

**ONTARIO
SUPERIOR COURT OF JUSTICE**

BETWEEN:

CINDY LOU STRATHDEE, MARIO NUNZIATO, MATTHEW STRATHDEE, SHAEDA
BEGUM FAROOQI-WILLISON, GERALD DOUGLAS WILLISON, THÉRÈSE BERNIER,
Deceased, by her Estate Representative MARILYNE BERNIER, MARILYNE BERNIER, JANET
HEATON and BARRY HEATON

Plaintiffs

-and-

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

Defendants



Proceeding under the *Class Proceedings Act*, 1992

STATEMENT OF CLAIM

TO THE DEFENDANTS:

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the plaintiffs.
The claim made against you is set out in the following pages.

IF YOU WISH TO DEFEND THIS PROCEEDING, you or an Ontario lawyer acting for you must prepare a statement of defence in Form 18A prescribed by the *Rules of Civil Procedure*, serve it on the plaintiffs' lawyer or, where the plaintiffs do not have a lawyer, serve it on the plaintiffs, and file it, with proof of service, in this court office, **WITHIN TWENTY DAYS** after this statement of claim is served on you, if you are served in Ontario.

If you are served in another province or territory of Canada or in the United States of America, the period for serving and filing your statement of defence is forty days. If you are served outside Canada and the United States of America, the period is sixty days.

Instead of serving and filing a statement of defence, you may serve and file a notice of intent to defend in Form 18B prescribed by the *Rules of Civil Procedure*. This will entitle you to ten more days within which to serve and file your statement of defence.

IF YOU FAIL TO DEFEND THIS PROCEEDING, JUDGMENT MAY BE GIVEN AGAINST YOU IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU. IF YOU WISH TO DEFEND

THIS PROCEEDING BUT ARE UNABLE TO PAY LEGAL FEES, LEGAL AID MAY BE AVAILABLE TO YOU BY CONTACTING A LOCAL LEGAL AID OFFICE.

TAKE NOTICE: THIS ACTION WILL AUTOMATICALLY BE DISMISSED if it has not been set down for trial or terminated by any means within five years after the action was commenced unless otherwise ordered by the court.

Issued Date: MAY 18 2016

Issued by:.....

Local Registrar

Address of court office:

393 University Avenue
10th Floor
Toronto, Ontario
M5G 1E6

TO: JOHNSON & JOHNSON INC.
8565 Autoroute Transcanadienne
Suite 300
Ville St.-Laurent QC H4S 1Z6

AND TO: JOHNSON & JOHNSON
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933
U.S.A.

AND TO: JOHNSON & JOHNSON CONSUMER COMPANIES, INC.
One Johnson & Johnson Plaza
New Brunswick, New Jersey 08933
U.S.A.

CLAIM

1. The plaintiffs, Cindy Lou Strathdee ("Cindy"), Mario Nunziato ("Mario"), Matthew Strathdee ("Matthew"), Shaeda Begum Farooqi-Willison ("Shaeda"), Gerald Douglas Willison ("Gerald"), Thérèse Bernier ("Thérèse"), by her estate representative Marilyne Bernier ("Marilyne") and Marilyne Bernier personally, Janet Heaton ("Janet") and Barry Heaton ("Barry"), on their own behalf and on behalf of all members of the classes of persons described below ("the Class" or "Class Members" and "the Family Class" or "Family Class Members") seek the following relief:

- a) an order certifying this action as a class proceeding and appointing Cindy, Shaeda, Marilyne as the representative of Thérèse's estate, and Janet as the representative plaintiffs of the Class and Mario, Matthew, Gerald, Marilyne and Barry as the representative plaintiffs of the Family Class, all pursuant to the *Class Proceedings Act, 1992* ("CPA");
- b) a declaration that the defendants owed a duty of care to the Class Members;
- c) a declaration that the defendants were negligent in the development, testing, design, manufacturing, licensing, distribution, marketing and sale of Johnson's Baby Powder ("Baby Powder") as defined below in paragraph 2, and are liable to the Classes for resulting damages;
- d) a declaration that the defendants breached their duty to warn the plaintiffs and other Class Members of the health risks associated with Baby Powder;
- e) a declaration that the packaging and labeling for Baby Powder was false, misleading, deceptive, unconscionable and amounted to deceptive and unfair business practices in breach of the Ontario *Consumer Protection Act* and equivalent provincial and territorial legislation;
- f) a declaration that the defendants breached their implied warranties relating to the safety of Baby Powder;
- g) a declaration that the defendants made representations related to the safety and efficacy of Baby Powder to Cindy, Shaeda, Thérèse, Janet and other Class Members that were false, misleading, deceptive and unconscionable and amounted to unfair practices;
- h) a declaration that the defendants are vicariously liable to the Classes for the acts and omissions of their officers, directors, agents, employees and representatives;
- i) general damages in an amount to be provided prior to trial or such other amount as may be proved in this Honourable Court;

- j) special damages in an amount to be provided prior to trial or such other amount as may be proved in this Honourable Court;
- k) punitive damages in an amount to be provided prior to trial or such other amount as may be proved in this Honourable Court;
- l) alternatively, a declaration that the plaintiffs and other Class Members are entitled to recover under restitutionary principles and an accounting and an order requiring disgorgement of all revenue received by the defendants from the sale of Baby Powder in Canada;
- m) the costs of notice and administering the plan of distribution of the recovery in this action plus applicable taxes pursuant to s. 26(9) of the *Class Proceedings Act, 1992*, S.O. 1992, c 6 ("CPA");
- n) an order directing a reference or such other directions as may be necessary to determine issues not determined at the trial of the common issues;
- o) pre-judgment and post-judgment interest pursuant to sections 128 and 129 of the *Courts of Justice Act*, R.S.O. 1990, c. C.43, as amended;
- p) the costs of this action on a substantial indemnity basis, together with all applicable taxes thereon; and
- q) such further and other relief as this Honourable Court deems just.

