UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JONI S. BYNUM, ROBIN COBURN, AND JAMES COBURN INDIVIDUALLY AND ON BEHALF OF A PROPOSED CLASS
Plaintiff,

v.

LLT MANAGEMENT LLC F/K/A LTL MANAGEMENT, LLC; JOHNSON & JOHNSON; NEW JJCI; JOHNSON & JOHNSON HOLDCO (NA) INC; JANSSEN PHARMACEUTICALS, INC.; KENVUE INC.; J&J SERVICES, INC.; AND JOHN DOES 1-100,
Defendants

JURY TRIAL DEMANDED ON ALL CLAIMS TRIABLE TO A JURY

Case No. _____

PLAINTIFF'S CLASS ACTION COMPLAINT AND JURY DEMAND

Plaintiffs, by and through their counsel bring this action, pursuant to Rule 23 of the Federal Rules of Civil Procedure, on their own behalf and as representatives of a Class of persons consisting of:

> (1) All female U.S. resident users of Defendants' talc-containing products Johnson's Baby Powder and/or Shower to Shower (hereinafter the "PRODUCTS") between 1960 and the present who, prior to the date of the Court's Preliminary Approval and Class Certification Order, utilized the Product(s) for genital application for a period of more than four (4) years, and have not commenced an individual, non-class lawsuit for the pursuit of any individual, non-class personal injury claims arising from the use and/or exposure to Defendants' Products ("Qualifying Talc Users"); (2) Authorized representatives, ordered by a court or other official of competent jurisdiction under applicable state law, of deceased or legally incapacitated or incompetent Qualifying Talc Users ("Representative Claimants"); and, (3) Spouses, parents, children who are dependents, or any other persons who properly under applicable state law assert the right to sue independently or derivatively by reason of their relationship with a Qualifying Talc User ("Derivative Claimants").

Additionally, the proposed Plaintiff Class includes two proposed subclasses:

Subclass 1: Qualifying Talc Users (Class Members) and the Representative Claimants of legally incapacitated or incompetent Qualifying Talc Users who as of the date of the Court's Preliminary Approval and Class Certification Order have not been diagnosed with a "Defined Injury", namely: epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer.

Subclass 2: Qualifying Talc Users (Class Members) who affirmatively consent (Opt-In) to membership in the Class and who as of the date of the Court's Preliminary Approval and Class Certification Order have been diagnosed with a "Defined Injury", namely: epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer, and their Representative and Derivative Claimants.

Excluded from the Class and proposed subclasses are: (i) Class members who request exclusion from the class; (ii) Putative members of Subclass 2 who do not affirmatively consent (Opt-In) to membership in the Class; (iii) Individuals employed by Defendants at any time between 1960 and the present; (iv) Judges on the United States District Court for the District of New Jersey and their law clerks serving during the pendency of this litigation; (v) Persons who have commenced an individual, non-class lawsuit arising from the use and/or exposure to Defendants' PRODUCTS prior to the date of the Court's Preliminary Approval and Class Certification Order; (vi) Persons who have been diagnosed with mesothelioma; (vii) Persons who are diagnosed with mesothelioma or lung cancer in the future; and, (viii) Persons who have settled, dismissed, or otherwise compromised their individual, non-class personal injury claims arising from their use and/or exposure to Defendants' PRODUCTS.

SUMMARY OF CLAIMS ASSERTED BY THE CLASS

Plaintiffs bring this action individually and as Class and Subclass representatives against LLT Management LLC ("LLT") f/k/a/ LTL Management, LLC ("LTL"), Johnson & Johnson ("J&J"), Johnson & Johnson Holdco (NA) Inc. ("New JJCI"), Janssen Pharmaceuticals, Inc.

("Janssen"), Kenvue Inc. ("Kenvue"), Johnson & Johnson Services, Inc. (J&J Services") (collectively, the "Defendants"), (i) to obtain relief in the form of medical monitoring (i.e., preventative and diagnostic care) for epithelial ovarian cancer, fallopian tube cancer, and primary peritoneal cancer (the "Defined Injuries") for those Class Members in Subclass 1 who have not been diagnosed with one of these cancers as of the date of the Court's Preliminary Approval and Class Certification Order; (ii) to obtain compensation for Class Members in Subclass 1 (and their Representative and/or Derivative Claimants) who have not been diagnosed with a Defined Injury as of the date of the Court's Preliminary Approval and Class Certification Order but may be subsequently diagnosed with a Defined Injury in the future; and (iii) to recover compensatory and punitive damages for the members of Subclass 2 [i.e., those Qualifying Talc Users who affirmatively consent (Opt-In) to membership in the Class] (and their Representative and/or Derivative Claimants) who have been diagnosed with a Defined Injury as of the date of the Court's Preliminary Approval and Class Certification Order.

This action arises from the fact that the Defendants' PRODUCTS are defective, dangerous to human health, unfit and unsuitable to be advertised, marketed, and sold in the United States, and lacked proper warnings associated with their use. A more complete recitation of the facts supporting the allegations and claims of the Class are provided hereinbelow.

PARTIES

A. Plaintiffs

1. Plaintiff, Joni S. Bynum, is a resident and citizen of Auburn, King County, Washington. Plaintiff Bynum purchased and utilized defendants PRODUCTS for genital application for a period of more than four (4) years between March 2006 and August 2019. Plaintiff Bynum has not been diagnosed with epithelial ovarian cancer, fallopian tube cancer, or

primary peritoneal cancer but is at increased risk of developing one of these Defined Injuries as a proximate result of her exposure to Defendants' PRODUCTS and, is therefore in need of medical monitoring. Additionally, since Plaintiff Bynum may be diagnosed with a Defined Injury after the date of the Court's Preliminary Approval and Class Certification Order, she seeks compensation for any such Defined Injuries. Plaintiff Bynum is a member of the putative Class and brings this case individually and on behalf of Subclass 1.

2. Plaintiff Robin Coburn is a resident and citizen of Theodore, Mobile County, Alabama. Plaintiff Robin Coburn purchased and utilized defendants PRODUCTS for genital application for a period of more than four (4) years between March 2012 and August 2023. On or about August 10, 2023, Plaintiff Robin Coburn was diagnosed with a Defined Injury namely, serous fallopian tube cancer. Plaintiff Robin Coburn has not filed an individual, non-class personal injury lawsuit against the Defendants over her use of Defendants' PRODUCTS and her subsequent Defined Injury. To date, Plaintiff Robin Coburn has not settled and/or compromised her individual personal injury claims against the Defendants. Plaintiff Robin Coburn seeks compensatory and punitive damages for her Defined Injury. Plaintiff Robin Coburn is a member of the putative Class and brings this case individually and on behalf of Subclass 2.

3. Plaintiff James Coburn is married to Plaintiff, Robin Coburn, and is a resident and citizen of Theodore, Mobile County, Alabama. Plaintiff James Coburn is a Derivative Claimant under Subclass 2 and brings this case individually and on behalf of Subclass 2. Plaintiff James Coburn has not filed an individual, non-class personal injury lawsuit against the Defendants over his spouse's use of Defendants' PRODUCTS and his derivative claims arising from his spouse's subsequent Defined Injury. To date, Plaintiff James Coburn has not settled and/or compromised his individual derivative claims against the Defendants.

B. Defendants

4. Defendant, Johnson & Johnson, is a New Jersey corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Johnson & Johnson may be served with process by serving its registered agent at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

5. At all relevant times, Johnson & Johnson was engaged in the business of manufacturing, formulating, marketing, testing, promoting, selling, and/or distributing the PRODUCTS. At all relevant times, Johnson & Johnson regularly transacted, solicited, and conducted business in all fifty states of the United States.

6. Defendant LLT is a Texas limited liability company which at all relevant times alleged in this Complaint operated as LTL, a North Carolina limited liability company with an address at 501 George Street, New Brunswick, New Jersey 08933. For convenience and consistency with pleadings in other matters referred to herein, as noted above, LLT is generally referred to as LTL.

7. Defendant New JJCI, individually and as successor in interest to Old JJCI, is a New Jersey corporation with its principal place of business in the State of New Jersey. New JJCI may be served with process by serving its registered agent located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

8. At all relevant times, upon information and belief, New JJCI was engaged in the business of manufacturing, formulating, marketing, testing, promoting, selling, and/or distributing the PRODUCTS. At all relevant times, New JJCI regularly transacted, solicited, and conducted business in all fifty states of the United States.

9. Defendant Janssen, individually and as successor in interest to Old JJCI and New JJCI, is a New Jersey Corporation with its principal place of business in the State of New Jersey. Janssen may be served with process by serving its General Counsel at 1125 Trenton-Harbourton Rd., Titusville, NJ 08560.

10. At all relevant times, upon information and belief, Janssen was engaged in the business of manufacturing, formulating, marketing, testing, promoting, selling, and/or distributing the PRODUCTS. At all relevant times, Janssen regularly transacted, solicited, and conducted business in all fifty states of the United States.

11. In the April 4, 2023, Declaration of John K. Kim in Support of First Day Pleadings, filed in LTL's second bankruptcy filing in In re: LTL Management LLC, Case no.: 23-12825, United States Bankruptcy Court District of New Jersey ("Kim LTL Decl."), Mr. Kim, as Chief Legal Officer for LTL Management, stated "in early January 2023, [New JJCI] transferred its Consumer Business assets to its parent entity." *See* **Exhibit A** Kim Decl. at ¶26. [1] Pursuant to Defendants' Organization Structure, Janssen is the parent entity of Defendant New JJCI. See Kim Decl. at Annex B.

12. Defendant Kenvue, individually and as successor in interest to Old JJCI and New JJCI, is a Delaware corporation with its principal place of business in the State of New Jersey. Kenvue may be served with process by serving its General Counsel at 199 Grandview Road, Skillman, NJ 08558.

13. At all relevant times, upon information and belief, Kenvue, or its predecessors, was engaged in the business of manufacturing, formulating, marketing, testing, promoting, selling,

[1] All exhibits referenced in this Class Complaint are appended hereto and incorporated by reference.

and/or distributing the PRODUCTS. At all relevant times, Kenvue, or its predecessors, regularly transacted, solicited, and conducted business in all fifty States of the United States.

14. In its initial SEC filing, Kenvue stated that "It is also possible that various parties will seek to bring and will be successful in bringing claims against us, including by raising allegations that we are liable for the Talc-Related Liabilities." Kenvue further stated that it "may be subject to additional claims . . . related to the sale of talc-based Johnson's Baby Powder in markets where we have discontinued this product (such as in the United States and Canada), including potential governmental inquiries, investigations, claims and consumer protection cases from state attorneys general." **Exhibit 1** (Kenvue Inc. Form S1 Registration Statement Under the Securities Act of 1933 (Jan. 4, 2023).

15. Defendant LTL is a North Carolina limited liability company. LTL's sole member is New JJCI. For purposes of diversity, LTL is a citizen of the State of New Jersey. LTL can be served with process by serving John Kim,[2] Chief Legal Officer, at 501 George Street, New Brunswick, NJ 08933.

16. Defendant Johnson & Johnson Services, Inc. ("J&J Services"), is a wholly owned subsidiary of J&J, and is headquartered in New Jersey. J&J Services can be served with process by serving John Kim, Chief Legal Officer, at 501 George Street, New Brunswick, NJ 08933.

17. At all relevant times, upon information and belief, LTL, or its predecessor, was engaged in the business of manufacturing, formulating, marketing, testing, promoting, selling,

[2] John Kim is an employee of Johnson & Johnson Services, Inc., a wholly owned subsidiary of Johnson & Johnson, and seconded to LTL Management LLC. Mr. Kim served as the Assistant General Counsel and Head of Product Liability Litigation for Johnson & Johnson immediately prior to accepting the position of Chief Legal Officer at LTL.

and/or distributing the PRODUCTS. At all relevant times, LTL, or its predecessor, regularly transacted, solicited, and conducted business in all fifty States of the United States.

18. At all relevant times, Defendants J&J, New JJCI, LTL, LLT, Janssen, Kenvue, and J&J Services have engaged in the research, development, formulation, manufacture, design, testing, licensing, sale, distribution, marketing and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the PRODUCTS.

19. Defendants New JJCI, LTL, LLT, Janssen, Kenvue, and J&J Services are and have been at all relevant times wholly owned subsidiaries of Defendant Johnson & Johnson, under the complete dominion and control of Defendant Johnson & Johnson. Hereinafter, unless otherwise delineated, these entities together shall be referred to as the "Johnson & Johnson Defendants."

20. Johnson & Johnson is one of the world's largest and most financially stable corporations, with a market capitalization of approximately $350 billion, a credit rating better than that of the United States, and approximately $30 billion in liquid assets.

21. Prior to October 2021, J&J's subsidiary Johnson & Johnson Consumer Inc. ("Old JJCI"), was a New Jersey corporation with its principal place of business in the State of New Jersey. Old JJCI engaged in the business of researching, developing, formulating, manufacturing, designing, testing, licensing, selling, distributing, marketing and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the PRODUCTS. As of October 2021, Old JJCI was worth approximately $61.5 billion.

22. In October 2021, facing adverse court judgments for ovarian cancer and mesothelioma caused by the PRODUCTS, and rather than declare bankruptcy themselves, J&J and Old JJCI engaged in a maneuver referred to as the "Texas Two-Step." First, at J&J's instruction, Old JJCI merged into Chenango Zero, LLC, a Texas limited liability company. Then,

Chenango Zero, LLC effected a divisional merger under the Texas Business Organizations Code, resulting in the dissolution of Chenango Zero, LLC and the formation of two new companies: Chenango One, LLC and Chenango Two, LLC. Following the divisional merger, Old JJCI ceased existence. All Old JJCI legacy talc-related liabilities were transferred to the newly created Chenango One, LLC, and the remaining Old JJCI operating assets were transferred to Chenango Two, LLC. Chenango One, LLC, then reincorporated in North Carolina and changed its name to LTL Management LLC. Chenango Two, LLC merged into Curahee Holding Company Inc., which name was then changed to Johnson & Johnson Consumer Inc. (Defendant "New JJCI").

23. Second, within 48 hours of the creation of LTL and transfer of Old JJCI operating assets to Defendant New JJCI, LTL declared bankruptcy, strategically leaving Old JJCI's productive operations and trade creditors outside of the bankruptcy. With no employees or pre-existing business, LTL had nothing to "reorganize." As acknowledged by the newly formed organization, LTL was created solely to resolve talc claims in bankruptcy, away from juries. The resulting bankruptcy operated for the benefit of non-debtors who sat outside the bankruptcy in control of the business—while litigation involving rapidly dying victims was halted.

24. LTL was a North Carolina limited liability company and a citizen of the State of New Jersey. LTL has now been converted to a Texas entity and renamed LLT Management LLC. At all relevant times, upon information and belief, LLT, or its predecessors, was engaged in the business of manufacturing, formulating, marketing, testing, promoting, selling, and/or distributing the PRODUCTS. At all relevant times, LLT, or its predecessor, regularly transacted, solicited, and conducted business in all fifty States of the United States.

25. On February 25, 2022, Chief Judge Michael B. Kaplan of the Unites States Bankruptcy Court, District of New Jersey, entered a Memorandum Opinion denying motions

seeking dismissal of the first LTL bankruptcy proceeding pursuant to 11 U.S.C. § 1112(b) as not having been filed in good faith.

26. On January 30, 2023, the United States Court of Appeals for the Third Circuit issued an Opinion in which it reversed the Bankruptcy Court's denial of motions to dismiss and remanded the case with the instruction to dismiss the Chapter 11 petition. Examining circuit precedent, decisions of other courts, and the Bankruptcy Code's structure, purpose, and legislative history, the panel reaffirmed the long-standing rule that debtors "who do[] not suffer from financial distress cannot demonstrate" a good-faith basis for filing for bankruptcy. On March 31, 2023, the Third Circuit issued a mandate to implement its decision, and Chief Judge Kaplan dismissed the LTL bankruptcy on April 4, 2023.

27. Also in January 2023, in and around the same time the Third Circuit ordered the dismissal of the LTL bankruptcy proceeding, and in an effort to shield assets from liability, New JJCI transferred all of its consumer business assets to its parent entity, Defendant Janssen.

28. On April 4, 2023, immediately following the dismissal of its first bankruptcy, LTL Management LLC filed a second bankruptcy, which Plaintiffs again believed was not filed in good faith, but as tactic to delay cases pending in federal and state courts.

29. On July 28, 2023, Chief Judge Michael Kaplan issued a Memorandum Opinion in which he ruled that LTL's second bankruptcy was not filed in good faith "due to LTL's lack of imminent and immediate financial distress." LTL Opinion at 39. Chief Judge Kaplan dismissed the bankruptcy by Order on August 11, 2023.

30. Defendants John Does/Jane Does 1-100 are those persons, agents, employees, and/or representatives of Defendants whose conduct as described herein caused or contributed to

the damages of Plaintiffs, all of whose names and legal identities are unknown to Plaintiffs at this time, but will be substituted by amendment when ascertained, individually and jointly.

JURISDICTION AND VENUE

31. The Court has subject matter jurisdiction under 28 U.S.C. § 1332(d) (diversity jurisdiction). This action satisfies, among other things, the requirements for diversity under 28 U.S.C. § 1332(d)(2), a provision of the Class Action Fairness Act of 2005.

32. The matter in controversy exceeds $5 million, exclusive of interest and costs.

33. Further, at least one class member is a citizen of a state different from any Defendant.

34. The Defendants are subject to this Court's personal jurisdiction because Defendants have purposefully availed themselves of the privilege of conducting business within New Jersey, and are domiciled here, have their principal place of business here, are registered to do business here, and carry on continuous and systematic business here. Additionally, many of the acts described in this complaint occurred in New Jersey.

35. Venue is proper in this District and Division under 28 U.S.C. § 1391(b)-(d) because Defendants are deemed to reside in any judicial district in which they are subject to personal jurisdiction when the action is commenced, and the Defendants' contacts with this District are sufficient to subject them to personal jurisdiction.

36. Plaintiffs demand a jury trial on all issues so triable.

CLASS ACTION ALLEGATIONS

37. Plaintiffs seek certification of the following Class:

> (1) All female U.S. resident users of Defendants' talc-containing products Johnson's Baby Powder and/or Shower to Shower (hereinafter the "PRODUCTS") between 1960 and the present who, prior to the date of the Court's Preliminary Approval and Class Certification Order, utilized the

> Product(s) for genital application for a period of more than four (4) years, and have not commenced an individual, non-class lawsuit for the pursuit of any individual, non-class personal injury claims arising from the use and/or exposure to Defendants' Products ("Qualifying Talc Users"); (2) Authorized representatives, ordered by a court or other official of competent jurisdiction under applicable state law, of deceased or legally incapacitated or incompetent Qualifying Talc Users ("Representative Claimants"); and, (3) Spouses, parents, children who are dependents, or any other persons who properly under applicable state law assert the right to sue independently or derivatively by reason of their relationship with a Qualifying Talc User ("Derivative Claimants").

