,

she would not have used the Products in that manner. Her use of the Products caused her

development of ovarian cancer.

214. As a proximate result of Defendants' design, manufacture, marketing, sale and distribution of the Products, Plaintiff has been injured catastrophically, and has been caused severe

pain, suffering, disability, and impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

Wherefore, Plaintiff requests a judgment against Defendants for damages in a sum to confer jurisdiction upon this Court together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

# <u>COUNT XVI</u> Punitive Damages as to all DEFENDANTS

215. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein. Plaintiff pleads all Counts of this Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice of law principles including the law of the Plaintiff's resident State.

216. Defendants sold the Products to Plaintiff and other consumers throughout the United States without doing adequate testing to ensure that the Products were reasonably safe for their intended use.

217. Defendants sold the Products to Plaintiff and other consumers throughout the United States in spite of their knowledge that the Products caused the problems heretofore set forth in this Complaint, thereby causing the severe and debilitating injuries suffered by the Plaintiff.

218. At all times pertinent, Defendants knew or should have known that the Products was inherently dangerous with respect risk of ovarian cancer, loss of life's enjoyment, an effort to cure the conditions proximately related to the use of the product, as well as other severe and personal injuries which are permanent and lasting in nature.

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219. At all times pertinent, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of the Products, including but not limited to information regarding the increased risk of developing ovarian cancer when the Products was used in the perineal area.

220. Defendants' misrepresentations included knowingly withholding material information from the consumers, including Plaintiff, concerning the safety and efficacy of the Products.

221. At all times pertinent, Defendants knew and intentionally and/or recklessly disregarded the fact that the Products cause debilitating and potentially lethal side effects with greater frequency than safer alternative products.

222. At all times pertinent, Defendants knew and intentionally and/or recklessly disregarded the fact that the Products cause debilitating and potentially lethal side effects with greater frequency than safer alternative products and recklessly failed to advise the public of the same.

223. At all times pertinent, Defendants intentionally misstated and misrepresented data and continue to misrepresent data so as to minimize the true and accurate risk of injuries and complications caused by the Products.

224. Notwithstanding the foregoing, Defendants continue to aggressively market the Products to consumers, without disclosing the true risk of side effects.

225. Defendants knew that the Products were defective and of an unreasonably dangerous nature, but continued to manufacture, produce, assemble, market, distribute, and sell the Products so as to maximize sales and profits at the expense of the health and safety of the Public, including Plaintiff, in conscious and/or reckless disregard of the foreseeable harm caused

by the Products.

226. Defendants continue to intentionally conceal and/or recklessly and/or grossly negligently fail to disclose to the public, including Plaintiff, the serious side effects of the Products in order to ensure continued and increased sales.

227. Defendants' intentional, reckless and/or grossly negligent failure to disclose information deprived Plaintiff of necessary information to enable her to weigh the true risks of using the Products against the benefits.

228. As a direct and proximate result of the foregoing acts and omissions, Plaintiff has required and will require health care and services, and have incurred medical, health care, incidental, and related expenses. Plaintiff is informed and believe and further allege that Plaintiffs and other members of the public will in the future be required to obtain further medical care and/or hospital care and medical services.

229. Defendants have engaged in conduct entitling Plaintiff to an award of punitive damages pursuant Common Law principles and the statutory provisions of the Plaintiff's respective home state and Defendants' home states.

230. Defendants' conduct as described herein shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which raises the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

Wherefore, Plaintiff requests a judgment against Defendants for damages in a sum to confer jurisdiction upon this Court together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

# PLAINTIFF REQUESTS A TRIAL BY JURY ON ALL COUNTS.

Dated: April 17, 2017

TAYLOR A. KING & ASSOCIATES, P.A.

D Hains

J.D. Hays, Jr. 808 W. Sunset Avenue Box 4 Springdale, AR 72764 (479) 935-1764 (479) 439-4327 facsimile jdhays@taylorkinglaw.com

Carmen S. Scott\* Motley Rice LLC 28 Bridgeside Blvd. Mount Pleasant, SC 29464 (843) 216-9160 (843) 216-9450 facsimile cscott@motleyrice.com \*Pro hac vice motion pending

# Case 3:17-cv-00086-JLH Document 1-1 Filed 04/19/17 Page 1 of 1 CIVIL COVER SHEET 3,17-CV&0

JS 44 (Rev. 08/16)

# CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

I. (a) PLAINTIFFS JAMIE ENGEL				DEFENDANTS JOHNSON & JOHNSON, JOHNSON & JOHNSON CONSUMER INC. f/k/a JOHNSON & JOHNSON CONSUMER COMPANIES, INC., IMERYS TALC		
(b) County of Residence of First Listed Plaintiff Clay County (EXCEPT IN U.S. PLAINTIFF CASES)				County of Residence of First Listed Defendant <u>Middlesex County, NJ</u> (IN U.S. PLAINTIFF CASES ONLY) NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.		
(c) Attorneys (Firm Name, Au J.D. Hays, Jr., Taylor A. K Box 4, Springdale, AR 72	ing & Associates, P.A	9 A., 808 W. Sunset /	Ave,	Attomeys (If Known)		
II. BASIS OF JURISDI	CTION (Place an "X" in O	ne Box Only)	III. CI	TIZENSHIP OF P	RINCIPAL PARTIES	(Place an "X" in One Box for Plaintiff
1 U.S. Government Plaintiff	3 Federal Question (U.S. Government Not a Party)		Citiz	(For Diversity Cases Only) P1 en of This State		
2 U.S. Government Defendant	<b>3</b> 4 Diversity (Indicate Citizenship of Parties in Item III)		Citiz	en of Another State	2 D 2 Incorporated and P of Business In A	Another State
				en or Subject of a reign Country	3 🗇 3 Foreign Nation	0606
IV. NATURE OF SUIT (Place an "X" in One Box Only) Click here for: <u>Nature of Suit Code Descriptions</u> .						
		RTS PERSONAL INJUR		ORFEITURE/PENALTY	BANKRUPTCY	☐ 375 False Claims Act
<ul> <li>130 Miller Act</li> <li>140 Negotiable Instrument</li> </ul>	PERSONAL INJURY ☐ 310 Airplane ☐ 315 Airplane Product Liability	<ul> <li>365 Personal Injury - Product Liability</li> <li>367 Health Care/</li> </ul>	_	25 Drug Related Seizure of Property 21 USC 881 90 Other	<ul> <li>422 Appeal 28 USC 158</li> <li>423 Withdrawal 28 USC 157</li> </ul>	<ul> <li>☐ 376 Qui Tam (31 USC 3729(a))</li> <li>☐ 400 State Reapportionment</li> </ul>
<ul> <li>150 Recovery of Overpayment &amp; Enforcement of Judgment</li> <li>151 Medicare Act</li> <li>152 Recovery of Defaulted</li> </ul>	<ul> <li>320 Assault, Libel &amp; Slander</li> <li>330 Federal Employers' Liability</li> </ul>	Pharmaceutical Personal Injury Product Liability 368 Asbestos Persona	1		PROPERTY RIGHTS         820 Copyrights         830 Patent         840 Trademark	<ul> <li>410 Antitrust</li> <li>430 Banks and Banking</li> <li>450 Commerce</li> <li>460 Deportation</li> </ul>
(Excludes Veterans) 153 Recovery of Overpayment	<ul> <li>340 Marine</li> <li>345 Marine Product Liability</li> <li>350 Motor Vehicle</li> </ul>	Injury Product Liability <b>PERSONAL PROPER</b> <b>3</b> 70 Other Fraud		LABOR 10 Fair Labor Standards Act	SOCIAL SECURITY           861 HIA (1395ff)           862 Black Lung (923)	<ul> <li>470 Racketeer Influenced and Corrupt Organizations</li> <li>480 Consumer Credit</li> <li>490 Cable/Sat TV</li> </ul>
<ul> <li>160 Stockholders' Suits</li> <li>190 Other Contract</li> <li>195 Contract Product Liability</li> <li>196 Franchise</li> </ul>	<ul> <li>355 Motor Vehicle Product Liability</li> <li>360 Other Personal Injury</li> </ul>	<ul> <li>371 Truth in Lending</li> <li>380 Other Personal Property Damage</li> <li>385 Property Damage</li> </ul>	0 74	20 Labor/Management Relations 40 Railway Labor Act 51 Family and Medical	<ul> <li>863 DIWC/DIWW (405(g))</li> <li>864 SSID Title XVI</li> <li>865 RSI (405(g))</li> </ul>	<ul> <li>B50 Securities/Commodities/ Exchange</li> <li>B90 Other Statutory Actions</li> <li>B91 Agricultural Acts</li> </ul>
	362 Personal Injury - Medical Malpractice	Product Liability	0 79	Leave Act 90 Other Labor Litigation	FEDERAL TAX SUITS	893 Environmental Matters     895 Freedom of Information     Act
REAL PROPERTY     210 Land Condemnation	CIVIL RIGHTS     440 Other Civil Rights	PRISONER PETITIO Habeas Corpus:		P1 Employee Retirement Income Security Act	870 Taxes (U.S. Plaintiff	896 Arbitration
<ul> <li>220 Foreclosure</li> <li>230 Rent Lease &amp; Ejectment</li> <li>240 Torts to Land</li> <li>245 Tort Product Liability</li> </ul>	<ul> <li>441 Voting</li> <li>442 Employment</li> <li>443 Housing/ Accommodations</li> </ul>	<ul> <li>463 Alien Detainee</li> <li>510 Motions to Vacate Sentence</li> <li>530 General</li> </ul>	e		or Defendant) 871 IRS—Third Party 26 USC 7609	<ul> <li>899 Administrative Procedure Act/Review or Appeal of Agency Decision</li> <li>950 Constitutionality of State Statutes</li> </ul>
□ 290 All Other Real Property	445 Amer. w/Disabilities -	535 Death Penalty		IMMIGRATION		
	Employment 446 Amer. w/Disabilities - Other 448 Education	Other: 540 Mandamus & Oth 550 Civil Rights 555 Prison Condition 560 Civil Detainee - Conditions of Confinement		52 Naturalization Application 55 Other Immigration Actions		
V. ORIGIN (Place an "X" in	One Box Only)	Commentent				
X 1 Original □ 2 Ren	noved from 🗖 3	Remanded from Appellate Court	□ 4 Rein Reo	, i i i i i i i i i i i i i i i i i i i	erred from r District b District C Multidistr Litigation Transfer	
VI. CAUSE OF ACTIO	N Brief description of ca	1391 and 1392	re filing (	Do not cite jurisdictional stat	tutes unless diversity):	
VII. REQUESTED IN COMPLAINT:       CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.			N D	DEMAND S CHECK YES only if demanded in complaint: JURY DEMAND: X Yes INO		
VIII. RELATED CASE IF ANY	<b>C(S)</b> (See instructions):	JUDGE Freda L. V	Volfson	(DNJ)	DOCKET NUMBER	DL # 2738 Talcum Powder
DATE 04/17/2017		SIGNATURE OF AT	TORNEY	OF RECORD		
FOR OFFICE USE ONLY RECEIPT # AM	IOUNT	APPLYING IFP		JUDGE	MAG. JUI	DGE