NATURE OF THE ACTION

2. This action relates to the pain and suffering and resulting damages suffered by the plaintiffs herein and other members of the Classes as a result of the defendants' negligent research and development, design, testing, manufacture, licensing, marketing, distribution and sale of perfumed talcum powder under the brand name of JOHNSON'S® baby powder ("Baby Powder") in Canada.

3. As detailed further below, Cindy used Baby Powder in her perineal area every day for nearly 30 years. In May 2012, Cindy was diagnosed with stage 3 epithelial ovarian cancer that had metastasized to her sigmoid colon. That same month, Cindy underwent emergency surgery that involved a total hysterectomy, removal of both her ovaries and her appendix, as well as a resection of

a mass on her sigmoid colon. She subsequently underwent six rounds of chemotherapy. As a result of her cancer, Cindy also experienced several pulmonary embolisms, necessitating the placement of an inferior vena cava (IVC) filter as well as ongoing anticoagulant treatment.

4. Shaeda used Baby Powder in her perineal area every day for approximately 40 years. In January 2005, Shaeda was diagnosed with stage 3 ovarian cancer. She consequently underwent a complete hysterectomy and had chemotherapy and radiation treatment. On September 30, 2005, Shaeda's healthcare providers declared her to be in remission, but warned her that the cancer would likely return. As a result of the cancer, Shaeda developed severe depression and is currently on medication and long-term disability.

5. Thérèse used Baby Powder in her perineal area every day for more than 50 years. Thérèse was diagnosed with ovarian cancer in March 2012 and, in May 2012, she underwent surgery for the removal of her uterus and both ovaries. Thérèse subsequently underwent a course of chemotherapy, and, in November 2012, her cancer was noted to be in remission. The cancer returned in February 2014, and Thérèse underwent a second course of chemotherapy, again being found in remission in February 2015. However, in June 2015, the cancer returned and had metastasized. Despite further treatment with chemotherapy, in March 2016, at the age of 66, Thérèse died of ovarian cancer.

6. Janet used Baby Powder in her perineal area every day for nearly 30 years. In or around November 2011, Janet was diagnosed with Level 4, Stage 1 ovarian cancer. She underwent six rounds of chemotherapy and was subsequently declared to be in remission. However, in January 2016, Janet again began to feel unwell, and testing revealed that the ovarian cancer had returned. Janet has since resumed chemotherapy and continues to undergo treatment.

7. Mario, Matthew, Gerald, Marilyne and Barry have suffered, and will continue to suffer, emotional anguish resulting from Cindy, Shaeda, Thérèse and Janet's extreme pain and suffering (and Thérèse's ultimate death) from ovarian cancer.

8. The plaintiffs allege that Baby Powder is defective and inherently dangerous in that it causes, materially contributes to, and materially increases the risks of ovarian cancer in females who apply it (or who have it applied) to their perineal area. The plaintiffs further allege that the defendants have known about these defects but have failed to disclose these defects and the resulting risks to the health and life of the plaintiffs, Class Members, their treating physicians and regulatory authorities in Canada and have failed to recall Baby Powder in Canada.

9. The defendants' failure to warn Class Members of the risks of perineal application of Baby Powder, is a material omission regarding the risks of using Baby Powder. In addition, the defendants' representations as to the safety of Baby Powder constitute false and misleading representations that deceive or tend to deceive consumers into believing that they are not at risk of developing ovarian cancer by using Baby Powder, in violation of the Ontario *Consumer Protection Act* and equivalent provincial and territorial legislation.

THE PARTIES

10. Cindy was born on January 12, 1960 and is currently 56 years old. She resides with her common-law spouse Mario in Mississauga, in the Province of Ontario. Matthew is her 25-year-old son.

11. Shaeda was born on March 6, 1958 and is currently 58 years old. She resides with Gerald in Toronto, in the Province of Ontario.

12. Thérèse was born on September 17, 1949 and resided in Montréal, in the Province of Québec. She died of ovarian cancer on March 24, 2016. She was 66 years old.

13. Marilynne was born on May 5, 1977 and resides in Montréal, in the Province of Québec.

14. Janet was born on March 8, 1949 and is currently 67 years old. She resides with Barry in Coboconk, in the Province of Ontario.

15. The defendant, Johnson & Johnson Inc. ("J&J Canada"), is a Canadian corporation with its headquarters in Ville St.-Laurent, Québec, and is a wholly owned subsidiary of Johnson & Johnson. At all times material to this action, J&J Canada engaged in the business of, or was successor in interest to, entities engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising and/or selling Baby Powder to Canadian consumers.

16. The defendant, Johnson & Johnson Consumer Companies, Inc. ("J&J Consumer Companies"), is a New Jersey corporation with its principle place of business in New Brunswick, New Jersey and is a wholly owned subsidiary of Johnson & Johnson. At all times material to this action, J&J Consumer Companies was engaged in the business of, or was successor in interest to, entities engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising, and/or selling Baby Powder to Canadian consumers.

17. The defendant, Johnson & Johnson ("J&J"), is a New Jersey corporation, which has its principle place of business in New Brunswick, New Jersey. At all times material to this action, J&J was engaged in the business of, or was successor in interest to, entities engaged in the business of researching,

licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising, and/or selling Baby Powder to Canadian consumers.

18. The business of each of the defendants herein (collectively referred to herein as “the defendants”) is inextricably interwoven with that of the other and each is the agent of the other for the purposes of the development, manufacture, marketing, sale and/or distribution of Baby Powder in Canada.

19. At all material times, the defendants each participated in and/or shared the common purpose of one of more of the following: designing, developing, manufacturing, testing, inspecting, marketing, supplying, exporting, importing, and selling Baby Powder in Canada for profit. The defendants also shared the common purpose of concealing the defects in Baby Powder from the plaintiffs and Class Members.