38. Additionally, the proposed Plaintiff Class includes two proposed subclasses:

Subclass 1: Qualifying Talc Users (Class Members) and the Representative Claimants of legally incapacitated or incompetent Qualifying Talc Users who as of the date of the Court's Preliminary Approval and Class Certification Order have not been diagnosed with a "Defined Injury", namely: epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer.

Subclass 2: Qualifying Talc Users (Class Members) who affirmatively consent (Opt-In) to membership in the Class and who as of the date of the Court's Preliminary Approval and Class Certification Order have been diagnosed with a "Defined Injury", namely: epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer, and their Representative and Derivative Claimants.

39. Excluded from the Class and proposed subclasses are: (i) Class members who request exclusion from the class; (ii) Putative members of Subclass 2 who do not affirmatively consent (Opt-In) to membership in the Class; (iii) Individuals employed by Defendants at any time between 1960 and the present; (iv) Judges on the United States District Court for the District of New Jersey and their law clerks serving during the pendency of this litigation; (v) Persons who have commenced an individual, non-class lawsuit arising from the use and/or exposure to Defendants' PRODUCTS prior to the date of the Court's Preliminary Approval and Class

Certification Order; (vi) Persons who have been diagnosed with mesothelioma; (vii) Persons who are diagnosed with mesothelioma or lung cancer in the future; and, (viii) Persons who have settled, dismissed, or otherwise compromised their individual, non-class personal injury claims arising from their use and/or exposure to Defendants' PRODUCTS.

40. Pursuant to Rule 23 of the Federal Rules of Civil Procedure, the Plaintiffs bring this action on behalf of the two Subclasses and seek relief as described below.

a. Plaintiff, Joni S. Bynum, individually and on behalf of Subclass 1 brings this action pursuant to Federal Rule of Civil Procedure 23(a)(1-4) & (b)(2) (with a right of opt-out) or, alternatively, Rule 23(b)(3) and seeks legal, equitable and injunctive relief to include a Court-supervised fund to provide medical monitoring in the form of preventative and diagnostic care for epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer for the members of Subclass 1, inasmuch as they have not been diagnosed with one of the aforementioned Defined Injuries but are at increased risk of developing one of these diseases as a result of their exposure to Defendants' PRODUCTS. Also, Plaintiff, Joni S. Bynum, individually and on behalf of Subclass 1 brings this action pursuant to Federal Rule of Civil Procedure 23(b)(3) and seeks an award of damages, including punitive damages, to compensate them for any Defined Injuries they (and their Representative and/or Derivative Claimants) may suffer in the future.

b. Plaintiffs, Robin Coburn and James Coburn, individually and on behalf of Subclass 2 bring this action pursuant to Federal Rule of Civil Procedure 23(b)(3) and seek compensatory and punitive damages for the Defined Injuries

they (and the Representative and/or Derivative Claimants of Subclass 2) have suffered.

41. This action may be properly maintained as a class action on behalf of the proposed Class and the subclasses described above, pursuant to the applicable and appropriate provisions of Rule 23(a)(1)-(4), Rule 23(b)(2), and Rule 23(b)(3).

A. Numerosity of the Class – Fed. R. Civ. P. 23(a)(1)

42. On information and belief, the Class consists of thousands of individuals. As such, it is so numerous that joinder of all members is impossible.

B. Commonality – Fed. R. Civ. P. 23(a)(2)

43. There are numerous questions of law and fact common to all Class members. Because Defendants' PRODUCTS and actions pertaining thereto are governed by federal regulations, the Class members will be subject to common questions of law.

44. Furthermore, the factual bases of Defendants' strict product liability and outrageous conduct are common to all Class members and represent a common thread of negligence, reckless conduct, gross negligence and willful, wanton, and reckless indifference for the rights of others, resulting in injury to all members of the Class. The Class members' claims arise from the same course of decision-making and events, and each Class member will make similar legal and factual arguments to prove Defendants' negligence, recklessness, willful misconduct, malice, wantonness, oppression, deplorable conduct, and liability.

45. Questions of law and fact common to the members of the Class and Subclasses 1 & 2 predominate over any questions affecting only individual members of the Class. These include but, are not limited to, the following:

a. Whether Plaintiff Bynum and the other members of Subclass 1 are entitled to relief in the form of a Court-supervised medical monitoring program.

b. Whether medical monitoring is reasonably necessary to obtain prompt and early diagnosis of epithelial ovarian cancer, fallopian tube cancer, and primary peritoneal cancer for Subclass 1 members.

c. Whether such medical monitoring is beyond the routine medical care provided to women of a similar age and/or background as members of the Class and Subclass 1.

d. Whether the early diagnosis of epithelial ovarian cancer, fallopian tube cancer, and primary peritoneal cancer will lead to improved outcomes, improved survivability rates, and improved treatment for such diseases.

e. Whether Plaintiff Bynum and the other members of Subclass 1 are entitled to compensation for the Defined Injuries they (and their Representative and/or Derivative Claimants) may sustain in the future.

f. Whether Plaintiffs Robin Coburn and James Coburn and the other members of Subclass 2 are entitled to compensation for the Defined Injuries they (and their Representative and/or Derivative Claimants) have sustained.

g. Whether the Defendants are liable under a theory of strict products liability as set forth in §402A of the Restatement of Torts (Second).

h. Whether use of the Defendants' PRODUCTS in the female perineal area significantly increases the risk of ovarian cancer in women.

i. Whether the Defendants' PRODUCTS contain carcinogenic substances including platy talc, fibrous talc, asbestos, heavy metals, and fragrance chemicals.

j. Whether the Defendants knew or should have known of the unreasonably dangerous and carcinogenic nature of the PRODUCTS, especially when applied to a woman's perineal regions, and whether the Defendants were properly warning consumers of this danger.

k. Whether the PRODUCTS mined, refined, screened, tested, supplied, formulated, designed, manufactured, marketed, promoted, sold and/or distributed by Defendants were defective and unreasonably dangerous.

l. Whether the Defendants knew or should have known that the use of the PRODUCTS in the female perineal area significantly increased the risk of ovarian cancer in women based upon scientific knowledge available to the Defendants for more than half a century.

m. Whether the PRODUCTS were defectively manufactured and designed by the Defendants in that their design and formulation were more dangerous than an ordinary consumer would expect when used in an intended and reasonably foreseeable manner.

n. Whether a reasonable and safer alternative design existed, which could have feasibly been employed by the Defendants to manufacture a product with the same cosmetic purpose as the PRODUCTS.

o. Whether the Defendants breached their express and implied warranties concerning the PRODUCTS.

p. Whether the Defendants had a duty to act with reasonable care in the design, development, marketing, labeling, manufacturing, formulating, testing, monitoring, distribution, and sale of the PRODUCTS.

q. Whether the Defendants were negligent in the design, development, marketing, labeling, manufacturing, formulating, testing, monitoring, distribution, oversight, and/or sale of the PRODUCTS.

r. Whether the Defendants intentionally, knowingly, recklessly, and/or negligently made public misrepresentations of material facts to, and/or concealed material facts from, consumers like Plaintiffs concerning the character, safety and effectiveness of the PRODUCTS.

s. Whether the Defendants' acts, omissions, and overall conduct with respect to the PRODUCTS amounted to willful misconduct, malice, fraud, wantonness, oppression or that entire want of care so as to raise the presumption of conscious indifference to the consequences to Plaintiffs and the Class.

t. Whether the Defendants engaged in the intentional spoliation of evidence which limits the Plaintiffs' ability to present and prove the claims on behalf of the Class.

u. Whether the Defendants have any affirmative defenses that can be litigated on a class-wide basis.

46. Common questions of law and fact also exist with respect to Defendants' punitive damages liability to the Class, including Defendants' outrageous, grossly negligent, willful, reckless, and wanton conduct; the calculation of the amount of punitive damages that may be imposed upon each of the Defendants consistent with due process; intra-class equity with respect to the allocation and utilization of punitive damages; and the most practicable and most equitable allocation, disbursement, and utilization of such damages for punishment of Defendants' wrongful

conduct toward Plaintiffs, the Class, and society, and in fulfillment of the deterrent policy and purpose of punitive damages.

C. Typicality – Fed. R. Civ. P. 23(a)(3)

47. The claims in this Class Action Complaint are typical of the claims of the Class in that the representative Plaintiffs are members of the Class and, like all Class members, were placed at risk of adverse health effects and/or other harms caused by their exposure to Defendants' PRODUCTS in the female perineal area, which significantly increased (or increase) their risk of epithelial ovarian cancer, fallopian tube cancer, and primary peritoneal cancer.

48. Each Class member's claim arises from the same acts, omissions and decision-making, and each Class member will make similar legal and factual arguments to prove Defendants' negligent, outrageous, grossly negligent, willful, reckless, and wanton conduct and liability under the same legal theories asserted herein.

49. The claims of Plaintiff Joni Bynum are typical of the claims of Subclass 1 members.

50. The claims of Plaintiff Robin Coburn and Plaintiff James Coburn are typical of the claims of Subclass 2 members.

D. Adequacy of Representation – Fed. R. Civ. P. 23(a)(4)

51. Plaintiffs will fairly and adequately represent and protect the interest of the Class. The Subclass representatives will fairly and adequately represent the Subclasses with separate legal representation for themselves and the different subclasses. Plaintiffs for each subclass are represented by counsel with substantial experience in prosecuting mass tort and complex class actions, including actions involving dangerous and defective consumer products. Plaintiffs and their separate counsel are committed to prosecuting this action vigorously on behalf of the Class

and have the financial resources to do so. Neither Plaintiffs nor their counsel have interests adverse to those of the Class or the individual subclasses.

E. Class Certification under Fed. R. Civ. P. 23(b)(2) or 23(b)(3) – Injunctive or Declaratory Relief

52. The Court may appropriately certify the medical monitoring claims of the Class and specifically, Subclass 1, under Rule 23(b)(2) because the Defendants have "acted or refused to act on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole."

53. Alternatively, the Court may appropriately certify the medical monitoring claims of the Class and specifically, Subclass 1, under Rule 23(b)(3) because common issues of fact and law predominate concerning these claims.

54. Although the Court is not required to grant notice or opt-out rights for a Rule 23(b)(2) class, it has the discretion to do so. Here, the Plaintiffs respectfully request that the Court exercise its discretion and grant Subclass 1 (b)(2) opt-out rights, should the Court elect to certify a (b)(2) Class for Subclass 1 members in this case.

F. Class Certification under Fed. R. Civ. P. 23(b)(3) – Predominance and Superiority

55. Common issues of fact and law predominate concerning the claims of the Class.

56. Defendants' conduct presents predominant common factual questions. Plaintiffs' proof of Defendants' negligent, grossly negligent, willful, reckless, wanton and fraudulent conduct will involve the same individuals, events, discovery, documents, fact witnesses, and experts. Common questions of fact also predominate concerning the determination of the aggregate amount of punitive damages necessary to fulfill the punishment and deterrence goals of such damages.

57. Because Defendants' behavior here is governed by federal regulations and state common law claims, the Class members will be subject to common questions of law and such questions will predominate over any individual issues.

58. A class action is a superior method for the fair and efficient adjudication of this controversy. Given the compensatory and other damages of each Class member's case, few could afford to shoulder the litigation costs of a complex matter such as this, which in turn means that few could likely obtain recourse. Absent a class action, Class members would continue to incur harm without remedy.

FACTUAL ALLEGATIONS

I. Facts Relating to Defendants' Successor Liability

a. The Assets, Operating Business, and Liabilities of Old JJCI Were Transferred to Defendants New JJCI, LTL, Janssen, and Kenvue

59. The Kim LTL Decl. summarizes J&J's and its affiliates' corporate history that is pertinent to the claims alleged herein against the Defendants as follows:

a. "J&J, a New Jersey company incorporated in 1887, first began selling JOHNSON'S® Baby Powder in 1894, launching its baby care line of products."

b. "In 1972, J&J established a formal operating division for its baby products business, which included JOHNSON'S® Baby Powder…. J&J transferred all its assets and liabilities associated with the baby products division to J&J Baby Products."

c. "In 1981, J&J Baby Products transferred all its assets, except those assets allocated to its diaper programs, to Omni Education Corporation ("Omni"), a wholly owned subsidiary of J&J Baby Products. In turn, Omni assumed all liabilities of J&J Baby Products except those liabilities related to its diaper program.

Immediately following the transaction, J&J Baby Products merged into another subsidiary of J&J and was renamed Personal Products Company, and Omni changed its name to Johnson & Johnson Baby Products Company."

d. "In 1988, Johnson & Johnson Baby Products Company transferred all its assets in respect of its baby products business to Johnson & Johnson Dental Products Company, which assumed all of its liabilities and was renamed Johnson & Johnson Consumer Products, Inc."

e. "In 1997, Johnson & Johnson Consumer Products, Inc. changed its name to Johnson & Johnson Consumer Companies, Inc. ("J&J Consumer Companies")."

f. "In 2015, J&J Consumer Companies merged with and into an affiliate, which then merged into McNeil-PPC, Inc. The resulting entity was renamed Johnson & Johnson Consumer Inc. (including all former names and historical forms, "Old JJCI")."

g. "Old JJCI became responsible for all claims alleging that JOHNSON'S® Baby Powder and other talc-containing products cause cancer or other diseases…. Old JJCI also became responsible for all claims alleging that Shower to Shower products, which contained talc, cause cancer or other diseases."[3]

60. J&J and its subsidiary, "Johnson & Johnson Consumer Inc.," both in the form of "Old JJCI" and "New JJCI" (which is identified and described below), were at all times material

[3] Plaintiffs do not agree with this statement that Old JJCI became responsible for all claims, especially not claims related to J&J's independent, non-derivative liability.

responsible for the design, labeling, marketing, distribution, and sale of J&J's body powder product lines, including the iconic Johnson & Johnson Baby Powder product line.

61. Each and every one of the J&J's corporate entities, including itself and its affiliated companies involved or associated with talc business and PRODUCTS, were at all times material to this case aware that raw talc ingredient and/or resulting talc-based PRODUCTS contained asbestos, and each and all collectively actively concealed such fact from the public for decades.

62. Prior to the 2021 implementation of J&J's multifaceted restructuring of its consumer product subsidiaries, Old JJCI and its predecessors milled, manufactured, labeled, sold, supplied, distributed, and/or marketed asbestos-containing PRODUCTS to which Plaintiff Class members were exposed.

63. In an effort to avoid or eliminate J&J and Old JJCI's respective responsibility and liability for injuries and harm caused by Johnson & Johnson Baby Powder, as well as other talc PRODUCTS, in or about October 2021, Old JJCI underwent a series of corporate restructuring transactions under Texas state corporation and business law in which it split itself into two separate entities through a device referred to as a "divisive merger," more commonly known as the "Texas Two Step."

64. The corporate restructuring was designed and undertaken with the intent to isolate the talc liabilities of Old JJCI into a newly invented company created by J&J. LTL is an acronym for "Legacy Talc Litigation."

65. LTL was immediately thereafter put into a Chapter 11 Bankruptcy wherein LTL and other J&J entities sought the protection of the Bankruptcy Code's processes and machinery to obtain a stay of all pending litigation and construct an aggregate resolution of its outstanding present and future asbestos liabilities that would foreclose jury trials and reduce the compensation they would owe to those harmed by its PRODUCTS and their families, given that J&J and its subsidiaries were increasingly being held liable by juries in lawsuits brought by talc asbestos claimants and were being ordered to pay compensatory and exemplary damages.

66. As part of J&J's liability avoidance/limiting corporate restructuring, all of the productive assets of Old JJCI, including those used to manufacture and market J&J Baby Powder, were transferred to a newly minted corporate entity named "Johnson & Johnson Consumer Inc." ("New JJCI"). New JJCI, upon receipt of the Old JJCI's operating assets continued to sell J&J Baby Powder, as Old JJCI had previously done, and as J&J itself had done when it directly marketed the product line through an internal division.

67. Over the objection of tens of thousands of personal injury and wrongful death tort plaintiffs, the Bankruptcy Court presiding over LTL's 2021 bankruptcy case stayed and enjoined prosecution of all litigation against not only the Debtor but all cosmetic talc injury related litigation involving J&J and New JJCI.

68. During LTL's bankruptcy proceedings, representatives of the affected personal injury and wrongful death tort victims challenged J&J's Texas Two Step scheme before the Bankruptcy Court. After losing their challenges before the Bankruptcy Court, they were ultimately

successful on appeal before the United States Court of Appeals for the Third Circuit, which on January 30, 2023, ruled that the Bankruptcy filing by LTL was not proper and ordered that LTL's 2021 Bankruptcy case be dismissed. In re: LTL Management, LLC, No. 22-0007, 2023 WL 2760479 (3d Cir., decided Jan. 30, 2023; opinion entered Mar. 31, 2023).

69. LTL's efforts to obtain re-argument before the Third Circuit panel hearing its appeal or an *en banc* hearing were denied, and the Appeals Court's mandate to the Bankruptcy Court was issued by the Third Circuit Clerk on March 31, 2023, thereby triggering the lower court's duty to enter an order dismissing the case.

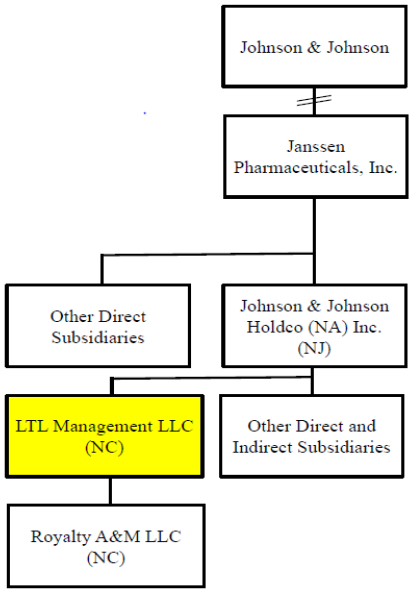
70. Within hours of the LTL Bankruptcy Court issuing its ensuing dismissal order on April 4, 2023, LTL filed a second Chapter 11 petition for bankruptcy protection in the same court, seeking the same relief as in the dismissed case, claiming its funding sources and arrangements had been replaced and reconfigured in such way that purportedly overcame the Third Circuit's reasons for ordering the earlier bankruptcy case be dismissed.

71. Unbeknownst to Plaintiffs, during the time the Third Circuit Court of Appeals was considering the propriety of LTL's bankruptcy filing, New JJCI began the process of moving its assets and business to yet another J&J subsidiary, Defendant Kenvue, Inc., by transfers through JJCI's direct parent, Janssen Pharmaceuticals, Inc.

72. According to the Kim Declaration, as part of J&J's further corporate restructuring, New JJCI changed its name to "Johnson & Johnson Holdco (NA) Inc." ("Holdco"), a New Jersey corporation. Kim's declaration before the Bankruptcy Court additionally revealed that "in early January 2023, [New JJCI] transferred its Consumer Business assets to its parent entity." *See* Kim LTL Decl. at ¶ 26.

73. While Mr. Kim's declaration does not expressly state who the parent entity is, a careful examination of the affidavit demonstrates that Janssen Pharmaceuticals, Inc, is the parent entity of Defendant New JJCI. Id. Figure 1 below is from an Exhibit to Mr. Kim's Declaration and shows that Janssen is the parent that received all the JJCI assets used to manufacture, market, and sell J&J Baby Powder.