20. At all relevant times, each of the defendants acted on behalf of each other and Johnson & Johnson exercised control over its subsidiaries, corporate divisions and licensees because, among other things:

- a) it operated itself and the other defendants as a single global entity;
- b) it controlled the day-to-day operations of its subsidiaries through its consolidated management structure;
- c) it prepared its financial statements on a consolidated basis; and
- d) it conspired with the other defendants to manufacture, market, sell, and distribute the defective Baby Powder.

21. At all material times, each defendant was the agent of the other and as such, each defendant is individually, as well as jointly and severally, liable to the plaintiffs and other Class Members for their injuries, losses and damages because:

- a) each company's business, insofar as it related to the manufacture, marketing and sale of Baby Powder in Canada, was operated so that it was inextricably interwoven with the business of the other;
- b) each company entered into a common business plan and shared the common purpose of developing, manufacturing and selling Baby Powder in Canada for profit;
- c) each company owed a duty to the other and to each Class Member and Family Class Member by virtue of the common business plan to manufacture and sell Baby Powder in Canada; and
- d) each company intended that its business, insofar as it related to the manufacture, marketing and sale of Baby Powder in Canada, be run as one global business organization.

THE CLASSES

22. Cindy, Shaeda, Marilyne as the representative of Thérèse's estate, and Janet bring this action on behalf of the members of the Class defined as follows:

"All women resident in Canada who purchased and/or used JOHNSON'S® baby powder and their estates, administrators or other legal representatives, heirs or beneficiaries ("the Class" or "Class Members")"

23. Mario, Matthew, Gerald, Marilyne and Barry bring this action on their own behalf and on behalf of the members of the Family Class defined as follows:

"All persons who on account of a personal relationship to a Class Member are entitled to assert a derivative claims for damages pursuant to section 61(1) of the *Family Law Act*, R.S.O. 1990, c.F.3, as amended and comparable provincial and territorial legislation ("the Family Class" or "Family Class Members")"

PLAINTIFFS' CIRCUMSTANCES*Cindy Lou Strathdee*

24. Cindy used Baby Powder as part of her personal hygiene routine, every day for nearly 30 years. She was loyal to the brand manufactured by the defendants, and never used any other brand of talcum powder. Cindy used the talc in various places on her body, including in her perineal area. She used the Baby Powder in accordance with the instructions on the label.

25. On March 26, 2012, Cindy went to the Emergency Room with severe abdominal pain. A CT scan was done which showed a large pelvic mass. On March 31, 2012, Cindy was admitted to the hospital for massive bilateral pulmonary emboli as well as the (as yet undiagnosed) pelvic mass. Cindy was placed on anticoagulant treatment and subsequently implanted with an inferior vena cava filter due to recurrent experiences with pulmonary emboli.

26. On May 1, 2012, Cindy underwent emergency surgery for the removal of the pelvic mass. The surgery involved a total hysterectomy, removal of both her ovaries and her appendix, as well as a resection of a mass on her sigmoid colon. Subsequent pathology revealed that Cindy had stage 3 epithelial ovarian cancer that had metastasized to her sigmoid colon. Her pulmonary emboli were found to be linked to her cancer.

27. On May 8, 2012, Cindy was discharged from the hospital and subsequently underwent six rounds of chemotherapy. She then attended for regular follow-up examinations with her oncologist, as well as for her anticoagulant treatment.

28. In 2015, for the first time, Cindy discovered that there are links between ovarian cancer and perineal use of Baby Powder. She discovered this not from the defendants, but from information she saw on television. Consequently, and after nearly 30 years of use, she stopped using Baby Powder.

29. Mario, Matthew and the rest of Cindy's family have suffered, and will continue to suffer, emotional anguish resulting from Cindy's extreme pain and suffering from ovarian cancer.

Shaeda Begum Farooqi-Willison

30. Shaeda used Baby Powder as part of her personal hygiene routine, every day for approximately 40 years. She was loyal to the brand manufactured by the defendants, and never used any other brand of talcum powder. Shaeda used the talc in various places on her body, including in her perineal area. She used the Baby Powder in accordance with the instructions on the label.

31. In January 2005, Shaeda was diagnosed with stage 3 ovarian cancer. Large tumours were discovered on both her ovaries and also in the uterine wall. On April 13, 2005, Shaeda had a complete hysterectomy in an effort to halt the spread of the cancer. She was subsequently given two treatments of chemotherapy, as well as radiation treatment.

32. On September 30, 2005, Shaeda's healthcare providers declared her to be in remission. She has been visiting her treating physician at Princess Margaret Hospital for regular checkups every six months since 2005, and has not had any cancer treatment since 2006. As a result of the cancer, Shaeda developed severe depression. Because of her depression, Shaeda is currently on long-term disability and takes medication. She also sees a psychiatrist on a monthly basis.

33. On May 23, 2014, for the first time, Shaeda discovered that there are links between ovarian cancer and perineal use of Baby Powder. She discovered this not from the defendants, but from an online article. That same day, and after 40 years of use, she stopped using Baby Powder.

34. Gerald and the rest of Shaeda's family have suffered, and will continue to suffer, emotional anguish resulting from Shaeda's extreme pain and suffering from ovarian cancer.

Thérèse Bernier

35. Thérèse used Baby Powder as part of her personal hygiene routine, every day for more than 50 years. She was loyal to the brand manufactured by the defendants, and never used any other brand of talcum powder. Thérèse used the talc in various places on her body, including in her perineal area. She used the Baby Powder in accordance with the instructions on the label.

36. On February 27, 2012, Thérèse underwent a pelvic scan due to pain in her left abdomen and several weeks of rectal bleeding. The scan showed a growth on her left ovary consistent with cancer. An MRI performed on March 6, 2012, confirmed the diagnosis of ovarian cancer.