Figure 1



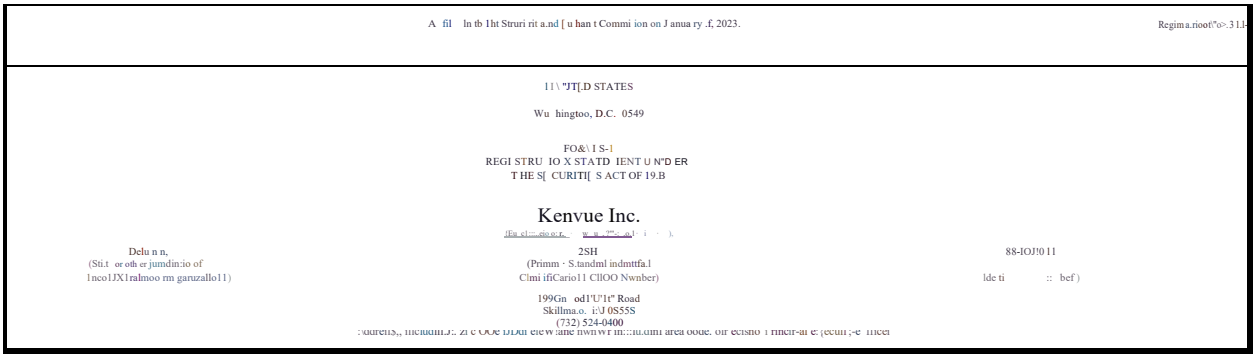
74. Accordingly, under New Jersey law, both Holdco and Janssen are successors to Old JJCI and responsible for the contractual undertakings and tortious conduct of Old JJCI.

75. The information gleaned from Mr. Kim's Declaration and one of J&J subsidiary's SEC filings shows that J&J is in the process of once again manipulating assets and responsibilities related to the sale of J&J's Baby Powder.

76. On January 4, 2023, Defendant Kenvue, another J&J subsidiary, submitted its first filing with the Securities and Exchange Commission ("SEC"), an S-1 registration of securities

form. Kenvue Inc. Form S-1 Registration Statement Under the Securities Act of 1933 (Jan. 4, 2023). Figure 2 below reproduces a portion of the filing's cover page.

Figure 2



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77. In its SEC registration filing, Kenvue sets forth the products that it claims to manufacture and sell in the United States. In this regard, Kenvue represented to the SEC and the public: "A number of **our products marketed in the United States**, including many of our products in our Skin Health and Beauty segment, are considered cosmetics regulated by the FDA through the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act. **Our cosmetic products include** Aveeno Restorative Skin Therapy Oat Repairing Cream, Aveeno Restorative Skin Therapy Sulfate-Free Body Wash, **Johnson's Baby Powder** and certain of our Listerine mouthwash products." *Id.* (emphasis added).

78. Kenvue acknowledged in its SEC S-1 filing that it may be held accountable for the harm caused by the talc-based PRODUCTS it is responsible for: "It is also possible that various parties will seek to bring **and will be successful** in bringing claims against us, including by raising allegations that we are liable for the Talc-Related Liabilities." *Id*.

79. Kenvue further acknowledges itself as the company responsible for the manufacture of Johnson's Baby Powder indicating that it "may be subject to additional claims . . . related to the sale of **talc-based Johnson's Baby Powder in markets where we have**

discontinued this product (**such as in the United States** and Canada), including potential governmental inquiries, investigations, claims and consumer protection cases from state attorneys general." *Id*. (emphasis added).

80. Kenvue also acknowledges that it is "responsible for all liabilities on account of or relating to harm arising out of, based upon, or resulting from, directly or indirectly, the presence of or exposure to talc or talc-containing products sold outside the United States or Canada." *Id*.

81. As such, Kenvue is responsible individually and as successor to all predecessor entities involved in the manufacturing, marketing, and sale of the asbestos-containing talc PRODUCTS to which the Plaintiff was exposed.

b. Defendants Continue the Business of Old JJCI, Including the Johnson's Baby Powder Product Line

82. In its SEC registration filing, Kenvue sets forth the products that it claims to manufacture and sell in the United States. In this regard, Kenvue represented to the SEC and the public: "A number of **our products marketed in the United States**, including many of our products in our Skin Health and Beauty segment, are considered cosmetics regulated by the FDA through the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act. **Our cosmetic products include** Aveeno Restorative Skin Therapy Oat Repairing Cream, Aveeno Restorative Skin Therapy Sulfate-Free Body Wash, **Johnson's Baby Powder** and certain of our Listerine mouthwash products." (Kenvue Inc. Form S-1 Registration Statement Under the Securities Act of 1933 (Jan. 4, 2023)). (emphasis added).

83. The bottle for the cornstarch-based formulation Johnson's® Baby Powder, which is sold today in the United States, states: "For over 125 years JOHNSON's® formulas have been specially designed for baby's unique and delicate skin. Great for kids and adults too!"

Figure 3

84. Kenvue admits in its SEC filing that while J&J transitioned to a cornstarch-based formula for Johnson's® Baby Powder in the United States and Canada in 2020, it is still distributing talc-based Johnson's® Baby Powder in other markets and will continue to do so until sometime in 2023. Id. at 63, 330.

85. It remains possible today, through Amazon's online shopping website, to purchase talc-based Johnson's Baby Powder and have it delivered to the customer. (Transcript of Motions May 24, 2023, *Naranjo, et. al., v. Johnson & Johnson, et al*., Vol. 1 of 2, at 44:18-45:10).

86. Kenvue's website lists Johnson's as one of its "iconic brands" under the categories of "Skin health & Beauty – Face & body" and "Essential health – Baby care". https://www.kenvue.com/brands.

87. Following the link to the Johnson's brand page, one finds Johnson's Baby Powder, amongst a variety of baby care products. https://www.johnsonsbaby.com/baby-products.

88. On Kenvue's Johnson's brand website's FAQ page, under the questions "Why did Johnson's® reformulate?" and "How have the Johnson's® products changed?" Kenvue indicates it has generally reformulated its line of Johnson's baby products recently based on its continued scientific research and input from parents. https://www.johnsonsbaby.com/faq#why-did-johnson-s-reformulate and https://www.johnsonsbaby.com/faq#how-have-the-johnson-s-products-. As with its corn-starch-based Johnson's Baby Powder, Kenvue continues to market these reformulated products under the trusted Johnson's brand name.

II. Overview of Talc & the PRODUCTS

89. Talc is an inorganic magnesium silicate mineral that may occur in a variety of forms (massive or platy, foliated, and fibrous).

90. Talc is used in a wide array of industrial, commercial and cosmetic substances. It is the main substance in talcum powders, talc-based body powders, and the PRODUCTS.

91. Talc is mined from deposits in the earth that can contain asbestos, heavy metals (nickel, cadmium, cobalt, chromium, arsenic, etc.), and other minerals.

92. The Johnson & Johnson Defendants manufactured the PRODUCTS.

93. Johnson & Johnson began the manufacture of Johnson's Baby Powder in approximately 1894.

94. During all relevant times, Johnson's Baby Powder® was composed primarily of talc along with other constituent elements found in talc such as asbestos, fibrous talc, and heavy metals (e.g., nickel, cadmium, cobalt, chromium, arsenic), and fragrance chemicals.

95. Johnson & Johnson began the manufacture of Shower to Shower in 1967.

96. Shower to Shower was manufactured through the same Johnson & Johnson divisions as Johnson's Baby Powder until Shower to Shower was sold in 2012.

97. During all relevant times, Shower to Shower was composed of talc and cornstarch, along with other constituent elements found in talc such as asbestos, fibrous talc, and heavy metals (e.g., nickel, cadmium, cobalt, chromium, arsenic), and fragrance chemicals.

98. Johnson & Johnson obtained the talc for the PRODUCTS from various sources including Guangxi, China, and the Fontane mine in the Germanasca Valley and Val Chisone region in Italy. J&J also obtained the talc for the PRODUCTS from the Johnson, Hammondsville, Rainbow, Hamm, and Argonaut mines in Vermont (collectively referred to as "Vermont mines"). *See* **Exhibit 2** (Feb. 15, 2019 Musco Dep. 63:7–64:5) (Hammondsville and Johnson mines were sources of cosmetic talc for Johnson's Baby Powder); *see also* **Exhibit 3** (Mar. 8, 2019 Musco Dep. 451:2–453:22) (Emtal 500 from Johnson Mine used in Cosmetics); **Exhibit 4** (Oct. 29, 1982 Miller Dep.); *see also* **Exhibit 5** (Trial Testimony of John Hopkins, July 22, 2019, *Barden et al. v. Johnson & Johnson* at 18:15-19:21).

99. From approximately 1967 until 2003, the primary source of talc for the PRODUCTS was Vermont mines including the Hammondsville, Rainbow, Hamm, and Argonaut mines. The mines were owned and operated by Johnson & Johnson's subsidiary, Windsor Minerals, with Johnson & Johnson exercising control over all key decisions concerning the mines.

100. In 1989, Johnson & Johnson sold the Vermont mines and mills used to supply talc for its talc products to Cyprus Mines Corporation ("Cyprus"). Cyprus Mines Corporation sold the mines to Rio Tinto Minerals, Inc. in 1992. In a series of later transactions, the mines were later transferred to Luzenac America, Inc., now known as Imerys Talc America, Inc. These Vermont mines were the primary source of Johnson & Johnson's talc products until 2003.

101. Over time, the trade names for the talc ore used by Johnson & Johnson in Johnson's Baby Powder and Shower to Shower included "Emtal," "Grade 66," "Grade 96," "1615," "Italian 00000," and "Supra" all of which contain asbestos.

102. At all relevant times, a feasible and safe alternative to talc has existed. For example, cornstarch is an organic carbohydrate that is quickly broken down by the body with no known adverse health effects. Cornstarch powders have been sold and marketed for the same uses as the PRODUCTS with nearly the same effectiveness as talcum powders. **Exhibit 6** (JNJ 000011777). See **Exhibit 7** (JNJ 000331979), cornstarch "can be absorbed into the body, tending not to cause severe granuloma as may be the case with talc." See **Exhibit 8** (JNJ 000332195), Johnson's baby powder, pure cornstarch, being marketed as "a change for the better."

103. As set forth herein, it was recommended that talc-based powders be replaced by cornstarch since at least the 1970s because of the potential risk of ovarian cancer with use in feminine hygiene. Once epidemiology studies were conducted beginning in 1982, the number of calls to abandon talc in favor of cornstarch grew, in both the medical community and in the medical and scientific community.

104. At various points in time, the Johnson & Johnson Defendants considered replacing talc with cornstarch-based powders which they began marketing in the early 1980s. For example, in 2000, representatives prepared a plan to abandon the production of talc-containing Johnson's

Baby Powder in the U.S. by December 1, 2000—weeks before the National Toxicology Program ("NTP") was set to consider the question of whether talc was a likely human carcinogen. Specifically, on November 20, 2000, there was a meeting of executives of the Johnson & Johnson Defendants to consider a plan to abandon the use of talc. That plan to abandon talc was developed weeks before by a "crisis management group" retained by Old JJCI, including a public relations company that assisted in preparing a "position brief to share with senior [J&J] management," a "summary" document and a "draft holding statement" to be presented to J&J management by executive, John McKeegan. *See* **Exhibit 9** (Deposition of John McKeegan, Sept. 27, 2021, at 195:3-15). This plan was developed after a confidential memorandum was prepared for all talc manufacturers and PCPC, which concluded that "the bottom line—except for a very few number of recruited experts—the cosmetic industry will be the lone voice" in arguing for the safety of talc and that "it would not be unwise for companies marketing talc-based products for use in babies and infants to consider ways to reformulate if necessary." *Id.* at 233:11-14; 237:23-238:2.

105. At a November 20, 2000 meeting, members of Old JJCI proposed to J&J that J&J announce the following: "J&J in the U.S. has made a decision to switch manufacturing entirely to cornstarch to ensure the commercial viability of its powder produced and ensure consumer peace of mind. . . . This switch will take place by December 1st, 2000." Id. at 204:3-9. Until recently, the plan to switch to cornstarch was abandoned.

106. On April 27, 2020, this Court denied the then-existing Johnson & Johnson Defendants' motion to exclude Plaintiffs' general causation experts, finding that the opinions of Plaintiffs' experts that talcum powder can cause ovarian cancer and that historical samples of Johnson's Baby Powder and Shower to Shower contain asbestos and fibrous talc are admissible evidence in all cases filed in the MDL.

107. On May 19, 2020, Johnson & Johnson announced the discontinuation of sale of all talc-based Johnson's Baby Powder in the United States and Canada. (Johnson & Johnson Consumer Health Announces Discontinuation of Talc-based Johnson's Baby Powder in U.S. and Canada, May 19, 2020, available at: https://www.jnj.com/our-company/johnson-johnson-consumer-health-announces-discontinuation-of-talc-based-johnsons-baby-powder-in-u-s-and-canada).

108. On August 11, 2022, Johnson & Johnson announced the worldwide discontinuation of sale of all talc-based Johnson's Baby Powder in 2023. (Johnson & Johnson Consumer Health to Transition Global Baby Powder Portfolio to Cornstarch, Aug. 11, 2022, available at: https://www.factsabouttalc.com/_document/johnson-johnson-consumer-health-to-transition-global-baby-powder-portfolio-to-cornstarch?id=00000182-8df9-d979-a797-edfb15d40000).

109. At all relevant times, Defendant Imerys Talc[4] mined, refined, screened, tested, and delivered the raw talc contained in the PRODUCTS.

110. At relevant times, Imerys Talc continually advertised and marketed talc as safe for human use and knew that its processed talc was intended for human use.

111. Beginning in 2006 and until the present, Imerys Talc supplied its customers, including the Johnson & Johnson Defendants, with Material Safety Data Sheets ("MSDS") for talc, which conveyed health and warning information about talc. *See* **Exhibit 10** (P-37 (IMERYS 081218).

112. At relevant times, the Johnson & Johnson Defendants advertised and marketed their "Johnson's Baby Powder" product as a symbol of "freshness" and "comfort," eliminating friction

[4] All allegations regarding actions taken by Imerys Talc also include actions taken while that entity was known as Luzenac America, Inc.

on the skin, absorbing "excess wetness" to keep skin feeling dry and comfortable, and "clinically proven gentle and mild." The Johnson & Johnson Defendants induced women through advertisements to dust themselves with this product to mask odors. The Johnson's Baby Powder bottle specifically targets women, stating: "For you, use every day to help feel soft, fresh, and comfortable." *See* **Exhibit 11** (P-121 (excerpts from www.johnsonbaby.com and www.showertoshower.com); **Exhibit 12** (P-125 (JNJ 000058760)); and **Exhibit 13** (P-49 (picture of Johnson & Johnson's Baby Powder bottle)).

113. At relevant times, the Johnson & Johnson Defendants advertised and marketed their "Shower to Shower" product as safe for use by women as evidenced in its slogan, "A sprinkle a day keeps odor away," and through advertisements such as: "Your body perspires in more places than just under your arms. Use SHOWER to SHOWER to feel dry, fresh, and comfortable throughout the day;" and "SHOWER to SHOWER can be used all over your body." The 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." *See* **Exhibit 14** (P-121 (excerpts from www.johnsonbaby.com and www.showertoshower.com)); **Ex. 13** (P-49 (picture of Johnson & Johnson's Baby Powder bottle)); and **Exhibit 15** (P-50 (picture of Johnson & Johnson's Shower to Shower bottle)).

114. Although the labels on the bottles for the Johnson & Johnson Baby Powder and Johnson & Johnson Shower to Shower products have changed over time, the core message has been the same: that women can safely use the products on their bodies including their genital areas.

III. Strong Scientific Evidence Links Talc Use to Ovarian Cancer

115. Internally, over decades, Johnson & Johnson discussed its corporate obligation that "if the results of any scientific studies show any question of safety of talc" use it would "not hesitate to take it off the market." *See* **Exhibit 16** (P-660 (JNJ000488208)); **Exhibit 17** (P-55 (JNJ000026241); and **Exhibit 18** (P-115 (JNJ000024495)). However, when faced with questions about the safety of talc, Johnson & Johnson refused to act.

116. In a 1948 paper, Johnson & Johnson scientists recognized talc as a hazard to human health. Eberl et al., *Comparative Evaluation of the Effects of Talcum and a New Absorbable Substitute on Surgical Gloves*, 25 Am. J. Surgery 493 (1948).

117. As early as 1961, research established that some particles, including particles like talc, can translocate from the exterior genital area to the ovaries in women. Egli & Newton, *The Transport of Carbon Particles in the Human Female Reproductive Tract*, 12 Fertility Sterility 2 (1961).

118. In 1964, Johnson & Johnson admitted in an internal company document that talc could not be safely absorbed in the vagina while cornstarch could be. *See* **Exhibit 19** (P-343 (JNJ 000265536 at 3 (cornstarch "replaced talc because [cornstarch]. . . was found to be absorbed safely in the vagina whereas, of course, talc was not")). *See also*, **Ex. 7** (JNJ 000331979 (cornstarch "can be absorbed into the body, tending not to cause severe granuloma as may be the case with talc.")).

119. Beginning in the 1970s, Johnson & Johnson had in its possession published scientific literature detailing specific cases involving consumers who developed extensive talcosis as a result of the liberal use of cosmetic powder. **Exhibit 20** (Nov. 28, 2018, Musco Dep. 107:12–109:10).

120. There is no dispute that for over half a century, there have been serious questions about whether talcum powder can cause cancer. For example, in 2021, Old JJCI's Chief Medical Officer, Edwin Kuffner testified that:

> Q And you would agree for at least a half century before you became CMO for Old JJCI in 2017 there were questions raised in the medical and scientific community about the safety of talcum powder, true?
>
> A Yes

Exhibit 21 (Testimony of Ed Kuffner, *In re: LTL Management LLC*, Nov. 5, 2021 at 417).

121. In fact, as early as 1973, proposals were made to Congress to both study the link of talc and ovarian cancer and whether to replace talc with cornstarch in cosmetics. See **Exhibit 22** (Toxic Substances Control Act of 1973 hearings before the U.S. Senate (February 23, 1973)). For example, because of studies finding talc in the ovaries of women with ovarian cancer, it was noted that an *"area which requires immediate investigation should be talcum powder and vaginal deodorants."* Id. at 170 (emphasis added). Indeed, at those 1973 Senate Hearings, it was noted that cornstarch could act as a safe alternative to talcum powder:

> Before 1895, when Johnson and Johnson began talc manufacture, babies were commonly dusted with com starch; this safe substitute is still available, and at one-fourth the cost of talc. We recommend it. Don't use feminine hygiene sprays which contain talc.

Id. at 173.

122. In or about 1971, the first study was conducted that suggested an association between talc and ovarian cancer. This study was conducted by Dr. W.J. Henderson and others in Cardiff, Wales. *See* **Exhibit 23** (P-1 (Henderson, WJ, et al., Talc and carcinoma of the ovary and cervix, 78 J. Obstetrics & Gynaecology of the British Commonwealth 266 (1971)). *See also* **Exhibit 24** (P-344 (JNJ 000327788)), JNJ forwarded tissue samples from Dr. Henderson to Dr. Langer at Mt. Sinai who confirmed Dr. Henderson's observations.

123. In or about 1979, migration of particulates from the vagina to the peritoneal cavity and ovaries was found, correlating previous findings in surgically removed specimens. *See* **Exhibit 25** (JNJ 000005093).

124. In 1982, the first epidemiologic study was performed on talc powder use in the female genital area. This study was conducted by Dr. Daniel Cramer and others. *See* **Exhibit 26** (P-3 (JNJ000020733)). This study found a 92% increased risk in ovarian cancer with women who reported genital talc use. Upon information and belief, shortly after this study was published, Dr. Bruce Semple of Johnson & Johnson visited Dr. Cramer about his study. Dr. Cramer advised Dr. Semple that Johnson & Johnson should place a warning on its talcum powder products about the ovarian cancer risks so that women could make an informed decision about their health.

125. A 1986 Johnson & Johnson Technology Forecast acknowledged that safety of cosmetic powders was a concern and that health professionals had decided that powders provide no health benefit. The document also acknowledged that "Retrospective studies have implicated talc use in the vaginal area with the incidence of ovarian cancer." *See* **Exhibit 27** (P-9 (JNJ00000523)).

126. Since publication of the Cramer study in 1982, there have been dozens of additional epidemiologic and other scientific studies providing data regarding the association of talc and ovarian cancer. Nearly all of the epidemiology studies have reported an elevated risk for ovarian cancer associated with genital talc use in women. Significantly, scientific studies have also provided biologically plausible explanations as to how genital talc use can cause ovarian cancer:

a. In 1983, a case-control study found a 150% increased risk of ovarian cancer for women who use talcum powder in the genital area. Hartge, P., *et al.* Talc and Ovarian Cancer. *JAMA*. 1983; 250(14):1844.

b. 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 genital area before their cancer diagnosis. The study showed a 40% increase in risk of ovarian cancer in women that used talcum powder on their genital area and the relative risk for talc use between 1 and 9 years, relative to a shorter duration, was 1.6 (p = 0.05). Whittemore AS, *et al.* Personal and environmental characteristics related to epithelial ovarian cancer. II. Exposures to talcum powder, tobacco, alcohol, and coffee. *Am. J. Epidemiol.* 1988 Dec; 128(6):1228-40.

c. A 1989 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 each week. In reporting their findings, the study authors warned women that they should refrain from genital talcum powder use. Booth, M., *et al*. Risk factors for ovarian cancer: a case-control study. *Br J Cancer*. 1989 Oct; 60(4):592-8.

d. In 1992, a case-control study found an 80% increased risk of ovarian cancer in women with more than 10,000 lifetime perineal applications of talc, demonstrating a positive dose-response relationship. Harlow BL, *et al.* Perineal exposure to talc and ovarian cancer risk. *Obstet Gynecol.* 1992 Jul; 80(1):19-26.

e. Another 1992 case-control study reported a 70% increased risk from genital talc use and a 379% significantly increased risk of ovarian cancer in women who used talc on sanitary napkins in their genital area. Rosenblatt, K.A. *et al.*

Mineral fiber exposure and the development of ovarian cancer. *Gynecol Oncol.* 1992 Apr; 45(1):20-5.

f. Yet another 1992 case-control study 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. J. Epidemiol.* 23-29 (1992).

g. In 1995, the largest study of its kind to date found a 27% increased risk in ovarian cancer for women who regularly use talc in the abdominal or perineal area. Purdie, D., *et al.* Reproductive and other factors and risk of epithelial ovarian cancer: An Australian case-control study. Survey of Women's Health Study Group. *Int J Cancer.* 1995 Sep 15; 62(6):678-84.

h. In 1996, a case-control study found a statistically significant 97% increased risk of ovarian cancer in women who used what they described as a "moderate" or higher use of talc-based powders in their genital area. In reporting their findings, the study authors warned women that they should refrain from genital talcum powder use. *See* Shushan, A., *et al.* Human menopausal gonadotropin and the risk of epithelial ovarian cancer. *Fertil. Steril.* 1996 Jan; 65(1):13-8.

i. In 1997, a case control study of 313 women with ovarian cancer and 422 without this disease found that the women with cancer were more likely to have applied talcum powder to their external genitalia area. Women who performed any perineal dusting or used genital deodorant spray respectively had a

statistically significant 60% to 90% higher risk of developing ovarian cancer. Cook, LS, *et al.* Perineal powder exposure and the risk of ovarian cancer. *Am. J Epidemiol.* 1997 Mar 1; 145(5):459-65.

j. In 1997, a case-control study involving over 1,000 women found a statistically significant increased risk of 42% for ovarian cancer for women who applied talc directly or via sanitary napkins to their perineal area. Chang, S, *et al.* Perineal talc exposure and risk of ovarian carcinoma. *Cancer*. 1997 Jun 15; 79(12):2396-401.

k. In 1998, a case-control study found a 149% increased risk of ovarian cancer in women who used talc-based powders on their perineal area. Godard, B., *et al.* Risk factors for familial and sporadic ovarian cancer among French Canadians: a case-control study. *Am J Obstet Gynecol.* 1998 Aug; 179(2):403-10.

l. Dr. Daniel Cramer conducted another case-control study in 1999, observing 563 women newly diagnosed with epithelial ovarian cancer and 523 women in a control. The study found a statistically significant 60% increased risk of ovarian cancer in women that used talc-based body powders on their perineal area and an 80% increase in risk for women with over 10,000 lifetime applications. Cramer, DW, *et al.* Genital talc exposure and risk of ovarian cancer. *Int J Cancer.* 1999 May 5; 81(3):351-56.

m. In 2000, a case-control study including over 2,000 women found a statistically significant 50% increased risk of ovarian cancer from genital talc use in women. Ness, RB, *et al.* Factors related to inflammation of the ovarian epithelium and risk of ovarian cancer. *Epidemiology*. 2000 Mar; 11(2):111-7.

n. In 2004, a case-control study of nearly 1,400 women from 22 counties in Central California found a statistically significant 37% increased risk of epithelial ovarian cancer from women's genital talc use, and a 77% increased risk of serous invasive ovarian cancer from women's genital talc use. Importantly, this study also examined women's use of cornstarch powders as an alternative to talc, and found no increased risk of ovarian cancer in women in the cornstarch group, supporting a safe alternative to talc for genital use. Mills, PK, *et al.* Perineal talc exposure and epithelial ovarian cancer risk in the Central Valley of California. *Int J Cancer.* 2004 Nov 10; 112(3):458-64.

o. In a 2007 study by Buz'Zard, *et al.*, talc was found to increase proliferation, induce neoplastic transformation and increase reactive oxygen species (ROS) generation time-dependently in the ovarian cells. The study concluded that talc may contribute to ovarian carcinogenesis in humans. The data suggested that talc may contribute to ovarian neoplastic transformation and Pycnogenol reduced the talc-induced transformation. *Phytotherapy Research: PTR* 21, no. 6 (June 2007): 579–86.

p. In 2008, a combined study of over 3,000 women from a New England-based case-control study found a 36% statistically significant increased risk for all types of epithelial ovarian cancer from genital talc use and a 60% increased risk of the serous invasive ovarian cancer subtype. The study also found a highly significant dose-response relationship between the cumulative talc exposure and incidence of ovarian cancer (and all serous invasive ovarian cancer), adding further support to the causal relationship. Gates, MA, *et al.* Talc Use, Variants

of the GSTM1, GSTT1, and NAT2 Genes, and Risk of Epithelial Ovarian Cancer. *Cancer Epidemiol Biomarkers Prev.* 2008 Sep; 17(9):2436-44.

q. A 2009 case-control study of over 1,200 women found the risk of ovarian cancer increased significantly with increasing frequency and duration of talc use, with an overall statistically significant 53% increased risk of ovarian cancer from genital talc use. That increased risk rose dramatically, to 108%, in women with the longest duration and most frequent talc use. Wu, AH, *et al.* Markers of inflammation and risk of ovarian cancer in Los Angeles County. *Int. J Cancer.* 2009 Mar 15; 124(6):1409-15.

r. In 2011, another case-control study of over 2,000 women found a 27% increased risk of ovarian cancer from genital talc use. Rosenblatt, KA, *et al.* Genital powder exposure and the risk of epithelial ovarian cancer. *Cancer Causes Control.* 2011 May; 22(5):737-42.

s. 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." Terry, KL, *et al.* Genital powder use and risk of ovarian cancer: a pooled analysis of 8,525 cases and 9,859 controls. *Cancer Prev Res (Phila).* 2013 Aug; 6(8):811.

t. 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 cohohrt). 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. Ness, R. Does talc exposure cause ovarian cancer? Intl. Jnl Gyn Cancer. 25 Suppl 1 (May 2015): 51.

u. Also in 2015, Cramer, *et a*l. performed a retrospective case-control study. 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. Epidemiology (Cambridge, Mass.), December 17, 2015.

v. A 2016 study of African-American women found that body powder was significantly associated 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 women. Schildkraut JM, et al. Association between Body Powder Use and Ovarian Cancer: the African American Cancer Epidemiology Study (AACES). Cancer epidemiology, biomarkers & prevention: a publication of the American

Association for Cancer Research, cosponsored by the American Society of Preventive Oncology. *Cancer Epidemiol Biomarkers Prev; 25(10); 1411–7.* [5]

w. A 2016 study examined 2,041 cases with epithelial ovarian cancer and 2,100 age- and-residence-matched controls. Genital use of talc was associated with a 1.33 OR with a trend for increasing risk by years of talc use. 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. In reporting their findings, the study authors warned women that they should refrain from genital talcum powder use. Cramer DW, et al. The association between talc use and ovarian cancer: a retrospective case-control study in two US states. *Epidemiology*. 2016; 27, 334-46.

x. In 2018, two meta-analyses were published. These meta-analyses, which combined prior epidemiological studies, concluded that the use of talcum products increased the risk of ovarian cancer. *See* Penninkilampi, Ross, and Guy D. Eslick. *"Perineal Talc Use and Ovarian Cancer: A Systematic Review and Meta-Analysis."* Epidemiology (Cambridge, Mass.) 29, no. 1 (January 2018): 41–49; *see also* Berge, Wera, et al. *"Genital Use of Talc and Risk of Ovarian Cancer: A Meta-Analysis."* European Journal of Cancer Prevention, January 2017, 1.

[5] Johnson & Johnson was aware of the high rate of usage among African Americans (52%) and among Hispanics (37.6%). **Exhibit 28** (P-10 (JNJ000021093)). Despite its knowledge of the increased risk of ovarian cancer, Johnson & Johnson targeted these populations in its marketing efforts. *Id.*

y. In 2018, Saed, et al. found that talc effects the redox state in human ovarian cells, a known biological pathway to cause cancer. The scientists concluded that this study demonstrated a cellular biological mechanism of how talc causes ovarian cancer. *See* Fletcher, NM, et al. *"Molecular Basis Supporting the Association of Talcum Powder Use with Increased Risk of Ovarian Cancer."* Reproductive Sciences 1-10 (2019).

z. In 2019, Taher et al. published a systematic review of the evidence linking talcum powder to ovarian cancer. This study concluded that "talc is a possible cause of cancer in humans based on the totality of evidence from multiple observational studies and a plausible biological pathway including chronic inflammation and oxidative stress." Taher et al., *Critical Review of the Association between Perineal Use of Talc Powder and Risk of Ovarian Cancer*, 90 Reproductive Toxicology 88, 99 (2019).

aa. In 2020, O'Brien, et al. published a pooled study in the Journal of American Medical Association (JAMA). The O'Brien investigators pooled data from the three (3) cohort studies: Nurse's Health Study I and II (NHS), Women's Health Initiative (WHI), and the Sisters' Study. This study included 252,745 subjects with a total of 1,884 medically confirmed ovarian cancers. The authors acknowledged the direct physical pathway between exposure of talcum powder to the genital area and the fallopian tubes and ovaries. There was a significantly elevated risk found in women with patent (open) reproductive tracts (RR 1.13; CI 1.01-1.26). In addition, a statistically significant increased risk of 19% was noted in frequent users (at least weekly) (RR 1.19 (1.03-1.37). O'Brien et al.,

Association of Powder Use in the Genital Area with Risk of Ovarian Cancer. 323 JAMA 49 (2020); O'Brien et al., Supplementary Online Content (2020).

bb. In 2022, Woolen, et al. published a meta-analysis of 10 case-controlled studies and a single cohort study which focused on the frequent use of genital use of talcum powder, defined as at least two times per week. The study included 66,876 patients and 6,542 ovarian cancer cases. Frequent talcum powder use was associated with an elevated risk of ovarian cancer of 47% (adjusted pooled summary odds ratio 1.47 (95% CI 1.31, 1.65, P<0.0001). Woolen, SA, et al., *Association Between the Frequent Use of Perineal Talcum Powder Products and Ovarian Cancer: A Systematic Review and Meta-analysis.* 37 J. Gen. Intern. Med. 2526-2532. (2022).

cc. In 2024, O'Brien, et al., published updated data from the Sister Study, a cohort study involving 50,884 women in the US and Puerto Rico who had a sister diagnosed with breast cancer. The publication included data from a fourth follow-up questionnaire. Genital use of talc was positively associated with ovarian cancer. After controlling for recall bias, women who used talc frequently had a statistically significant increased risk of 1.81 (1.29 to 2.53) and women who used genital talc long-term (greater than or equal to 2 decades) the risk was even greater, 2.01 (1.39 to 2.91). Genital use of talcum powder during the 20s resulted in an increased risk of 1.88 (1.37 to 2.57) and for those who used in their 30s, 2.08 (1.50 to 2.89), both after correcting for recall bias.

dd. In addition, over the past four decades, there have been numerous animal and human ovarian cell studies that show talc is harmful and can increase the risk of developing ovarian cancer.

127. Although questions about the PRODUCTS' safety have persisted since the 1970's, the Johnson & Johnson Defendants did not adequately study whether these products, which were advertised for feminine hygiene, could cause ovarian cancer.

128. In fact, upon information and belief, the only study ever supported by Johnson & Johnson was a 1995 study, Gross & Berg, A Meta-Analytical Approach Examining the Potential Relationship Between Talc Exposure and Ovarian Cancer, 5 J. Exposure Analysis Environ. Epi. 181 (1995). In that study, the authors concluded that "…the results of this metanalysis do suggest the possibility of an increased risk of ovarian cancer and perineal talc use. **Further research is warranted by these results."** *Gross & Berg* at 193. Upon information and belief, despite these findings, Johnson & Johnson did no further research.

129. Even though the onus of ensuring the safety of the PRODUCTS rested with the Johnson & Johnson Defendants and the potential risk of cancer was raised in the medical and scientific literature, and the Gross & Berg study said "additional studies are warranted," the Johnson & Johnson Defendants did not commission additional studies to prove safety or study the potential risk of ovarian cancer.

130. In 1995, the same year that the Berg and Gross Study was published, Donald Jones of Old JJCI recommended that "J&J sponsor a new, highly structured epidemiology study focused to examine the possibility that cosmetic talc use can lead to increased risk of ovarian cancer." The proposed study would have cost less than $400,000. *See* **Exhibit 29** (JNJ 000000082).

131. J&J scientists described the proposed Muscat study as one which should "replace all others as the definitive treatise on this issue" *Id.* Inexplicably, Johnson & Johnson never funded this "definitive" study. The committee that considered the proposal included Johnson & Johnson's product liability attorney, John O'Shaughnessy.

132. When asked whether J&J ever gave a reason for not funding his definitive ovarian cancer study, Dr. Muscat stated that he was never given an explanation: "There was obviously a point where we knew it was not going to be funded so…" *See* **Exhibit 30** (Deposition of Joshua Muscat, Sept 25, 2018, at 100).

IV. Johnson & Johnson Had an Independent Duty to Ensure the Safety of All Johnson & Johnson Products

133. Johnson & Johnson, through its Chief Medical Officer, had the independent and ultimate responsibility for the safety of talc and all products developed and sold by all J&J subsidiaries, including all of the Johnson & Johnson Defendants.

134. As described by Ed Kuffner, MD., former Chief Medical Officer of Old JJCI, Old JJCI had a Consumer Medical Safety Committee (CMSC), which was initially responsible for the review of safety of consumer products produced by Old JJCI at that sector level. However, J&J had a separate and distinct J&J Medical Safety Council (JJMSC), which was responsible for all products sold by any J&J Subsidiary. *See* **Exhibit 31** (Testimony of Ed Kuffner, MD, *In re: LTL Management LLC*, Nov. 5, 2021, at 396-398). One of the products within the JJMSC was Johnson's Baby Powder.

135. While the JJMSC was comprised of representatives from different J&J subsidiaries within the Consumer Products, Pharmaceuticals, and Medical Devices divisions, the Committee Chair was a Johnson & Johnson employee, the J&J Chief Medical Officer, who had ultimate responsibility to make decisions regarding safety of any product sold by any subsidiaries.

136. J&J's internal Policies and Procedures described the JJMSC as the highest body of the Johnson & Johnson Enterprise engaged in "setting the standards for medical safety" across the J&J enterprise. According to J&J's Policies and Procedures, the role of the JJMSC was to: (a) "Set [] medical safety standards to protect safety of patients, consumers, and users of products marketed by Johnson & Johnson companies"; and (b) To "provid[e] review and consultation on matters of medical safety at the Enterprise level." *Id.* at 401. The purpose of the JJMSC was to review and, where necessary, correct the safety decisions made by subsidiaries "to make sure that they are in accord with the overall safety standards of" J&J. *Id.* at 404.

137. The decision-making authority of the J&J Chief Medical Officer over any product sold by any subsidiary—including the PRODUCTS—is clear. According to J&J's Policies and Procedures, the J&J Chief Medical Officer makes the final decision on any issue relating to safety and can summarily overrule every member of the JJMSC.

138. In a 2017 video released by Johnson & Johnson, J&J made clear that all issues concerning the safety of all J&J products rest with the J&J Chief Medical Officer. According to J&J Chief Medical Officer Joanne Waldstreicher, M.D., her authority "includes changes to development programs, labeling updates, warnings, and, when necessary, product withdrawals." See https://www.youtube.com/watch?v=yhhaD03Vjeo. Dr. Waldstreicher further explained that "When questions are raised regarding the safety of our products, members of the OCMO team are dedicated to understanding the concerns."

139. According to Mr. Kim, LTL Chief Legal Officer and former J&J Associate General Counsel, the role of J&J as described in the J&J Policies and Procedures has long been the practice at J&J.

V. Asbestos and Other Constituents in Talc

140. The PRODUCTS contain platy talc, fibrous talc (talc fibers or asbestiform talc), asbestos, heavy metals, and fragrance chemicals, and Defendants failed to warn the public, including Plaintiffs, about the fact that the PRODUCTS contained such carcinogenic substances.