37. On May 22, 2012 Thérèse underwent surgery for the removal of her uterus and one of her ovaries. During surgery, tumours were also found on both ovaries and both were removed. Thérèse subsequently underwent a course of chemotherapy, as well as numerous procedures to drain fluid from her abdomen, caused by the ovarian cancer. On November 22, 2012, Thérèse's cancer was noted to be in remission.

38. On December 16, 2013, a pelvic scan showed a possible recurrence of the cancer. This was confirmed with a PET scan performed on February 13, 2014. Thérèse underwent a second course of chemotherapy. On February 5, 2015, she was found to once again be cancer-free.

39. However, in May 2015, Thérèse reported a recurrence of abdominal pain. A CT scan was performed on June 12, 2015, which showed that the cancer had returned and had metastasized. Thérèse was referred for a third course of chemotherapy.

40. Unfortunately, the treatment was unsuccessful. On March 24, 2016, at the age of 66, Thérèse died of ovarian cancer.

41. Marilyne and the rest of Thérèse's family have suffered, and will continue to suffer, emotional anguish resulting from Thérèse's extreme pain and suffering, and ultimate death, from ovarian cancer.

Janet Heaton

42. Janet used Baby Powder as part of her personal hygiene routine, every day for nearly 30 years. She was loyal to the brand manufactured by the defendants, and never used any other brand of talcum powder. Janet used the talc in various places on her body, including in her perineal area. She used the Baby Powder in accordance with the instructions on the label. Around the year 2000, Janet stopped using Baby Powder regularly, because she was no longer working, but she continued using it occasionally. Some time around 2014, Janet stopped using Baby Powder completely because she felt she no longer required it.

43. In October 2011, Janet underwent an ultrasound for a problem with her gallbladder. She subsequently had surgery on her gallbladder and, during the surgical procedure, a cyst was found on her ovary. The ovary was removed, and a tumour was found underneath. Two biopsies revealed that the tumour was malignant, and Janet was diagnosed with Level 4, Stage 1 ovarian cancer.

44. Janet commenced chemotherapy at Durham Regional Cancer Centre in Oshawa. After six rounds of treatment, Janet's cancer went into remission. She was cancer-free for approximately four years.

45. In January 2016, Janet began to feel unwell and her stomach swelled up. Testing revealed that her CA 125 levels were extremely high, indicating the return of her ovarian cancer. She has since resumed chemotherapy and continues to undergo treatment.

46. Barry and the rest of Janet's family have, and will continue to suffer emotional anguish resulting from Janet's extreme pain and suffering from ovarian cancer.

FACTS

Talcum Powder

47. Talc is an inorganic clay mineral composed of hydrated magnesium silicate. It is one of the softest known minerals, and is mined from the earth. At all material times, Imerys Talc America, Inc. (formerly known as Luzenac America, Inc.) mined talc and supplied it to the defendants for use in Baby Powder. Baby Powder is composed almost entirely of talc, with the only other ingredient being "parfum" (scent).

48. The defendants first placed Baby Powder on the market in the U.S.A. in 1893, and it became available in Canada shortly thereafter. The defendants market Baby Powder as a means of keeping skin cool and comfortable. In addition to its well-known use on infants, the defendants also market the Baby Powder for women to "[u]se anytime you want skin to feel soft, fresh and comfortable." The defendants have continually advertised and marketed talc as safe for human use. Such representations are made on its website, packaging and other marketing materials.

49. Consumers expect Baby Powder to be safe to use. In fact, the only warnings the defendants provide to consumers about the dangers of Baby Powder is to keep the powder away from eyes, avoid inhalation of the powder, and use the powder externally. The defendants do not provide any other warnings about Baby Powder.

50. As indicated further below, Baby Powder is not safe. Numerous studies have confirmed that perineal application of Baby Powder leads to a significantly increased risk of ovarian cancer. Women who used talc-based powders to powder their perineal area have a 33% increased risk of ovarian cancer compared to those women who have never used the powders.

51. Despite these risks, the defendants continue to represent that Baby Powder is safe when used as intended, including in perineal application. As recently as May 12, 2014, the defendants stated that, “the safety of cosmetic talc is supported by decades of scientific evidence and independent peer-reviewed studies.”

52. At all material times, a safe alternative to talcum powder was available, namely, corn starch. In fact, the defendants themselves market JOHNSON’S® baby pure cornstarch powder, and should therefore have known that cornstarch powders have been sold and marketed for the same uses as talc, with nearly the same effectiveness. Cornstarch is much safer than talc, in that it is an organic carbohydrate that is quickly broken down by the body with no known health effects. Despite the availability of this alternative product, the defendants continued to market Baby Powder as safe in the face of overwhelming evidence to the contrary.

Defendants' Knowledge of Risks of Ovarian Cancer through Talc Use

53. From at least as early as 1971, the scientific literature has indicated a link between perineal application of talcum powder and ovarian cancer, as well as the migration of talc fibres through the vagina and fallopian tubes and into the ovaries. The defendants knew of these studies; not only did they fail to take any action based on them, but they attempted to minimize the results of the studies and conceal the risks of talc use from the Class Members and the public at large.

54. In 1971, Dr. W. J. Henderson and others published the first study suggesting a link between perineal talc use and ovarian cancer. Dr. Henderson and his team used an extraction-replication technique to examine tissue from patients with ovarian and cervical tumours. In both conditions, talc particles were found deeply embedded within the tumour tissue.

55. In June 1972, a symposium on "Carcinoma of the Ovary" was held in London England, with the results published in the *Postgraduate Medical Journal* in February 1973. These results referred back to the 1971 Henderson study, and discussed new technologies for the detection of talc fibres in ovarian tumours.

56. In 1979, the British medical journal *The Lancet* published a number of letters and editorials discussing the link between perineal talc use and ovarian cancer. These included an August 1979 article editorial by Dr. D.L. Longo et al, which suggested that ovarian cancer could be caused by talc fibres passing directly through the female reproductive tract to the ovarian surface. A letter from Dr. Longo in November 1979 stated that "talc is known to elicit potent inflammatory responses in man when found in the lungs, pleural cavity, and peritoneal cavity." Dr. Longo further stated that, "[c]onsumers have a right to expect that manufacturers will investigate potential risks to ensure that conventional use of their products is not hazardous."

57. In 1982, Cramer et al conducted the first epidemiological study on the association between cosmetic talcum powder use in the perineal area and ovarian cancer. This study demonstrated that women who had regularly dusted their perineum with talc and had used it on sanitary napkins were more than three times more likely to develop ovarian cancer than women with neither kind of exposure to talc.

58. Shortly after this study was published, Dr. Bruce Semple, an employee of the defendants, visited Dr. Cramer in order to discuss his study. Dr. Cramer advised Dr. Semple that the defendants should place a warning on their Baby Powder packaging, regarding the link between perineal talc use and ovarian cancer, so that women could make informed decisions about their health.

59. Since 1982, there have been more than 20 additional epidemiological studies regarding the association between perineal talc use and ovarian cancer. Nearly all of these studies, many of which are cited below, report an elevated risk of ovarian cancer associated with perineal talc use. The defendants knew about these studies, but neither recalled Baby Powder in Canada nor warned Canadian consumers about the risks of ovarian cancer with perineal talc use.

60. In 1983, Patricia Hartge and Robert Hoover of the National Cancer Institute and Linda Lester and Larry McGowan of the George Washington University Medical Center, performed a case-control study and found a 150% increased risk of ovarian cancer for women who use talcum powder in the genital area.

61. In 1986, Dr. W. J. Henderson again published a study on the link between perineal talc use and ovarian cancer. The study found that talc particles placed in both the uterine cavity and the vagina of the rat were shown to migrate to the ovary and become localized within its substance.

62. In 1988, a case control study of 188 women diagnosed with epithelial ovarian cancer and 539 control women found that 52% of the cancer patients habitually used talcum powder on the perineum before their cancer diagnosis. The study showed a 40% increase in risk of ovarian cancer in women that used talcum powder on their perineum and a positive dose-response relationship.

63. Another 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 a 29% increased risk in ovarian cancer with women who reported genital talcum powder use more than once per week.

64. In 1989, Dr. Bernard Harlow published a study in the *American Journal of Epidemiology* that showed that women who used deodorizing powders alone, or in combination with other talc-containing powders, were 2.8 times more likely to develop ovarian cancer than women who had not had perineal exposure to powder.

65. In 1992, a study by Dr. Yong Chen et al. published in the *International Journal of Epidemiology* found an elevated risk of ovarian cancer in women with a history of long-term (more than 3 months) application of talcum powder to the lower abdomen and perineum. Another study published by Dr. Bernard Harlow in the same year found support for the concept that a lifetime pattern of perineal talc use may increase the risk for epithelial ovarian cancer. Similarly, a study published by Dr. K. Rosenblatt et al in the same year found a link between long-term exposure to talc fibres and the development of epithelial ovarian cancer.

66. In 1992, the US National Toxicology Program (NTP) published a study that established the carcinogenic nature of non-asbestiform talc (talc that does not contain asbestos). In response to the NTP's study, the Cosmetic Toiletry and Fragrance Association (CTFA) formed the Talc Interested Party Task Force (TIPTF). The defendants were members of and major contributors to the TIPTF. The

goal of the TIPTF was to defend the cosmetic use of talc, and prevent its regulation by the US Food and Drugs Administration (FDA). The TIPTF lobbied with the government and regulators, and promoted the safety of talc to the public, despite the numerous scientific studies showing the risks of ovarian cancer with perineal talc use.

67. In August 1992, the defendants decided to market to African-American, African-Canadian and Hispanic women in an effort to boost flagging sales. Marketing studies had shown that these communities used talc at higher rates. Instead of warning regular talc users and loyal customers, the defendants instead chose to increase the marketing push to those communities.

68. In November 1994, the US Cancer Prevention Coalition wrote to the CEO of the defendant, Johnson & Johnson, informing him that studies from as far back as the 1960s revealed “conclusively that the frequent use of talcum powder in the genital area poses a serious health risk of ovarian cancer.” The letter cited Dr. Bernard Harlow’s study, discussed *supra*, that discouraged the use of talc in the perineal area. The Cancer Prevention Coalition asked the defendants to withdraw talc products from the market because of the alternative of cornstarch powders, or to place warning information on its packaging about the link between perineal talc use and ovarian cancer.

69. In 1995, in an Australian case-control study published in the *International Journal of Cancer*, Dr. David Purdie et al found a link between ovarian cancer and the use of talc in the abdominal or perineal region.

70. In 1996, condom manufacturers stopped using talc on condoms in response to a request by the Food and Drug Administration (FDA), due to fears for women’s health based on the link between talc and ovarian cancer.

71. In 1997, a study published by the American Cancer Society found that exposure to talc, via sanitary napkins, direct application to the perineum, or both, was significantly associated with risk of ovarian carcinoma. A study published in the *American Journal of Epidemiology* the same year made similar findings.

72. In 1997, Dr. Alfred P. Wehner, a biomedical consultant employed by the defendant Johnson & Johnson, wrote to Michael Chudkowski, Johnson & Johnson's Manager of Preclinical Toxicology. Dr. Wehner pointed out that the Cosmetic Toiletry and Fragrance Association had released "outright false information about the safety of talc to the public on 3 separate occasions."

73. Dr. Wehner wrote that, on one such occasion in November 1994, the CTFA had stated that studies "are insufficient to demonstrate any real association" between perineal talc use and ovarian cancer. Dr. Wehner pointed out that, at that time, approximately nine studies in the scientific literature did show a statistically significant association between hygienic talc use and ovarian cancer. He stated that such an association had been "undeniably" established by several independent investigators, and that numerous reputable scientists/clinicians, including Bernard Harlow, would "without doubt" readily attest to such a link. Dr. Wehner concluded by stating that, "Anybody who denies this [link] 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."