141. Beginning in the 1930s, medical and scientific literature emerged indicating talc was commonly, if not invariably, contaminated with substances known or suspected of being carcinogenic, such as asbestos, silica, quartz, nickel and arsenic. Over the next several decades, a growing body of medical and scientific literature demonstrated that direct and secondary exposure to talc, including asbestos-containing talc, was hazardous to exposed persons' health in that it could cause lung disease, cancer and death.

142. The United States Geological Survey on Commercial Talc Production conducted in 1965, as well as those dating back to the 1800s, noted the presence of tremolite, anthophyllite and chrysotile commonly among those minerals found within talc deposits.

143. In 1968, a scientific study of store-bought, commercially available talcum powders conducted by the Occupational Health Program, National Center for Urban Industrial Health, was published and presented by the American Industrial Hygiene Association revealing that, contrary to popular belief, talcum powders were not entirely pure, but rather contained various fibrous minerals, including tremolite, anthophyllite, and chrysotile. This was not unexpected, as the study explains, because these types of fibers are often present in fibrous talc mineral deposits like those mined by Defendants for use in the Products. Available documents indicate that during the same year and in the years following, at least one company began testing store-bought talcum powders for asbestos content. Despite tests showing some commercial talcum powders contained asbestos, there is no evidence that these positive results or the brand names of contaminated products were

communicated to any governmental agency, the media or the public. The study concluded that "[a]ll of the 22 talcum products analyzed have a . . . fiber content . . . averaging 19%. The fibrous material was predominantly talc but probably contained minor amounts of tremolite, anthophyllite, and chrysotile [asbestos-like fibers] as these are often present in fibrous talc mineral deposits . . . Unknown significant amounts of such materials in products that may be used without precautions may create an unsuspected problem." **Exhibit 32**, L. J. Cralley et al., *Fibrous and Mineral Content of Cosmetic Talcum Products*, 29 AM. INDUSTRIAL HYGIENE ASSOC. J. 350-354 (1968).

144. In 1971, the New York City Environmental Protection Administration Air Resources Board conducted a study of two "leading" brands of talcum powder using transmission electron microscopy ("TEM") and X-ray diffraction analysis ("XRD") and found them to contain 5-25% tremolite and anthophyllite asbestos fibers.

145. A 1976 follow-up study concluded that "[t]he presence in these products of asbestiform anthophyllite and tremolite, chrysotile, and quartz indicates the need for a regulatory standard for cosmetic talc . . . We also recommend that evaluation be made to determine the possible health hazards associated with the use of these products." **Exhibit 33** (Arthur Rohl, et al., *Consumer talcums and powders: mineral and chemical characterization*, 2 J TOXICOL ENVIRON HEALTH 255-284 (1976).

146. In 1981, Lockey in *Nonasbestos fibrous materials* (1981), reported that talc frequently exists in complex deposits containing quartz and asbestos, and that talc free from asbestos also contains talc in fibrous form.

147. In Paoletti et al. *Evaluation by Electron Microscopy Techniques of Asbestos Contamination in Industrial, Cosmetic, and Pharmaceutical Talcs* (1983), talc powders from national and international markets were analyzed in order to assess their fiber contents and the

proportion of asbestos in the fibrous material. Analysis of talcum powder samples revealed that the powders contained fiber content up to 30% of total particles. About a half of the talc powders revealed the presence of asbestos.

148. In 1991, Alice Blount tested talcum powder mined from Vermont, including Johnson's Baby Powder, and found that the powder contained asbestos fibers and needles. Blount, A M., Amphibole Content of Cosmetic and Pharmaceutical Talcs, 94 Environmental Health Perspectives 225 (August 1991); *see also* **Exhibit 34**, Deposition of Alice Blount (April 13, 2018) at 30:16-33:8; 47:15-25.

149. On November 14, 2018, Drs. William Longo and Mark Rigler published a report detailing results from tests they performed on samples of the PRODUCTS provided by Johnson & Johnson dating from the 1960s to the early 2000s. Sixty-eight (68%) of the samples tested contained amphibole asbestos. The authors further found that 98% of the samples contained fibrous talc.

150. In 2019, the U.S. Food and Drug Administration (FDA) contracted AMA Analytical Services, Inc. to test samples of talc-containing cosmetics, including Johnson's Baby Powder. AMA identified chrysotile asbestos and talc fibers in a sample of Johnson's Baby Powder. As a result, Johnson & Johnson issued a recall of all bottles (approximately 33,000) from the sampled lot.

VI. Johnson & Johnson Concealed Evidence of Asbestos in the PRODUCTS Despite Knowing the Risks to Consumers

151. Beginning as early as the 1950s, Johnson & Johnson tested its talc for contaminant or co-minerals, including "asbestos" and "tremolite," because the company knew there were deleterious minerals that could be harmful to a person's health and thus should not be found in talc-based cosmetic products.

152. At all times relevant hereto Johnson & Johnson understood the dangers posed by asbestos exposure and that asbestos was a known contaminant of talc used in cosmetic and industrial products.

153. Internally, Johnson and Johnson historically defined "asbestos" as "the fibrous serpentine chrysotile and the fibrous forms of … anthophyllite, … tremolite, and actinolite." **Exhibit 35** (Aug. 16, 2018 Hopkins Dep. 174:24–175:23).

154. In addition to conducting its own internal tests described above, Johnson & Johnson hired testing laboratories, such as the Battelle Memorial Institute, McCrone Associates, the Colorado School of Mines Research Institute, and others to test for asbestos contamination (or co-mineralization) in the source talc ore used to manufacture Johnson's Baby Powder and Johnson & Johnson cosmetic products.[6]

155. All of these testing laboratories found asbestos minerals both in the source talc ore and Johnson & Johnson's cosmetic talc products.[7]

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[6] *See, e.g.,* **Exhibit 36** (4/12/1960 Battelle Memorial Institute report); **Exhibit 37** (10/15/1957 Battelle Memorial Institute report); **Exhibit 38** (5/23/1958 Battelle Memorial Institute report); **Exhibit 39** (7/31/1959 Battelle Memorial Institute report); **Exhibit 40** (8/31/1959 Battelle Memorial Institute report); **Exhibit 41** (9/15/1959 Battelle Memorial Institute report); **Exhibit 42** (12/31/1959 Battelle Memorial Institute report); **Exhibit 43** (1/24/1968 Battelle Memorial Institute report); **Exhibit 44** (5/9/1958 Battelle Memorial Institute report); **Exhibit 45** (3/8/1960 Battelle Memorial Institute report); **Exhibit 46** (6/6/1961 Battelle Memorial Institute memo from W.L. Smith to W.H. Ashton summarizing observations of Smith Gouverneur, NY and Hammondsville, VT ore deposits, beneficiation products); **Exhibit 47** (8/25/1961 Battelle Memorial Institute memo from W.L. Smith to W.H. Ashton evaluating exploration work on Hammondsville talc deposit).

[7] *See, e.g.* **Exhibit 48** (4/14/1971, Colorado School of Mines Institute letter to Johnson & Johnson); **Exhibit 49** (10/27/1972, McCrone report); **Exhibit 50** (2/26/1973, Colorado School of Mines Institute to W. Ashton of Johnson & Johnson re: Mineralogical Exam of Five Talc Samples); **Exhibit 51** (6/6/1973, Johnson & Johnson memorandum); **Exhibit 52** (2/11/1974, McCrone to JJ Rolle); **Exhibit 53** (4/10/1974, McCrone to JJ Russell); **Exhibit 54** (4/24/1974, McCrone report); **Exhibit 55** (4/27/1973, Microscopic Exam of Johnson's Baby Powder); **Exhibit 56** (5/8/1974,

156. Tests performed by Johnson & Johnson and its consultants in the 1960s, 1970s, 1980s, and 1990s demonstrated that there was asbestos in the talc mined from Johnson & Johnson's Vermont mines.[8]

157. Contaminants satisfying Johnson & Johnson's own definition of asbestos have been found in Johnson & Johnson talc, include "chrysotile," "tremolite," "anthophyllite," and/or "actinolite". *See, e.g.*, **Exhibit 79** (12/4/1970 Colorado School of Mines Institute testing results); **Exhibit 80** (6/30/1971 Colorado School of Mines Institute testing results); **Exhibit 81** *(Barden*

McCrone report); **Exhibit 57** (7/8/1974, McCrone to J.J. Rolle); **Exhibit 58** (10/10/1974, McCrone to Windsor Minerals Inc.); **Exhibit 59** (12/9/1974, McCrone to Johnson & Johnson); **Exhibit 60** (7/1/1975, McCrone to Windsor Minerals Inc.); **Exhibit 61** (8/31/1976, Johnson & Johnson Memo Re: Vermont 66 Talc); **Exhibit 62** (9/11/1975, Stewart to V. Zeitz); **Exhibit 63** (11/5/1975, McCrone to Windsor Minerals Inc.); **Exhibit 64** (11/19/1975 McCrone to Windsor Minerals Inc.); **Exhibit 65** (7/5/1976, Colorado School of Mines Research Institute report); **Exhibit 66** (1/25/1977, F. Pooley to J.J. Rolle); **Exhibit 67** (4/1/1977, EMV Report to Johnson & Johnson); **Exhibit 68** (10/5/1978, McCrone to Windsor Minerals Inc.); **Exhibit 69** (2/9/1979, handwritten notes regarding conversation with Harold Cohen); **Exhibit 70** (11/6/1980, McCrone to Windsor Minerals Inc.); **Exhibit 71** (8/22/1985, McCrone to Windsor Minerals Inc.); **Exhibit 72** (4/29/1986, McCrone to Windsor Minerals Inc.); **Exhibit 73** (3/25/1992, Johnson & Johnson Interoffice Memo by Munro); **Exhibit 74** (12/4/1997, Bain Environmental Report); **Exhibit 75** (5/23/2002, Luzenac America Inc. (hereinafter "Luzenac") Technical Report); **Exhibit 76** (2/26/2004, Luzenac Product Certification Report); **Exhibit 77** (2/27/2004 Luzenac - Product Certification); **Exhibit 78** (3/4/2011, Summary of TEM Asbestos Results: Grade 66/96 USP Product Composites).

[8] *See* **Exhibit 84** (11/10/1971, Letter from A.M. Langer to G. Hildick-Smith); **Exhibit 85** (8/24/1972, Memo from W. Nashed to R.A. Fuller); **Exhibit 86** (9/25/1972, Memo from W. Nashed to Fuller, Hildick-Smith, on Shower-to-Shower/Asbestos FDA Meeting 9/21/1972); **Exhibit 87** (6/12/1972, ES Laboratories Talc Analysis (Asbestos); **Exhibit 88** (12/13/1973, Memo from M.J.M. Oerlemans to J.H. Smids, H.L. Farlow, Re: Asbestos in Baby Powder); **Exhibit 89** (9/9/1975, Memo from G. Lee Re: A.M. Langer Analysis of Talcum Powder Products – Edinburgh Meeting); **Exhibit 90** (4/23/1998, Letter from A.M. Blount to R. Hatcher); **Exhibit 91** (Meeting with Dr. Langer on July 9 Concerning Analytical Analysis of Talc); **Exhibit 92** (University of Minnesota Investigation of Possible Asbestos Contaminations in Talc Samples).

Trial Ex. P3695-082-86: Summary chart of testing of Johnson's Baby Powder detecting asbestos and asbestos minerals).

158. The existence of laboratory tests finding asbestos in Johnson & Johnson cosmetic talc products and source talc used in those products was verified by Johnson & Johnson under cross examination in recent litigation. **Exhibit 82** (*Barden v. J&J,* 8/14/19 at 148:17-21.)

159. As detailed in the following paragraphs, Johnson & Johnson executives acknowledged and communicated internally about the results of testing demonstrating the presence of asbestos in Johnson & Johnson's consumer talc products and the source ore used to make these products.

160. In 1972, for example, Johnson & Johnson's Al Goudie confirmed that McCrone found trace tremolite and that these findings are "not new." **Exhibit 83** (handwritten note from W. Nashed to Dr. Goudie).

161. In May 1973, Roger Miller, the President of Johnson & Johnson's mining company, Windsor Minerals, informed Dr. Dewitt Petterson of Johnson & Johnson that "the ore body contains actinolite." **Exhibit 93** (5/1/1973, Memo from R.N. Miller to Dr. Petterson). This talc ore body was actively used to produce Johnson & Johnson's cosmetic talc products.

162. One week later, Johnson & Johnson's William Ashton informed Dr. Petterson that "[t]he first showing of actinolite we know about is October 1972." **Exhibit 94** (5/8/1973, Memo from W. Ashton to D. Petterson).

163. In April 1969, Johnson & Johnson discussed the need to firm up the company's position on tremolite in talc because of potential dangers to human health and safety noted in the medical literature and by environmental health agencies. **Exhibit 95** (4/9/1969 Ashton to Hildick Smith - Alternate Domestic Talc Sources File No. 101).

164. Johnson & Johnson was concerned that the presence of tremolite in its cosmetic talc products, and thus, the resultant inhalation of talc with these needle-like crystalline structures, was related to the rising incidence of pulmonary diseases and cancer and increased the risk that the company would be drawn into litigation relating to these diseases and cancer. **Exhibit 96** (4/15/1969 Thompson to Ashton - Alternate Domestic Talc Sources File No. 101).

165. In July 1971, Johnson & Johnson reported a conversation with Dr. Clark Cooper, a professor at the School of Public Health at the University of California, Berkley, who expressed his concern that there is no place for asbestos in talc and any talc with asbestos should be removed from the market. **Exhibit 97** (7/30/1971 Hildick Smith to R.A. Fuller). According to Dr. Cooper, no level of asbestos in talc is acceptable for cosmetic use. *Id*.

166. Johnson & Johnson was aware of studies demonstrating that both talc and asbestos have been found in the tissue of women who never worked with asbestos or talc. **Exhibit 98** (2/19/2019 Nicholson Dep. 83:6-11).

167. Johnson & Johnson has known for many years that the talc used in Johnson's Baby Powder could be inhaled and reach deep into the lung. **Ex. 20** (11/28/2018 Musco Dep. 91:7-19; *see also id.* at 130:1-21).

168. For decades, Johnson & Johnson has known about the dangers of talc powder inhalation during the normal and expected use of its talc-based cosmetic products, especially to babies. *Id.* at 111:2–112:15; *see also id.* at 116:11–119:18; **Exhibit 99** (5/27/2009 email from Nancy Musco).

VII. Actions by Regulatory Bodies and Health Organizations

169. In the early 1970s, the FDA began an inquiry into whether to regulate and require warnings on consumer talcum powder products. The Johnson & Johnson Defendants and PCPC

conspired and worked in concert to block efforts to label and warn consumers regarding the dangers associated with cosmetic talcum powder products, such as the PRODUCTS.

170. Contemporaneously, evidence began to emerge from testing conducted by various regulatory agencies revealing that asbestos was being found in food, beer and drugs, including intravenously injected medicines. In 1972, and later in 1973, the FDA filed notices of proposed rulemaking requiring talc used in food, food packing and drugs to be asbestos-free. These were some of the same grades of talc used and supplied by Defendants.

171. In 1987, the International Agency for Research on Cancer (IARC), the specialized cancer agency of the World Health Organization, published a paper in which it classified talc containing asbestiform fibers as a "Group 1" human carcinogen, finding sufficient evidence linking talc containing asbestiform fibers to the development of cancer in humans. *See* **Exhibit 100** (JNJ 000018820).

172. Upon information and belief, in or about 1990, the FDA asked manufacturers to voluntarily stop putting talc on surgical gloves because mounting scientific evidence showed that it caused adhesions in surgical patients, an indication of a foreign body reaction. On December 19, 2016, the FDA issued a ban on powdered surgical gloves, stating that "the risk of illness or injury posted by powdered gloves is unreasonable and substantial." *See* **Exhibit 101** (FDA, 21 CFR Parts 878, 880, and 895 [Docket No. FDA–2015–N–5017] RIN 0910–AH02 Banned Devices; Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove).

173. In or about 1993, the United States National Toxicology Program 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. **Exhibit**

102 (P-11 (JNJ000008945)).

174. On or about November 10, 1994, the Cancer Prevention Coalition mailed a letter to then Johnson & Johnson C.E.O., Ralph Larson, informing his company that studies as far back as 1960's ". . . show[ ] conclusively that the frequent use of talcum powder in the genital area pose[ ] a serious health risk of ovarian cancer." The letter cited a study by Dr. Bernard Harlow from Harvard Medical School confirming this fact and quoted a portion of the study where Dr. Harlow and his colleagues discouraged the use of talc in the female genital area. The letter further stated that 14,000 women per year die from ovarian cancer and that this type of cancer is very difficult to detect and has a low survival rate. The letter concluded by requesting that Johnson & Johnson withdraw talc products from the market because of the alternative of cornstarch powders, or at a minimum, place warning information on its talc-based body powders about the ovarian cancer risk they pose. *See* **Exhibit 103** (P-18 (JNJ 000016645)).

175. Upon information and belief, in or about 1996 and at the request of the FDA, the condom industry stopped dusting condoms with talc due to growing health concerns. *See* **Exhibit 104** (P-19 (LUZ011817)).

176. In or about 2006, the Canadian government, under The Hazardous Products Act and associated Controlled Products Regulations, classified talc as a "D2A," "very toxic," "cancer causing" substance under its Workplace Hazardous Materials Information System (WHMIS). Asbestos is also classified as "D2A." *See* **Exhibit 105** (P-215 (IMERYS 255900)).

177. In 2008, the Cancer Prevention Coalition submitted a second "Petition Seeking a Cancer Warning on Cosmetic Talc Products" to the FDA. The first Citizen Petition had been filed on November 17, 1994. The second Petition requested that the FDA immediately require cosmetic 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. *See* **Exhibit 106** (P-47).

178. In February 2010, the International Association for the Research of Cancer (IARC), the specialized cancer agency of the World Health Organization, published a paper whereby it classified perineal use of talc-based body powder as a "Group 2B" human carcinogen. *See* **Exhibit 107** (P-29 (JNJ000381975)). IARC, which is universally accepted as an international authority on determining the carcinogenicity of chemical substances and cancer issues, concluded that studies from around the world consistently found an increased risk of ovarian cancer in women who used talc in the perineal area. IARC found that between 16-52% of women in the world were using talc to dust their perineum and found an increased risk of ovarian cancer in women talc users ranging from 30-60%.

179. In 2012, IARC published monograph in which it concluded that exposure to asbestos and talc containing asbestiform fibers (fibrous talc or talc fiber) can cause ovarian cancer and listed asbestos and talc containing asbestiform fibers as "Group 1" human carcinogens. *See* **Exhibit 108** (P-817 (JNJ 000451296)).

180. Despite the IARC listing talc and its constituents as possible human carcinogens, documents show that industry, spearheaded by PCPC, continued their national, state, and local promotional campaigns touting talc safety and recruiting scientists to publish articles that raised doubt about the link between perineal talc use and ovarian cancer. *See* **Exhibit 109** (P-78 (IMERYS-A_0005090)); **Exhibit 110** (P-92 (IMERYS-A_0001252)); **Exhibit 111** (P-348 (IMERYS 287251)); **Exhibit 112** (P-650 (IMERYS 288001)); and **Exhibit 113** (P-32 (IMERYS-A_0000127)).