74. In a 1998 case-controlled study conducted in Canada by Beatrice Godard et al, a 149% increased risk of ovarian cancer was found in women who used talc-based powders on their perineum.

75. In 1999, Dr. Daniel W. Cramer of Harvard Medical School stated, in a letter published in *Obstetrics and Gynecology*, that "[t]he weight of epidemiologic evidence still favors an association;

gynecologists should advise patients who regularly use talc in the genital area that this practice may be harmful.”

76. In 2000, the National Toxicology Program (NTP) nominated talc to be listed in their Report of Carcinogens, based on the recommendations of two internal review panels. However, the Cosmetic Toiletry and Fragrance Association got involved and was able to have the vote on this issue deferred.

77. In 2000, Roberta Ness from the University of Pennsylvania produced a case- control study of over 2,000 women. This study found a statistically significant 50% increased risk of ovarian cancer from genital talc use in women. The study also found that talc causes inflammation and that inflammation contributes to cancer cell development.

78. Also in 2000, a prospective cohort study considered to be the most informative study to date, found a 40% increase in invasive serous cancers from women who applied talcum powder to their perineum.

79. In March 2002, Richard Zazenski, Director of Product Safety at Luzenac, wrote to Bill Ashton at Johnson & Johnson, stating that the industry had so far succeeded in fending off NTP classification (of talc as a carcinogen). However, Zazenski expressed concern for the International Agency for Research on Cancer (IARC, part of the World Health Organization) because “unlike the NTP, IARC is answerable to no one politically.”

80. In 2004, Dr. Paul Mills et al, of the George Washington University School of Public Health and Health Services, performed a case-control study of nearly 1,400 women from 22 counties in Central California. This study found a statistically significant 37% increased risk of epithelial ovarian cancer

from women's perineal talc use. The study also found a 77% increased risk of serous invasive ovarian cancer from women's perineal talc use.

81. In February 2006, IARC published a paper whereby it classified perineal use of talc as a "Group 2B" human carcinogen. IARC concluded that international studies consistently found an increased risk of ovarian cancer in women from perineal use of talc. IARC found that this increased risk ranged from 30-60%.

82. In approximately 2006, the Canadian federal government under the *Hazardous Products Act*, RSC 1985, c H-3, classified non-asbestiform talc as a "D2A" carcinogen under its Workplace Hazardous Materials Information System (WHMIS). Asbestos is also classified as "D2A". Talc is described in the WHMIS as "very toxic causing toxic effects" and "causes damage to organs through prolonged or repeated exposure".

83. In 2006, Luzenac began placing a warning on the talcum powder it provided to the defendants, stating that perineal use of talcum powder could cause ovarian cancer. These warnings advised of the IARC classification as well as the Canadian government's D2A classification of talc. The defendants did not pass this warning on to consumers. To this day, they still do not.

84. In 2007, Amber Buz'Zard and Benjamin Lau performed a study whereby they induced carcinogenesis by applying talc to normal human epithelial and granulosa ovarian cancer cell lines.

85. According to a study published by Langseth et al in 2008, epidemiological evidence suggests that use of cosmetic talc in the perineal area may be associated with ovarian cancer risk. In that same year, Margaret Gates, of the Department of Epidemiology and Biostatistics at the Harvard School of Public Health, performed a combined study of over 3,000 women from a New England-based case-

control study and a prospective Nurses' Health Study with additional cases and years of follow up from these studies. This study found a 36% statistically significant increased risk of epithelial ovarian cancer from perineal talc use. A 60% increased risk of the serous invasive subtype was also found.

86. In 2008, Melissa Merritt, from the Australian Ovarian Cancer Study Group, conducted a case-controlled study of over 3,000 women where a statistically significant 17% increased risk of ovarian cancer for women who used talc on their perineum was confirmed. This study also confirmed a statistically significant 21% increased risk of ovarian cancer of a serous subtype in women who used talc on their perineum.

87. In 2009, a case-controlled study of over 1,200 women found the risk of ovarian cancer increased significantly with increasing frequency and duration of talc use. The study found an overall statistically significant 53% increased risk of ovarian cancer from genital talc use. The study also found a 108% statistically significant increased risk of ovarian cancer in women with the longest duration and most frequent talc use.

88. In 2011, Daniel Cramer of Brigham and Women's Hospital, Harvard Medical School, made public another case-controlled study of over 4,000 women. This study, found a 200-300 per cent increased risk of ovarian cancer for women who applied talc-based body powders to their perineum. In the same year, another case-controlled study of over 2,000 women found a 27% increased risk of ovarian cancer from perineal talc use.

89. In 2012, the defendant Johnson & Johnson announced that it would remove "harmful chemicals" from its baby products including Triclosan which, like perineally-applied talc, is classified as an IARC 2B carcinogen. However, Johnson & Johnson did not take any action to warn its consumers of the dangers of talcum powder.

90. In 2013, Kathryn Terry et al., published a pooled analysis of over 18,000 women in eight case-control studies and found a 20% to 30% increased risk of women developing epithelial ovarian cancer from perineal talcum powder use.

91. Thus, for many decades, there has been concern for and evidence of an increased risk for ovarian cancer with the perineal use of Baby Powder. Although a robust body of scientific evidence demonstrates that the product is inherently dangerous and has indicated that Baby Powder can cause, materially contribute to or materially increase the risk of ovarian cancer and has in fact resulted in numerous cases of ovarian cancer worldwide, the defendants have failed to withdraw Baby Powder from the Canadian stream of commerce and have continued to profit from the sale of Baby Powder in Canada.