181. In 2006, The Gilda Radner Familial Ovarian Cancer Registry, Roswell Park Center

Institute, and the Department of Gynecologic Oncology at University of Vermont published 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." **Exhibit 114** (P-212).

182. In December 2018, Health Canada published a draft screening assessment on the safety of talc. The comprehensive assessment included a Bradford Hill analysis of relevant epidemiological and animal studies. Health Canada concluded that there is a "statistically significant positive association between perineal exposure to talc and ovarian cancer" and "available data are indicative of a causal effect." **Exhibit 115** (JNJTALC001094046).

183. In April 2021, Health Canada confirmed its draft finding and issued its final screening assessment. In its final assessment, Health Canada concluded: "With regards to perineal exposure, analyses of the available human studies in the peer-reviewed literature indicate a consistent and statistically significant positive association between perineal exposure to talc and ovarian cancer. The available data are indicative of a causal effect." **Exhibit 116** (Health Canada, Screening Assessment, at iii (April 2021).

VIII. Defendants' Actions in Response to the Evidence of Cancer Risk

184. Upon information and belief, since these early 1970s studies and the publications related to them, Defendants have been on notice of an association between talc exposure and ovarian cancer. Even before these studies specifically linking talcum powder to ovarian cancer, Defendants were aware of the human health hazards posed by talc as far back as the 1930s.

185. Johnson & Johnson was aware of the Henderson 1971 study and Tenovus data suggesting an association between talc and ovarian cancer. In an internal document, Defendants admit that this knowledge "puts them on notice" of the association. At or around this same time,

Johnson & Johnson sent a donation to the Cardiff Scientific Society to obtain information concerning research being conducted by the Tenovus Institute, further proving they were on notice of the "talc and ovarian cancer problem." **Ex. 17** (P-55 (JNJ 000026241)).

186. For decades, Johnson & Johnson has been repeatedly asked by consumers whether its cosmetic talc product ever contained any amount of asbestos. **Ex. 20** (11/28/2018 Musco Dep. 40:17–41:12).

187. In response to these inquires, Johnson & Johnson has always assured consumers "Asbestos has never been found in Johnson's Baby Powder and it never will." *Id.* at 49:17–50:25, 51:17–52:10. Historically, when pressed, Johnson & Johnson always responded that there "is no evidence that Johnson's Baby Powder contained any amount of asbestos and there never was." *Id.* at 59:1-10.

188. Johnson & Johnson repeatedly told consumers and the public that "Baby Powder does not contain asbestos and never will. We test every single lot to ensure it." **Exhibit 117** (12/19/2018 Johnson & Johnson Ad).

189. Johnson's Baby Powder product label says it was the "Purest Protection" and it was advertised as "the best you can buy" and "the purest." **Exhibit 118** (P3695-265).

190. The intent of these representations to consumers has always been "to reassure them they could feel safe and comfortable using Johnson's Baby Powder because it does not contain asbestos" and to convey that in using Johnson's Baby Powder, there was "zero chance" of exposing their families to asbestos. **Ex. 20** (11/28/2018 Musco Dep. 61:21–62:7); *see also* **Ex. 2** (2/15/2019 Musco Dep. 39:7–42:8).

191. The statements made to consumers by Johnson & Johnson, including that Johnson's Baby Powder does not contain asbestos and that there was "zero chance" consumers were exposing

their families to asbestos, were false when they were made, and Johnson & Johnson knew they were false when they made those statements.

192. As a direct result of Johnson & Johnson's false representations that Johnson's Baby Powder never contained asbestos, millions of people, including babies, were unwittingly and needlessly exposed to asbestos. *See* **Ex. 20** (11/28/2018 Musco Dep. 68:3–69:10).

193. Johnson & Johnson has never communicated to the public or federal government that it knew that its asbestos containing talc-based cosmetic products would be aerosolized and inhaled during normal use. *Id.* at 114:6-25.

194. Johnson & Johnson has never placed warnings on its talc-based powder products about the potential hazards presented by the product being aerosolized in normal application. *Id.* at 188:2-9.

195. Johnson & Johnson never placed warnings on its talc-based powder products about the risk of asbestos exposure. *Id.* at 188:13-17.

196. Johnson & Johnson purposely withheld from their spokespeople, whose job it was to communicate the "no evidence of asbestos" message, any reports indicating there was in fact evidence of asbestos in Johnson's Baby Powder. *Id.* at 59:15–60:5, 61:16-20, 140:3-10, 215:13-18.

197. In 1973, PCPC created a talc subcommittee and the Scientific Advisory Committee to develop a testing methodology for detecting asbestos in talc. Initially, PCPC designated a group of its members to test talc grades used in talcum powder utilizing the methodology proposed by the FDA in its notice of rulemaking. Six samples of talc used in commercially available talcum powders, plus one talc sample purposely spiked with tremolite and chrysotile, were circulated among the members, including representatives of Defendants. Of the eight participating members,

four found asbestos in every sample, three did not find asbestos in any sample (including the spiked sample), and one found asbestos only in the spiked sample. In conclusion, all members agreed that the best and most reliable method of detecting asbestos in talc is not optical microscopy, but rather TEM and electron diffraction. The same members, however, dispensed with this analytical method, claiming TEM and electron diffraction equipment was too expensive, despite Defendants then owning or having unfettered access to same.

198. Going forward, the difference between what Defendants knew diverged from what they were representing to the FDA. Defendants and others in the industry knew that there was no such thing as asbestos-free talc—only talc in which asbestos could not be detected using the adopted and most economical analytical methodology, XRD, which at the time could not accurately identify chrysotile asbestos in talc, nor detect tremolite asbestos contamination levels below 2-5%.

199. Defendants and third parties collectively met with and corresponded with the PCPC and also met with the FDA to individually and collectively advocate for the use of "voluntary" XRD testing of miniscule portions of the tons of talc to be used in consumer products. Defendants' "voluntary" method—that was developed collectively by Defendants and advocated to the FDA in lieu of regulations requiring asbestos labeling or warnings on talcum powder products—was inadequate because levels of asbestos contamination in talc commonly fell below the detection limit of XRD. Defendants knew that the XRD detection limits were inadequate. Defendants also knew that asbestos contamination was not uniformly distributed, such that the miniscule amounts tested would not reveal the true level of contamination in talc products, such as those to which Plaintiffs were exposed.

200. In support of their voluntary XRD methodology, which was finally published in 1977, PCPC produced letters to the FDA written by its members, including Defendants, identifying tests conducted showing talcum powder products did not contain asbestos. PCPC, Defendants and other talc product producers, however, never informed the FDA of the hundreds of positive tests showing talc and talcum powders contained asbestos and other carcinogens. Defendants made and published representations claiming that their testing method was adequate, that they were ensuring that talcum powder products were safe, and that the talc reaching consumers was "safe," despite having substantial knowledge and evidence to the contrary. Defendants intentionally and knowingly did so to avoid FDA regulations that may have required them to place warnings regarding the asbestos content of their products, and thereby inform the public, including Plaintiffs, that talc-containing products contained asbestos.

201. The Defendants have represented to various news media outlets and the public at large that their products are "asbestos-free," when, in fact, their products did test positive for asbestos and those that did not were merely the result of inadequate and imprecise testing methods. "No asbestos detected" means something much different than "no asbestos," but due to Defendants' repeated conflation of the terms, the public has been led to erroneously believe talc products are safe.

202. Between 1970 and the 1990s, tests conducted by and on behalf of Defendants and the talc industry continued to show that talc and talcum powder products contained asbestos as well as other constituents such as fibrous talc, cadmium, cobalt, chromium, copper, iron, manganese, and nickel. None of these positive tests were ever produced or made known to any regulatory agency until late 2019, and only after knowledge of their existence became known in civil litigation.

203. Since at least 1979, Defendants have conducted a campaign to convince the public that their products are regulated by the FDA, that their tests are conducted pursuant to FDA regulations, and that talcum powder products are therefore safe. Nothing could be further from the truth: while defendants' products were on the market, the FDA had never been granted the regulatory authority by Congress to regulate cosmetics, including talcum powders.

204. Defendants, collectively by their agreement and conspiracy, controlled industry standards regarding the testing, manufacture, sale, distribution and use of talcum powder products, and controlled the level of knowledge and information available to the public, including Plaintiffs, regarding the hazards of exposure to carcinogens, including talc, asbestos, and fibrous talc. Defendants knowingly and intentionally released, published and disseminated invalid, inaccurate, outdated and misleading scientific data, literature containing misinformation and false statements regarding the health risks associated with the use of talc and talcum powder products, including those to which Plaintiffs were exposed.

205. Defendants, while cognizant of the aforementioned data, deliberately chose to ignore the health and safety issues raised in the data and embarked upon a plan of deception intended to deprive the public at large, including Plaintiffs, of alarming medical and scientific findings surrounding the safety of asbestos-containing talc and talcum powder products, many of which remained in their exclusive possession and under their exclusive control.

206. Defendants conspired and/or acted in concert with each other and/or with other entities through agreement and consciously parallel behavior: (a) to withhold from users of their products—and from persons who Defendants knew and should have known would be exposed thereto—information regarding the health risks of asbestos, talc, and other carcinogens contained in the PRODUCTS; (b) to eliminate or prevent investigation into the health hazards of exposure

to asbestos, talc and other carcinogens in the PRODUCTS; (c) to ensure that asbestos-containing talc and talcum powder products became widely used in commerce, irrespective of the potential and actual risk of harm to the users and consumers from the asbestos, talc and other carcinogens therein; and (d) to falsely represent that talc and talcum powder products, including those of Defendants, were safe for use by consumers.

207. McCrone Associates, the laboratory selected by several talc producers—including Defendants—to analyze their products, was already using TEM for asbestos analysis. An article by McCrone and Stewart from 1974 describes the advantages of TEM for asbestos analysis and states that TEM "only recently installed in our laboratory will undoubtedly be the ideal instrument for the detection and identification of very fine asbestos fibers."

208. The PCPC "Method J4-1," published on October 7, 1976, states that TEM-SAED "offers greater sensitivity, but is not presented since it is unsuitable for normal quality control applications." The published J4-1 method did not rely on TEM, but on XRD with "the level of detection of amphibole by this method [being] 0.5% and above." PCPC met with and corresponded with Defendants and third parties, to individually and collectively advocate to the FDA for the use of inadequate XRD testing on miniscule portions of the tons of talc obtained from the mining sources to be used in the consumer products, followed by tests by TEM when XRD was positive or suspicious.

209. This voluntary method was developed by PCPC and Defendants and was advocated to the FDA by PCPC and Defendants in lieu of regulations requiring labeling and warnings on talcum powder products, even though PCPC and Defendants knew that the J4-1 method would not reveal the true level of asbestos in the talc that reached consumers. In fact, the first "round robin"

tests, which analyzed a "PCPC Tremolite-Spiked Talc," resulted in 6 of 7 participating laboratories failing to detect the tremolite.

210. In other words, 84% of the industry's laboratories failed to detect asbestos in a sample known to contain tremolite asbestos while using PCPC's own J4-1 method. There is no evidence that the Defendants ever shared this remarkable failure with the FDA or the public.

211. The FDA, and ultimately Plaintiffs, directly and/or indirectly relied upon PCPC's false representations regarding the safety of cosmetic talc. In fact, an FDA letter dated January 11, 1979, states "In cooperation with scientists from industry, our scientists have been making progress in the development of such regulatory methods." The continuing lack of FDA awareness regarding PCPC's and Defendants' misrepresentations and concealment was obvious seven years later. In a response to a July 11, 1986 citizen petition requesting an asbestos warning label on cosmetic talc, the FDA stated that an "analytical methodology was sufficiently developed" to ensure that "such talc [is] free of fibrous amphibole…" PCPC's J4-1 method has continued for the past four decades to be the cosmetic talc industry's method for "ensuring" "asbestos-free" talc.

212. In 1990, Kremer and Millette published a TEM method for analysis of asbestos in talc with a theoretical detection limit of about 0.00005%. Despite such improvements in analytical techniques, the cosmetic talc industry continues, three decades later, to use and promote its antiquated and wholly inadequate J4-1 method.

213. On or about September 17, 1997, Johnson & Johnson's own toxicology consultant, Dr. Alfred Wehner, informed the company about false public statements being made by the Defendants regarding talc safety. **Exhibit 119** (P-20 (JNJ000040596)).

214. In response to safety issues related to talc and talc-based body powders, the Cosmetic Toiletry and Fragrance Association (CTFA), now known as PCPC, formed the Talc

Interested Party Task Force (TIPTF). The TIPTF, which was originally formed in anticipation of litigation related safety issues, periodically convened, including in the 1970s and 1980s, to defend talc in response to safety concerns about talc. The TIPTF once again convened in and around 1992 to combat the United States National Toxicology Program's study. J&J, Old JJCI, and Luzenac – now known as Defendant Imerys Talc – were the primary actors and contributors to the TIPTF. *See* **Exhibit 120** (P-14 (JNJ000011704), **Exhibit 121** (P-83 (LUZ011963)); and **Exhibit 122** (02/18/2016 Mark Pollak Dep. Exhibit No. 2 Spreadsheet: Talc IP – Revenue Received; Date Initiated: 08/17/92).

215. The stated purpose of the TIPTF was to pool financial resources of these companies in an effort to collectively defend the use of talc and, specifically, talc-based body powders at all costs, in anticipation of future litigation, ensure self-regulation, and to prevent local, state, or federal regulation of any type over this industry. Imerys and the Johnson & Johnson Defendants wielded considerable influence on TIPTF. TIPTF hired scientists to perform biased research regarding the safety of talc. Members of TIPTF, including Johnson & Johnson and Luzenac, 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 TIPTF knowingly released false information about the safety of talc to the consuming public, and used political and economic influence on local, state and federal regulatory bodies regarding talc. These activities were conducted by these companies and organizations, including the Johnson & Johnson Defendants, PCPC, and Luzenac, 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. *See* **Ex. 120** (P-14 (JNJ000011704); **Exhibit 123** (P-13 (JNJTALC000249618)); **Exhibit 124** (P-122 (JNJ000021035)); **Exhibit 125** (P-66 (IMERYS-A_0006056)); **Exhibit 126** (P-90 (IMERYS

179104)); **Ex. 113** (P-32 (IMERYS-A_0000127); **Ex. 119** (P-20 (JNJ000040596)); **Exhibit 127** (P-12 (IMERYS-A_0021921); **Exhibit 128** (P-27 (JNJ000000636)); **Exhibit 129** (P-24 (JNJTALC000716846)); **Exhibit 130** (JNJTALC000224218).

216. At all times relevant, in anticipation of litigation and regulatory action, PCPC coordinated the defense of talc and talc-based body powder and acted as a mouthpiece for the members of the TIPTF, including the Johnson & Johnson Defendants and Imerys. PCPC, completely reliant on funding from cosmetic-industry companies, was motivated to defend talc and talc-based body powders to retain its members involved with these products and retain their revenues. Upon information and belief, and at all times relevant, PCPC's revenue has been predominantly generated through a dues system based in part on its members' annual sales. In addition, PCPC's salaries are nearly equivalent to the membership dues received, creating a direct pecuniary interest in defending the safety of talc, talc-based body powders and the PRODUCTS. *See* **Exhibit 131** (08/29/2018 Mark Pollak Dep. 104:11 – 105:18).

217. In and around the mid-1970s, the Cosmetic Ingredient Review ("CIR") was formed to give PCPC and the cosmetic industry more credibility for self-regulation. Since that time, 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. *See* **Exhibit 132** (10/02/2018 Linda Loretz Dep. 828:23 – 829:7; 831:10 - 833:18; 834:20 - 835:2).

218. Over the years, CIR has reviewed thousands of ingredients used in the cosmetics industry but has only found 13 ingredients to be "unsafe for use in cosmetics." In contrast, CIR has deemed more than 1,800 ingredients to be "safe as used." The CIR Expert Panel holds two-

day quarterly meetings to review substances. On average, the panel reviews 500 ingredients per year. This allows for an average of 20 minutes to be spent discussing the safety of each ingredient. *See* **Exhibit 133** (08/10/2017 Alan Andersen trial testimony, *Echeverria v. JNJ*, 3126:25 – 27), and **Exhibit 134** (08/11/2017 Alan Andersen trial testimony, *Echeverria v. JNJ*, 3291:10 – 3292:1).

219. Even though PCPC knew of the safety concerns surrounding talc and talc-based body powders for almost three decades, 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 and PCPC, influenced the CIR scientists writing and performing 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.

220. In or about 2006, Imerys Talc began placing a warning on the Material Safety Data Sheet (MSDS) it provided to the Johnson & Johnson Defendants regarding the talc it sold to them to be used in the PRODUCTS. These MSDSs provided warning information that IARC designated that the perineal use of talc-based body powder is possibly carcinogenic to humans or a Group B carcinogen. *See* **Ex. 10** (IMERYS 081218 (2006) (referencing IARC's review of "talc not containing asbestiform fibers")).

221. Defendants knew of the adverse risks of using talc and talc-based body powders in the perineal area and ovarian cancer and had a duty to warn about the potential hazards associated with the use of the PRODUCTS. *See* **Exhibit 137** (P-341 (IMERYS 284935)).

222. Defendants, though having knowledge of the increased risk of ovarian cancer associated with genital use of talc-based body powder, nevertheless actively marketed the safety of the product to users and failed to inform customers and end users of the PRODUCTS of a known

catastrophic health hazard associated with the use of the PRODUCTS, particularly when used by women in the perineal area. *See* **Ex. 18** (P-115 (JNJ000024495)); **Exhibit 135** (P-374 (JNJ000093556)); **Exhibit 136** (P-81 (IMERYS-A_0001298)); and **Ex. 28** (P-10 (JNJ000021093)).

223. In addition, Defendants procured and disseminated false, misleading, and biased information regarding the safety of talc, talc-based body powders and the PRODUCTS to the public, and used influence over federal, state, and local governmental and regulatory bodies regarding talc and talc-based body powder. *See* **Ex. 119** (P-20 (JNJ000040596)); **Ex. 28** (P-10 (JNJ000021093)); and **Exhibit 138** (P-26 (IMERYS-A_0013094)).

224. In 2012, Johnson & Johnson sold Shower to Shower to Valeant Pharmaceuticals n/k/a Bausch Health Co. Inc. In 2019, Bausch Health announced that it had reformulated Shower to Shower to replace the talc in the product with cornstarch.

225. In 2016, Johnson & Johnson registered Baby Powder under the California Safe Cosmetics Act. This law was established to compel cosmetic manufacturers to register ingredients that are "known" or "suspected" carcinogens. Nevertheless, Johnson & Johnson continued to tout its Baby Powder as safe and containing no asbestos.

226. Defendants engaged in wrongful conduct and were negligent and created a dangerous and unreasonable risk of harm to others, including Plaintiffs, by mining, milling, processing, supplying, distributing, designing, manufacturing, and selling talcum powder products which contained asbestos and fibrous talc, which Defendants knew or should have known were dangerous and posed substantial risks of harm to others, including Plaintiffs.