92. Further, despite this ever-growing body of knowledge, of which the defendants were aware or ought to have been aware, in relation to the increased risk for ovarian cancer with Baby Powder exposure, Baby Powder marketed in Canada has never included warnings about this significant increased risk of developing ovarian cancer. Indeed, the packaging and website for Baby Powder in Canada contains no information whatsoever about an association with ovarian cancer, so as to allow Class Members to make an informed decision about using the product.

CAUSES OF ACTION

Negligence

93. Baby Powder was designed, developed, tested, manufactured, licensed, assembled, distributed, imported and/or exported, marketed, and/or sold by the defendants. At all material times, the

defendants owed a duty of care to the plaintiffs and to the Classes to provide a safely manufactured product. The defendants breached the standard of care expected in the circumstances.

94. The defendants also owed a duty to the plaintiffs and other Class Members to initiate rigorous scientific studies to assess the possible association between Baby Powder use and the development of ovarian cancer, to carefully monitor the safety and post-market performance of Baby Powder and to warn the plaintiffs and the other Class Members and Canadian regulators of the defective nature of Baby Powder and to recall it from the Canadian market when it became obvious that the product could not be safely used, thereby causing risk of or actual serious personal injury and/or death.

95. The circumstances of the defendants being in the business of designing, manufacturing and placing Baby Powder into the Canadian stream of commerce are such that the defendants were in a position of legal proximity to the Class Members and therefore under an obligation to be fully aware of their safety when designing, manufacturing, assembling and marketing a product such as Baby Powder.

96. It was reasonably foreseeable that a failure by the defendants to design and manufacture a reasonably safe product, and thereafter to monitor its performance following market introduction (and to take corrective measures when required) would cause, materially contribute to, or materially increase the risk of harm to the plaintiffs and the other members of the Classes. The Class Members used Baby Powder in their perineal area, which was a reasonably foreseeable use of Baby Powder.

97. The defendants were negligent in the design, development, testing, manufacturing, licensing, assembly, distribution, importing and/or exporting, marketing and sale of Baby Powder. Particulars of some, but not all, of the defendants' acts of negligence follow:

- a) they knew or should have known that Baby Powder was unreasonably and dangerously defective and failed to warn the public and the regulatory authorities in a timely manner;
- b) they failed to adequately test the safety and efficacy of Baby Powder before marketing and distributing it;
- c) they failed to conduct any or adequate follow-up studies on the efficacy and safety of Baby Powder;
- d) they failed to adequately design, manufacture and/or test Baby Powder to ensure that it was safe and free from defects prior to selling or distributing it;
- e) they failed to manufacture Baby Powder in such a manner that it would work safely and effectively without exposing the defendants' consumers to injury or loss;
- f) they knew or ought to have known that Baby Powder was defective and that Baby Powder would not properly perform the functions or purposes for which it was intended;
- g) after receiving actual or constructive notice of the significant increased risk of developing ovarian cancer with the perineal use of Baby Powder, they failed to issue adequate or any warnings, withdraw or recall Baby Powder, publicize the problem(s) and/or otherwise act properly and in a timely manner to alert the plaintiffs and Class Members, the public and regulators that Baby Powder was defective;
- h) they failed to provide clear instructions to consumers, including precautions to be taken, so as to avoid injury or damages from Baby Powder;
- i) they concealed the fact that Baby Powder was defective from the public, health care providers and the regulatory authorities, including the FDA and Health Canada;
- j) they concealed adverse information regarding the testing and safety of Baby Powder from the public and the regulatory authorities, including the FDA and Health Canada;
- k) they failed to monitor and follow up on reports of adverse reactions to Baby Powder;
- l) they failed to issue a safety notice or to recall Baby Powder in a timely manner or at all; and
- m) such further and other particulars of negligence within the knowledge of the defendants.

98. At all times relevant to this action the defendants knew, and had reason to know, that Baby Powder was not safe for use in the perineal area and that such use led to a statistically significant increase in the risk of ovarian cancer. The defendants knew and had reason to know of the defects in

Baby Powder, but concealed this information and did not warn the plaintiffs, the other Class Members or regulators, thereby preventing the plaintiffs and the Class Members from making informed choices about the use of Baby Powder. Had Cindy, Shaeda, Thérèse, Janet and the Class Members been warned about the dangers of Baby Powder use, they would not have used Baby Powder.

Waiver of Tort

99. As a result of the defendants' conduct described herein, the plaintiffs reserve the right to elect at the trial of the common issues to waive the tort of negligence and to have damages assessed in an amount equal to the gross revenues earned by the defendants, or the disgorgement of all income received by the defendants, or a percent of the proceeds from the sale of Baby Powder as a result of the defendants' conduct.

100. Such an election is appropriate for the following reasons:

- a) revenue was acquired in a manner in which the defendants cannot in good conscience retain it;
- b) the integrity of the marketplace would be undermined if an accounting was not required;
- c) absent the defendants' tortious conduct Baby Powder could not have been marketed nor would they have received any revenue in Canada; and
- d) the defendants engaged in wrongful conduct by putting into the marketplace a product which causes, materially contributes to, or materially increases the risk of injury.

DAMAGES

101. As a result of the negligence of the defendants, the plaintiffs and Classes have suffered the following damages:

- a) serious injury and, in some cases, death;

- b) emotional and psychological trauma;
- c) special damages for out of pocket expenses;
- d) cost of future care and services;
- e) loss of income; and,
- f) such further and other damages the particulars of which will be provided prior to trial.

102. As a result of the defendants' negligence, Mario, Matthew, Gerald, Marilyne, Barry and other members of the Family Class have suffered the following damages:

- a) actual expenses reasonably incurred for the benefit of a Class Member;
- b) a reasonable allowance for travel expenses actually incurred in visiting the Class Member during her treatment or recovery;
- c) where, as a result of the injury, nursing, housekeeping or other services have been provided for a Class Member, a reasonable allowance for loss of income or the value of the services; and
- d) an amount to compensate for the loss of guidance, care and companionship that the Family Class Member might reasonably have expected to receive from a related Class Member if the injury or death had not occurred.