227. Defendants have long employed and/or consulted with doctors, scientists, geologists, mineralogists, and toxicologists, and they have maintained extensive medical and

scientific libraries and archives containing materials relating to the health hazards of talc and the presence of asbestos and asbestiform talc fibers in talc and talc deposits. Despite the wealth of knowledge, Defendants continued to mine, mill, process, supply, distribute, design, manufacture, and sell talcum powder products which Defendants knew or should have known were dangerous and posed substantial risks of harm to others, including Plaintiffs.

IX. Defendants Misrepresented or Concealed Information about Asbestos in the PRODUCTS from the Government and the Public

228. Since the early 1970's the FDA has repeatedly asked Johnson & Johnson whether it's talc-based products contained asbestos (**Ex. 98** (2/19/2019 Nicholson Dep. at 87:10-23) including, whether there was any evidence of any amount of asbestos in any Johnson & Johnson cosmetic talc product. *Id.* at 88:20-24.

229. Johnson & Johnson's answer to the FDA's inquiries was always the same: there is no evidence of any amount of asbestos in any Johnson & Johnson cosmetic talc product. *Id.* at 89:3-8.

230. While Johnson & Johnson's CEO proclaimed that "we have always cooperated fully and openly with the FDA and other regulators and have given them full access to our talc testing results" the record is to the contrary. *See* **Ex. 117** (12/19/2018 Johnson & Johnson Ad); *see also* **Exhibit 139** (Alex Gorsky Video)11 (Johnson & Johnson claims that it "has cooperated fully with the U.S. FDA and other global regulators providing them with all the information they requested over decades.").

231. In the early 1970s, independent scientists publicly reported finding asbestos in Johnson & Johnson talc products. *See* **Ex. 84** (11/10/1971, Letter from A.M. Langer to G. Hildick-Smith), **Ex. 89** (9/9/1975, Memo from G. Lee Re: A.M. Langer Analysis of Talcum Powder

Products – Edinburgh Meeting), and **Ex. 91** (Meeting with Dr. Langer on July 9 Concerning Analytical Analysis of Talc).

232. In response, Johnson & Johnson sought to discredit the independent scientists' results and hired consultants to refute the asbestos in talc findings. Some of Johnson & Johnson's experts found asbestos when evaluating consumer talc products. These results were reported to Johnson & Johnson though the company never provided those results to the FDA. Johnson & Johnson's claim that it provided the FDA with its "entire background file on asbestos talc testing" related to the company's cosmetic talc products was untrue because it never provided the FDA with the test results it received that identified asbestos in its talc and cosmetic talc products. *See* **Ex. 98** at 184:20–185:9 (2/19/19 Nicholson Deposition).

233. Johnson & Johnson did not tell the FDA that it possessed test results finding asbestos in the mine ore and the finished talc product, nor did it give those results to the FDA. *Id*. at 105:2-5.

234. Under cross-examination, Johnson & Johnson's representative was forced to admit that despite claiming it provided all testing to the FDA, Johnson & Johnson never provided any results of asbestos testing of its talc products or ore to the FDA for the Vermont mine after 1973. **Exhibit 140** (3/6/2019 Nicholson Dep. 293:12–294:19). These include tests in which fibers matching the Johnson & Johnson definition of asbestos were found. *Id.* at 349:6–353:23.

235. Since the early 1970s, Johnson & Johnson represented to the FDA that there was no tremolite or fibrous talc in its talc-based cosmetic products. **Ex. 98** (2/19/2019 Nicholson Dep. 89:17–90:8); *see also* **Exhibit 141** (7/21/1971 J&J Memo to File: Special Talc Project No. 503 FDA Meeting).

236. Over the course of more than 4 decades, Johnson & Johnson represented to the FDA "over and over again" that there is not a single instance or report of asbestos – including chrysotile asbestos – in its products. **Ex. 98** (2/19/2019 Nicholson Dep. 98:10-19).

237. Beginning in early 1970s, Johnson & Johnson represented to the FDA that its data "conclusively proves that Johnson's Baby Powder is free of asbestos." *Id.* (2/19/19 Nicholson Dep. 90:9-23); *see also* **Exhibit 142** (9/21/1971 Letter from W. Nashed to FDA Director R. Schaffner) ("It is seen that the data conclusively proves that Johnson's Baby Powder is free of asbestos.").

238. Johnson & Johnson has represented to the FDA that "no amphibole materials have been detected" in the company's talc-based products. **Ex. 98** (2/19/2019 Nicholson Dep. 99:2-21); *see also* **Exhibit 143** (3/15/1976 Letter from G. Lee re: Examination of Asbestos in Talc at 6).

239. When pressed, Johnson & Johnson went so far as to represent to the FDA that "there wasn't a shred of evidence to support the idea that either our Johnson's Baby Powder or Shower to Shower contained any chrysotile asbestos." **Exhibit 144** (12/13/1972 J&J Memo re: Meeting Nov. 1, 1972 with Dr. Schaffner – FDA); *see also* **Ex. 98** (2/19/2019 Nicholson Dep. 90:24–91:18).

240. Johnson & Johnson knew that its consultant, McCrone, purposely omitted findings of asbestos in its talc-based products because it "would only tend to confuse the issue perhaps with the FDA" and offered that if Johnson & Johnson "decide[d] to use these reports with the FDA" to "please call us." **Exhibit 145** (10/12/1971 Letter from G. Grieger to A. Goudie); *see also* **Ex. 140** (3/6/2019 Nicholson Dep. 327:14–328:21).

241. As a part of its testing and reporting protocol for Johnson & Johnson's talc-based products, McCrone would segregate any test results that were positive for the presence of asbestos in talc ore or cosmetic talc products from those that allegedly found "no quantifiable" asbestos.

For instance, on April 29, 1986, under McCrone Project No. ME-2275 and Purchase Order WS-0503, McCrone authored two separate reports of test results for Windsor Minerals. The first was for 11 talc samples in which "no quantifiable" amounts of asbestiform were found. The second was for the three talc samples (noticeably extracted from the numbering sequence) in which traces of chrysotile were found. *Compare* **Exhibit 146** (Musco Dep. Ex. 8B, Tab 73) with **Ex. 72** (4/29/1986 Edley Samples).

242. As further explained in the paragraphs below, McCrone and Johnson & Johnson worked together to manipulate the asbestos testing results of Johnson & Johnson products done by outside laboratories and reported those manipulated findings to the FDA as negative results.

243. Although aware of McCrone reports to the contrary, Johnson & Johnson represented to the FDA that its consultant McCrone Associates never found asbestos in the talc ore that was used to make the PRODUCTS. **Ex. 140** (3/6/2019 Nicholson Dep. 316:8-23; 326:20–327:2 (Johnson & Johnson cites McCrone tests to the FDA to support its position that there was "no evidence" of asbestos in the Shower to Shower product)). This statement to the FDA was false.

244. In 1972, after Johnson & Johnson was notified that an FDA consultant found asbestos in the Johnson & Johnson talc products, Johnson & Johnson hired Professor Hutchinson from the Minnesota Space Center to privately test the products with the intention of refuting the FDA consultant's findings.

245. On September 20, 1972, in anticipation of a meeting with the FDA to discuss the asbestos test results, Johnson & Johnson executives arranged for its consultant, Ian Stewart of McCrone, to meet with Professor Hutchinson in the Chicago O'Hare airport. At that meeting, Professor Hutchinson informed Ian Stewart that he found "incontrovertible asbestos" in Johnson & Johnson's talc-based products **Exhibit 147** (handwritten notes by Professor Hutchinson). From

there Mr. Stewart, on behalf of Johnson & Johnson, flew directly to Washington DC to meet with the FDA to discuss test results. Mr. Stewart never disclosed Dr. Hutchinson's findings of asbestos to the FDA. **Exhibit 148** (Ian Stewart Traveling Expense report).

246. Thereafter, Professor Hutchinson provided Johnson & Johnson with a formal report documenting his asbestos findings with photographs of the asbestos he found in the Johnson & Johnson products. Johnson & Johnson produced excerpts of the report to the FDA, removing all references to Professor Hutchinson's "incontrovertible" findings of chrysotile asbestos. **Ex. 140** (3/6/2019 Nicholson Dep. 339:20–341:9, 345:11-21).

247. Johnson & Johnson similarly never informed the FDA that it was aware of additional evidence demonstrating the presence of actinolite in Johnson's Baby Powder. *Id.* at 325:4-15. For example, Johnson & Johnson did not submit a March 1974 test result from Professor Reynolds at Dartmouth College that "Actinolite is the dominant fiberform amphibole in the ore and talc product provided by Windsor Minerals." *Id.* at 346:24–347:2; *see also* **Exhibit 149** (JNJ 000266903, Mar. 1974 Memo re: Analysis of Talc Products and Ores for Asbestiform Amphiboles).

248. Instead, Johnson & Johnson submitted test results to the FDA from Dartmouth claiming that no amphiboles were found in the company's talc products. **Ex. 98** (2/19/2019 Nicholson Dep. 158:10–159:1).

249. As part of its plan to mislead the FDA and falsely claim its talc ore and cosmetic talc products were free of any asbestos, Johnson & Johnson hired outside consultants to conduct tests of Johnson & Johnson talc products using test methods Johnson & Johnson knew would not detect asbestos at low levels. *Id.* at 196:19-24, 197:24–198:8.

250. Thereafter, Johnson & Johnson submitted test reports to the FDA as proof that its talc was asbestos free knowing that the methods used would not detect asbestos at low levels and, thus, were not reliable to rule out the presence of asbestos. **Ex. 140** (3/6/19 Nicholson Dep. 255:23-256:4).

251. Instead of utilizing a method it knew was sensitive enough to find asbestos at low levels, Johnson & Johnson routinely used a testing method that was not sufficient to detect asbestos at those level and continued to submit the same false negative testing results to the FDA. This method was known as J4-1.

252. The J4-1 testing method utilized "XRD" as the initial screen to determine if any further testing was necessary (with a level of detection of about 1%). **Exhibit 150** (CTFA Method J4-1 Part I & Part II). If the XRD test result was negative, no more testing would occur, and the sample would be reported as "none detected." This process virtually guaranteed that low levels of asbestos would never be found.

253. Johnson & Johnson similarly knew that XRD could not detect chrysotile at levels below two or three percent of the talc product and was also incapable of detecting low levels of tremolite. **Ex. 98** (2/19/2019 Nicholson Dep. 196:19-198:8).

254. In the unlikely event an XRD test result was positive, Johnson & Johnson implemented a second step, polarized light microscopy ("PLM"), but instructed the PLM analyst not to count all of the fibers he or she would actually see under the microscope. **Ex. 150** (CTFA Method J4-1 Part I & Part II). Short fibers, below a defined size, recognized as carcinogenic, were excluded from any reporting. According to the J4-1 method, a fiber must have an aspect ratio (length to width) of 5:1 or greater, and both dispersion testing and fibrous morphology criteria must be satisfied before a particle can be identified as asbestiform. *Id.* and **Exhibit 151**

(JNJNL61_000005032 (8/21/1995, Johnson & Johnson TM7024 TEM Analysis of Talc for Asbestiform Minerals)).

255. Johnson & Johnson knew and was advised of other methods of testing talc that were sensitive enough to detect the presence of small fibers of asbestos in its talc ore and/or cosmetic talc products and, thus, provide more accurate results than the testing it purposely utilized to increase the likelihood of negative results. One of those methods was the "pre-concentration" method. **Exhibit 152** (JNJ 000268037, 12/27/1973 Colorado School of Mines Research Institute report); **Ex. 51** (6/6/1973, Memo JNJAZ55_000005081 to Pooley from Rolle); **Ex. 149** (JNJ000266903, 3/1974 Memo from R.C. Reynolds, Jr. to Windsor Minerals, Inc.)("a concentration technique is mandatory because it brings the amphiboles into a reasonable concentration range for optical or other methods of analysis.")); **Exhibit 153** (JNJNL61_000007330, Special Talc Studies Monthly Report, March, 1974 – Assay Methods for Asbestos Minerals in Talc); **Exhibit 154** (JNJ 000250919, 3/11/1974, Memo from J.P. Schelz to F.R. Rolle); **Exhibit 155** (JNJNL61_000062964, 11/26/1974, Memo from J.P. Schelz to F.R. Rolle)) (collectively referred to as "concentration method").

256. Internal Johnson & Johnson memoranda prove the company considered "the limitation" of the concentration method "is that it may be too sensitive" and when used found traces of tremolite which the J&J testing methods would fail to expose. **Exhibit 156** (JNJAZ55_00001892, 5/16/1973 Memo from F.R. Rolle to T.H. Shelley).

257. When Dr. Fred Pooley, a Johnson & Johnson consultant, told Johnson & Johnson that the concentration method was being used in Great Britain, Johnson & Johnson rejected the method as not "in the worldwide company interest." **Exhibit 157** (JNJNL61_000062953, 2/18/1975 Johnson & Johnson Limited letter to Johnson & Johnson).

258. Although many of Johnson & Johnson's consultants — including the Colorado Research School of Mines, Professor Pooley of Cardiff University, Professor Reynolds of Dartmouth College, and Professor Alice Blount of Rutgers University — found asbestos in Johnson & Johnson's talc-based cosmetic products using the pre-concentration method, the company did not provide any of those test results to the FDA. **Ex. 98** (2/19/19 Nicholson Dep. 172:8-15).

259. Johnson & Johnson was also urged by its consultants to use TEM to test for asbestos as it was far more sensitive than the J4-1 method used by Johnson & Johnson. *See, e.g.*, **Exhibit 158** (JNJNL61_000006726, 5/18/1973 Message on from G.E. Heinze to W. Ashton et al. – Talc Symposium); **Exhibit 159** (JNJ 000035507, 9/30/1992 Notes on Meeting with Professor F. Pooley, Cardiff) ("TEM is the only suitable method for looking for fibers of biologically relevant dimensions in lungs, therefore it is logical to use the same technique for examining mineral products for biologically relevant fibers.")); **Exhibit 160** (Johnson & Johnson correspondence at FDA_FOIA_013573) ("I think we all recognize XRD, PCM, and PLM are simply not sensitive enough to provide complete assurance that the talc is free of detectable asbestos.").

260. Eventually, Johnson & Johnson began to use TEM as a testing method on a limited basis but implemented a TEM reporting methodology designed to yield negative, rather than accurate results. In this regard, Johnson & Johnson intentionally limited the amount of each sample that was analyzed and required a high fiber count of the same mineral type before a positive result could be reported. Johnson & Johnson called its method TM7024.

261. According to Johnson & Johnson's TM7024 method, Johnson & Johnson would report the test results as negative and "not quantifiable" unless the scientist, who was directed to look only at approximately 10 percent of the material available to examine under the microscope,

counted 5 or more asbestos fibers of the same variety. **Ex. 151** (JNJNL_000005032 (8/21/1995, Johnson & Johnson TM7024 TEM Analysis of Talc for Asbestiform Minerals)). Thus, even if the examiner counted as many as 16 asbestos fibers (i.e., four fibers each of tremolite, actinolite, anthophyllite, and chrysotile) looking only at 10% of the sample seen under the microscope, it would be reported as not finding asbestos or "not quantifiable."

262. Johnson & Johnson's position about the scientific propriety of its TM7024 testing protocol was and remains inconsistent with that of environmental and health agencies. The United States Environmental Protection Agency ("EPA") has refused to limit its concern to only the type of identifiable asbestos fibers Johnson & Johnson instructs its microscopists to count. **Exhibit 161** (4/20/2006 US EPA Region IX Response to the November 2005 R.J. Lee Group, Inc.).

263. To further reduce the likelihood of detecting asbestos in its cosmetic talc ore, Johnson & Johnson required J4-1 method testing on only a composite sample from every two silos of talc (each silo containing hundreds of tons of talc), TM7024 testing only quarterly from a composite of all siloed talc, and a monthly composite of float feed. **Exhibit 162** (JNJMX68_000002913 (10/4/1984, Memo from J.A. Molnar to B. Semple, on Evaluation Program for Talc)). As a result, the total amount of talcum powder Johnson & Johnson ever put under a microscope to test for asbestos was approximately 1/100 of a breath mint by weight. **Exhibit 163** (Testimony of Matthew Sanchez 1/29/20 134:19-135:20).

264. Even though Johnson & Johnson tested miniscule amounts of product, and utilized methods specifically designed to yield negative results, asbestos was still found in Johnson & Johnson's cosmetic talc. **Exhibit 164** (chart of various testing results). Johnson & Johnson did not produce these asbestos-positive test results until 2017, when documents were produced in this litigation.

265. In 1976, Johnson & Johnson rejected the FDA's request to provide the results of its respective periodic monitoring for asbestos. *See* **Ex. 140** (3/6/19 Nicholson Dep. at 255:17-256:6.)

266. Johnson & Johnson also submitted false and misleading statements through its trade association (CTFA).

267. In March of 1976, the CTFA told the FDA that all industry testing had shown all talcum powder products to be completely free of asbestos. **Exhibit 165** (JNJ000330157).

268. On March 15, 1976, George Lee, Director of Applied Research for Johnson & Johnson, wrote to the CTFA, with the "understanding that you would wish to submit this information to the FDA," that it was "erroneously reported in 1971 that our powder contained asbestos," that the Vermont talc is "highly purified," and that Johnson & Johnson confirms the "absence of asbestos materials in this talc." **Exhibit 166** (WCD000009). This false information was then transmitted by the CTFA to the FDA to "give assurance as to the freedom from contamination by asbestos form materials of cosmetic talc products." *See* **Ex. 165** (JNJ000330157).

269. Two weeks later, on March 31, 1976, Johnson & Johnson met privately in Hillside, New Jersey. During this meeting, Defendants congratulated themselves on the "success" of the "presentations" to the FDA and agreed that they should not bind themselves to having to further update the FDA. *See* **Exhibit 167** (JNJ000299024).

270. On March 1, 1978, John Schelz, the Chairman of the CTFA Task Force On Round Robin Testing and then current employee of Johnson & Johnson, instructed the CTFA to "destroy your copy of the table" containing the results of the CTFA Task Force on Round Robin Testing of Consumer Talcum Products for Asbestiform Amphibole Minerals. **Exhibit 168** (JNJNL_000062534 (3/1/1978 correspondence from Johnson & Johnson to the CTFA)).

271. Although possessing test results indicating that the talc used in its talc-based products contained tremolite and chrysotile asbestos — reportable as asbestos under federal regulations — Johnson & Johnson represented to the National Toxicology Project (NTP) that there was never any evidence of asbestos in the talc used in Johnson's Baby Powder. **Ex. 20** (11/28/18 Musco Dep. 200:12-25.)

272. Decades after asbestos was first reported, Johnson & Johnson continued to represent to the FDA that it had confirmed "the absence of asbestiform minerals" in its finished talc-based products. **Exhibit 169** (JNJ 000021285 (6/27/1995 Comments of CTFA in Response to a Citizens Petition at 7-8)).