103. The plaintiffs and the other Class Members are also entitled to recover, as damages or costs in accordance with the *Class Proceedings Act, 1992*, S.O. 1992, c. 6, the costs of administering the plan to distribute the recovery of this action.

PUNITIVE DAMAGES

104. The plaintiffs plead that the defendants have acted in such a high-handed, wanton and reckless manner, without regard to public safety, as to warrant a claim for punitive damages. In particular, the defendants' conduct in the design, development, testing, manufacture, licensing, assembly, distribution, marketing, and sale of Baby Powder, the failure to recall Baby Powder sooner or at all, the wilful

concealment of the defects in Baby Powder and the facts pleaded above were entirely without care, deliberate, callous, disgraceful, wilful, and an intentional disregard of the Class Members' rights and safety, indifferent to the consequences, and motivated by economic considerations such as maintaining revenue and market.

PROVINCIAL HEALTH INSURERS

105. The provincial and territorial health insurers in Canada have incurred various expenses with respect to the medical treatment of Cindy, Shaeda, Thérèse, Janet and other Class Members as a result of the defendants' negligence. As a result, they have suffered and will continue to suffer damages for which they are entitled to be compensated by virtue of their subrogated and direct rights of action in respect of all past and future insured services. This action is maintained on behalf of all such provincial and territorial health insurers.

LEGISLATION

106. The plaintiffs plead and rely upon, *inter alia*, the following statutes and the regulations made thereunder (all as amended):

- a) *Alberta Health Care Insurance Act*, R.S.A. 200, c. A-20;
- b) *Business Practices and Consumer Protection Act*, S.B.C. 2004, c. 2;
- c) *Civil Code of Québec*, CQLR c C-1991;
- d) *Class Proceedings Act*, R.S.O. 1992, S.O. 1992, c.6;
- e) *Courts of Justice Act*, R.S.O. 1990, c.43;
- f) *Consumer Protection Act, 2002*, S.O. 2002, c. 30, Sch. A;
- g) *Consumer Protection and Business Practices Act*, S.N.L. 2009 c. C-31.1;
- h) *The Consumer Protection Act*, S.S. 1996, c C-30.1;

- i) *Consumer Protection Act*, CQLR c P-40.1;
- j) *Family Law Act*, R.S.O. 1990, c. F.3;
- k) *Fatal Accidents Act*, R.S.N.L. 1990, c. F.6;
- l) *Fatal Accidents Act*, C.C.S.M. c.F.50;
- m) *Fatal Accidents Act*, R.S.A. 2000, c. F-8;
- n) *Fatal Accidents Act*, R.S.N.B. 1973, c. F-7;
- o) *Fatal Accidents Act*, R.S.N.W.T. 1988, c. F-3;
- p) *Fatal Accidents Act*, R.S.P.E.T. 1988, c. F-5;
- q) *Fatal Accidents Act*, R.S.S. 1978, c.F-11, s.3;
- r) *Fatal Accidents Act*, R.S.Y. 2002, c.86;
- s) *Fatal Injuries Act*, R.S.N.S. 1989, c. 163;
- t) *Food and Drugs Act*, R.S.C. 1985, c. F-27;
- u) *Health Insurance Act*, R.S.O. 1990, c. 11.6;
- v) *Health Insurance Act*, CQLR c A-29;
- w) *Health Services and Insurance Act*, R.S.N.S. 1989, c. 197;
- x) *Health Services Insurance Act*, C.C.S.M., C.1135;
- y) *Hospital and Diagnostic Services Insurance Act*, R.S.P.E.I. 1988, c. H-8;
- z) *Hospital Insurance Agreement Act*, R.S.N.I. 1990, c.11-7;
- aa) *Hospital Insurance and Health and Social Services Administration Act*, R.S.N.W.T. 1988, c. T-3;
- bb) *Hospital Insurance Services Act*, R.S.Y. 2002, c. 112;
- cc) *Hospital Services Act*, R.S.N.B. 1973, c. 11-9;
- dd) *Hospitals Act*, R.S.A. 2000, c. 11-12;
- ee) *Negligence Act*, R.S.O. 1990, c. N.1;
- ff) *Sale of Goods Act*, R.S.O. 1990, c. S.1;
- gg) *Trustee Act*, C.C.S.M. c. T160;

- hh) *Trustee Act*, R.S.N.W.T. 1988, c. T-8; and
- ii) *Trustee Act*, R.S.O. 1990, c. T.23.

REAL AND SUBSTANTIAL CONNECTION

107. There is a real and substantial connection between the subject matter of this action and the Province of Ontario for the following reasons:

- a) the defendants have registered places of business in Ontario and manufacture, distribute, market, promote and/or sell Baby Powder in Ontario and derive substantial revenue from such sales;
- b) Cindy, Shaeda, Thérèse, Janet and other members of the Class used Baby Powder in Ontario;
- c) Cindy, Shaeda, Thérèse, Janet and other members of the Classes resident in Ontario sustained their damages in Ontario; and
- d) Approval for the sale of Baby Powder in Canada was granted in Ottawa, Ontario.

SERVICE OUTSIDE OF ONTARIO

108. This statement of claim may be served without court order outside Ontario because the claim is:

- a) in respect of a tort committed in Ontario (rule 17.02(g));
- b) in respect of damages sustained in Ontario arising from a tort or breach of contract however committed (rule 17.02(h));
- c) against a person outside Ontario who is a necessary and proper party to this proceeding properly brought against another person served in Ontario (rule 17.02(o)); and
- d) against a person carrying on business in Ontario (rule 17.02(p)).

PLACE OF TRIAL

109. The plaintiffs propose that this action be tried in Toronto.

Date: May 18, 2016

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Defendants

ONTARIO
SUPERIOR COURT OF JUSTICE

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