273. As recent as 2016, Johnson & Johnson represented to the FDA that no asbestos structures have ever been found in its talc-based products in any testing anywhere in the world. **Ex. 98** (2/19/2019 Nicholson Dep. 99:18–100:9); *see also* **Exhibit 170** (JNJ 000489313 (3/17/2016 J&J Response to FDA Request for Information on Talc at 12)). This statement made to the FDA was false.

274. In about 2013, while editing information for its website, Johnson & Johnson even acknowledged internally that it "cannot say our talc-based consumer products have always been asbestos free".[9] but made the representations anyway. **Exhibit 171** (Draft 1 – Copy for SafetyandCareCommitment Website).

X. Johnson & Johnson Destroyed or Secreted Away Relevant Evidence

275. Johnson & Johnson has had the duty to preserve evidence and documents relevant to foreseeable litigation, including the responsibility to suspend any document destruction policies on or about 1971.

[9] See n. 2, supra.

276. Since at least 1969, Johnson & Johnson was aware that it was foreseeable and likely that it would be sued in personal injury litigation alleging pulmonary injuries – including asbestos-related disease – attributable to Johnson & Johnson's talc-based products.

277. On April 15, 1969, Dr. T.M. Thompson, Medical Director for Johnson & Johnson, wrote to Mr. William H. Ashton, a Johnson & Johnson executive supervising the company's talc-based products, to advise him of danger relative to "inhalation" of the "spicule" or "needle-like" crystals of tremolite in Johnson & Johnson's talc. *See* **Ex. 96** (JNJ000087991 (4/15/1969 Letter from T. Thompson to W. Ashton Re: Alternate Domestic Talc Sources) ("[S]ince pulmonary diseases, including inflammatory, fibroplastic and neoplastic types, appear to be on the increase, it would seem prudent to limit any possible content of tremolite in our powder formulations to an absolute minimum.")).

278. Although Dr. Thompson states that he was not aware of "any litigation involving either skin or lung penetration by our talc formulations," he cautioned Mr. Ashton that "since the usage of these products is so widespread, and the existence of pulmonary disease is increasing, it is not inconceivable that [Johnson & Johnson] could become involved in litigation in which pulmonary fibrosis or other changes might be rightfully or wrongfully attributed to inhalation of our powder formulations." Id. To that end, Dr. Thompson recommended that "someone in the Law Department should be consulted with regard to the defensibility of our position in the event that such a situation could ever arise." *Id.; see also* **Ex. 2** (2/15/2019 Musco Dep. 64:18–68:1).

279. Dr. Thompson further forewarned Mr. Ashton that the company could confront a situation where the company would be more or less compelled to remove its talc products from the market "if it became known that our talc formulations contained any significant amount of

Tremolite." *See* **Ex. 96** (JNJ000087991 (4/15/1969 Letter from T. Thompson to W. Ashton Re: Alternate Domestic Talc Sources)).

280. Dr. Thompson's prediction of litigation came to fruition shortly thereafter. By the early 1970's, Johnson and Johnson was involved in litigating and planning its defense to personal injury cases related to its talc products.

281. Through the litigation process, Johnson & Johnson has been forced to identify documents from as early as 1971 (and from every year thereafter) relating to "ongoing," "pending," and "anticipated" litigation regarding Johnson's Baby Powder. **Ex. 2** (2/15/2019 Musco Dep. 74:23–76:7, 93:3-16.).

282. Since at least 1971, Johnson & Johnson has known and recognized that information and documentation in the company's possession relevant to or produced in any particular talc-based lawsuit would be relevant to discovery in future talc-based cases. *Id*. (2/15/19 Musco Dep. 25:13-20).

283. Johnson & Johnson has reported that during the 1970s alone, the company was sued in talc-based cases in nearly each year of the decade. *Id.* (2/15/2019 Musco Dep. 81:25–82:18). Although Johnson & Johnson was legally obligated to retain the evidence, it does not know where the documents and evidence related to these cases are located or whether they even exist. *Id.* at 78:25-79:23; 80:6-81:24.

284. While the evidence from the cases is missing, documents listed on Johnson & Johnson's privilege log related to these cases date back to 1971. *Id.* at 93:3-16. The entries on the privilege log indicate that samples of talcum powder used in litigation existed at the time the litigation in the 1970s was pending, but those samples have not been produced. *Id.* at 93:17-94:16.

285. Although Johnson & Johnson, by its own admission, had an obligation to preserve evidence once litigation concerning the health effects of its talc products was foreseeable, it failed to do so. *Id.* (2/15/19 Musco) 278:24-280:23.

286. Johnson & Johnson knew and understood that evidence produced in litigation concerning the health effects of its talc products would be material and relevant to other anticipated cases. *Id.* Yet Johnson & Johnson failed to preserve records from any of the lawsuits that alleged injuries as a result of Johnson's Baby Powder, talc, or asbestos, even though Johnson & Johnson knew that relevant and material documents existed and were in its possession.

287. While Johnson and Johnson internally recognized there could be dire consequences for failing to preserve evidence, there is no record of a litigation hold ever being imposed prior to 1997. Even then, Johnson & Johnson's General Counsel, John O'Shaughnessy, only preserved evidence when there was a case actually pending and not when anticipated. *See* **Exhibit 172** (June 29, 2021 Deposition of John O'Shaughnessy at 310:20-311:5).

288. Johnson & Johnson did not retain any samples of its talc ore or milled talc used in its talc-based cosmetic products, which it tested regularly, albeit insufficiently, for the presence of asbestos and asbestiform minerals at any time until 2017. *See* **Exhibit 173** (10/18/2018 Mittenthal Dep. 405:22-407:9; 424:2-425:7).

289. Although litigation was pending and anticipated, the samples chosen by Johnson & Johnson specifically to create test results were not retained under the company's evidence retention schedules and were not subject to any litigation hold. *Id.* at 371:14-374:9; 384:8:387:4; 405:22-407:9.

290. Johnson & Johnson's failure to institute a litigation hold also made certain that the testing results were destroyed in accordance with its document retention policy. *Id.* at 405:22-407:1.

291. At all times relevant to this current lawsuit, Johnson & Johnson has been in complete control of all aspects of the domestic and foreign subsidiaries implicated in its talc, including, but not limited to, the testing of talc source ore mines and testing of finished Johnson's Baby Powder and Shower to Shower products. Johnson & Johnson knew, or should have known, that this material would be material in pending and anticipated cases alleging injury resulting from exposure to its talc products and, therefore, had a duty to preserve that testing evidence. Johnson & Johnson destroyed those testing results and discarded its samples of talc.

292. Johnson & Johnson failed to preserve talc samples maintained in its museum after 1982 when the museum was suspended, even though litigation was pending and anticipated at that time. **Exhibit 174** (7/12/2018 Gurowitz Dep. 157:3–160:17).

293. Johnson & Johnson did not instruct its consultants that repeatedly tested its talc ore and products to retain the samples tested, even though litigation was pending and anticipated. *See, e.g., id.* (7/12/2018 Gurowitz Dep. 158:12–159:16). Although Johnson & Johnson was acutely aware that it was McCrone's policy to dispose of samples 30 days after testing results were generated, it never instructed McCrone to retain any samples. *See, e.g.*, **Exhibit 175** (1/28/87 McCrone Letter at JNJTALC000387715).

294. Johnson & Johnson failed to retain all test results for the presence of asbestos and asbestiform minerals of the talc ore and milled talc used in its talc-based cosmetic products. **Ex. 173** (10/18/18 Mittenthal Dep. 405:22-406:24).

295. Even after a litigation hold was finally issued in 2000, Johnson & Johnson failed to retain samples from its Worldwide Talc Survey. *See* **Exhibit 176** (JNJNL_000015761 (10/20/2000 Letter)).

296. In 2008, nearly ten years after the first litigation hold, Johnson & Johnson, when asked about retention time for "information related to the CTFA ingredient surveys" directed its employees to "PITCH them." *See* **Exhibit 177** (JNJ 000368489).

297. Any test results that Johnson & Johnson has not yet produced are presumed to be destroyed, as the disposal of these results were mandated by the company's evidence retention scheduled absent a litigation hold. *Id.*

298. In addition to final testing results, Johnson & Johnson failed to preserve any of the original scientific data underlying these results. Besides failing to retain the actual talc ore and milled talc samples, Johnson & Johnson did not retain photomicrographs, count sheets, or TEM grids and knowingly allowed for this evidence to be destroyed.

299. This missing scientific data is of utmost importance to the fair and proper vetting of Johnson & Johnson's defense. The limited underlying scientific data that still exists confirms that the reports of "no detectable" asbestos are belied by the underlying scientific data, which shows evidence of asbestos. *Compare* page 1 with pages 4 and 10 in **Exhibit 178** (JNJMX68_000012851 PL Ex 2035). There are countless similar non-detect letters with no underlying data.

300. Johnson & Johnson has not located the photomicrographs underlying the reported findings of asbestos minerals conducted by the University of Minnesota. **Ex. 140** (3/6/2019 Nicholson Dep. 333:8-23).

301. In 1989, after facing litigation related to its talc-based products for nearly two decades and anticipating further litigation, Johnson & Johnson intentionally destroyed records relating to its Hammondsville, Vermont mining operations. **Exhibit 179** (JNJ 000240739 (11/23/1993 Denton to Ashton and Jones at p. 3)).

302. Johnson & Johnson has represented that "[i]f we had any reason to believe our talc was unsafe, it would be off our shelves immediately." **Ex. 117** (12/19/2018 Johnson & Johnson Ad).

303. Yet in the Joly case, Johnson & Johnson's Medical Services Department – including the company's Medical Director – recognized that the plaintiff, who had used Johnson's Baby Powder for years, had "scarring of lung tissue [that] was noted on x-ray." Furthermore, "Pulmonary function studies revealed very severe obstruction of the small airways. Consumer did not respond to bronchodilators. Talc crystals were identified in the consumer's sputum." *See* **Ex. 2** (2/15/2019 Musco Dep. 155:18–158:25); *see also* **Exhibit 180** (JNJ 000058414 (5/10/1985 J&J Ingestions and Inhalations Memorandum)).

304. Besides this report, Johnson & Johnson has not located its records related to the Joly litigation even though Mr. George Lee, a Johnson & Johnson scientist, had a file on the case in his possession as late as July 1988. *See* **Ex. 2** (2/15/2019 Musco Dep. 170:16–172:20). Yet, J&J's designated corporate representative concerning the history and substance of prior litigation was not supplied with a single piece of paper regarding the *Joly* case. *Id*. at 159:21-161:11.

305. Evidence indicates that Johnson & Johnson historically preserved no records whatsoever from the majority of cases in which it has been sued for causing talc-related injuries.

306. For those cases where there is at least some documentation, Johnson & Johnson either lost or destroyed most of the material evidence related to historical litigation alleging

asbestos-related disease from its talc-based products. *See e.g.*, **Ex. 3** (3/8/2019 Musco Dep. 361:24-362:17) (missing *Westfall* photographs); **Ex. 2** (2/15/2019 Musco Dep. 232:9-17) (missing *Edley* interrogatories); *id.* at 111:23–112:3 (no records from the *Cunningham* case); *id.* at 112:10-25) (no records from the *Kreppel* case); *id.* at 113:12–114:3) (no records from the *Lopez* case); *id.* at 114:19-22) (no records from the *Sheldon* case).

307. Despite being involved in countless cases dating back to 1971, Johnson & Johnson could only locate two sets of discovery responses for its corporate representative to review. *See id.* at 202:2-13).

308. Johnson & Johnson once maintained a paper file documenting all of its telephone conversations with the FDA related to its talc-based cosmetic products dating to the early 1970s. **Ex. 98** (2/19/2019 Nicholson Dep. 48:9–15). The "FDA Call File" no longer exists. *Id.* at 113:25–114:19).

309. William Ashton, otherwise known within J&J as "Mr. Talc", was intimately involved in issues affecting the safety of talc for the entire length of his Johnson & Johnson career, spanning many decades. As part of his responsibility, Ashton maintained his own set of files concerning J&J talc. Those files concerning talc and asbestos maintained by William Ashton, while litigation was pending remain unaccounted for. *See* **Exhibit 181** (Note from Rebecca Farlow to William Ashton with a "list of TALC files from the last case.").

310. According to Johnson and Johnson, McCrone was the primary outside consultant charged with testing J&J talc for asbestos. The original McCrone testing files were sent to in-house counsel while litigation was pending. Instead of producing those files to litigants alleging talc related injuries, the files were secreted away in the offices of outside counsel. *See* **Exhibit 182** (Letter Dated 1/3/1995) and **Exhibit 183** (June 30, 2021, Deposition of John O'Shaughnessy at

442:10-444:17, 712:6-16.). While some McCrone testing results were finally produced after 2016, the complete McCrone files were secreted away in the offices of outside counsel and were not produced. Virtually all of the underlying scientific data was either lost or destroyed.

311. Johnson & Johnson once maintained toxicology information in boxes and binders. This toxicology information was never disclosed. *See* **Ex. 20** (11/28/18 Musco Dep. 149:7–152:24).

312. In 1977, the Talc Task Force conducted "round robin" testing of talcum powder products manufactured by member companies.

313. John P. Schelz, a Johnson & Johnson employee and chair of the Talc Task Force, coordinated the testing and review of the testing data. *See* **Exhibit 184** (JNJ 000250596).

314. Once the testing data was received, Schelz compiled the data in a table and assigned each sample a coded value. He then created a separate "code key" to interpret the coded value assigned to each sample.

315. He did not send the code key to any of the other companies. *See* **Exhibit 185** (JNJ 000265120).

316. Schelz sent the only other copy of the code key to Charles Haynes at PCPC with instructions to destroy the code key after Haynes called the companies to inform them of the results. Id.

317. Upon information and belief, both Schelz and Haynes destroyed the code keys to the "round robin" testing results. As a result, it's impossible to determine which products were tested. Id.

318. All companies involved in the "round robin" testing agreed to the process of destroying the code key.

319. From the 1950s to the 2000s, Defendant Johnson & Johnson (or outside laboratories, including RJ Lee and McCrone) tested samples of talc for asbestos content.

320. Upon information and belief, Defendant Johnson & Johnson failed to ensure the preservation of these samples, TEM grids, count sheets, photomicrographs, and other documents generated during the testing and, as a result, the samples, TEM grids, count sheets, photomicrographs, and other documents generated during the testing were destroyed.

321. Defendant Johnson & Johnson intentionally failed to preserve relevant documents generated in litigation in a number of cases filed against it between the 1960s to the 1990s.

XI. Federal Standards and Requirements

322. Certain federal standards and requirements apply to both talc as a cosmetic ingredient and talc-based body powder products. *See* **Exhibit 186** (P-324 (21 C.F.R. 740.1)).

323. At all relevant times, Defendants had the obligation to comply with federal standards and regulations in the manufacture, design, marketing, branding, labeling, distribution, and sale of the PRODUCTS.

324. At all times that Johnsons Baby Powder and Shower to Shower Powder was marketed in the United States, J&J did not have to submit its PRODUCTS to FDA for approval for sale. According to FDA: "FDA's legal authority over cosmetics is different from our authority over other products we regulate, such as drugs, biologics, and medical devices. Under the law, cosmetic products and ingredients do not need FDA premarket approval, with the exception of color additives."[10]

[10] https://www.fda.gov/cosmetics/cosmetics-laws-regulations/fda-authority-over-cosmetics-how-cosmetics-are-not-fda-approved-are-fda-regulated.

325. At all relevant times, the responsibility to study the safety of Johnsons Baby Powder rested solely with J&J and Old JJCI. According to the FDA: *"Companies and individuals who manufacture or market cosmetics have a legal responsibility to ensure the safety of their products*. Neither the law nor FDA regulations require specific tests to demonstrate the safety of individual products or ingredients. The law also does not require cosmetic companies to share their safety information with FDA."[11]

326. Defendants, each individually, *in solido*, and/or jointly, violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, et seq., and regulations promulgated thereunder.

327. Defendants have or may have failed to comply with federal standards and requirements governing the manufacture, design, marketing, branding and sale of the PRODUCTS including, but not limited to, the following violations of sections and subsections of the United States Code and the Code of Federal Regulations:

a. The PRODUCTS are adulterated pursuant in violation of 21 U.S.C. § 361 because, among other things, they contain a poisonous or deleterious substance which may render them injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual.
b. The PRODUCTS are misbranded in violation of 21 U.S.C. § 362 because, among other things, their labeling is false or misleading.
c. The PRODUCTS are misbranded in violation 21 U.S.C. § 362 because words, statements or other information required by or under authority of 21 U.S.C. § 362 are not prominently placed thereon with such conspicuousness and in such terms as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

[11] *Id.*

d. The PRODUCTS are misbranded in violation of 21 C.F.R. § 701.1 because they contain false or misleading representations that they are safe for daily application to all parts of the female body.

e. The PRODUCTS do not bear a warning statement, in violation of 21 C.F.R. § 740.1, to prevent a health hazard that may be associated with the PRODUCTS, namely that the PRODUCTS may cause ovarian cancer or a heightened risk of ovarian cancer when applied to the perineal area.

f. The PRODUCTS do not prominently and conspicuously bear a warning statement, in violation of 21 C.F.R. § 740.2, as to the risk of ovarian cancer caused by use of the PRODUCTS when applied to the perineal area, in such terms and design that it is likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

g. The PRODUCTS, in violation of 21 C.F.R. § 740.10, do not conspicuously state on their principal display panel that the safety of the PRODUCTS have not been determined and/or that the safety of the PRODUCTS' principal ingredients have not been determined.

CAUSES OF ACTION

COUNT I – MEDICAL MONITORING
(Against The Johnson & Johnson Defendants)

328. Plaintiffs, individually and on behalf of the Class, incorporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs and the Class plead all Counts of this Class Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles, including the laws of the Plaintiffs' and Class members' resident States.

329. Based upon knowledge available to the Defendants since at least 1971, they knew or reasonably should have known that the use of their PRODUCTS in the female perineal area significantly increased the risk of ovarian cancer in women.

330. Yet, despite this knowledge, the Defendants failed to provide adequate warning or instruction to consumers, including Plaintiffs and Class members, regarding the increased risk of ovarian cancer when the PRODUCTS are applied to the female perineal area.

331. As a proximate result of the Defendants' tortious conduct, the Qualifying Talc Users in the Class and, more specifically, the members of Subclass 1 have experienced an increased risk of developing the Defined Injuries, namely: epithelial ovarian cancer, fallopian tube cancer, and primary peritoneal cancer.

332. Epithelial ovarian cancer, fallopian tube cancer, and primary peritoneal cancer require specialized diagnostic testing and preventative measures that are not generally given to the public at large.

333. The available medical monitoring techniques that are specific to women who have utilized the Defendants' talc-based PRODUCTS for genital application for many years are different from what is normally recommended in the absence of exposure to this risk of harm.

334. Medical monitoring includes, but is not limited to, baseline tests and diagnostic examinations which will assist in diagnosing epithelial ovarian cancer, fallopian tube cancer, and primary peritoneal cancer.

335. The early and accurate diagnosis of these cancers will greatly expand the treatment options available to Class members and drastically improve their short and long-term survival rates.

336. Likewise, medical monitoring can incorporate preventative treatments and measures designed to halt or impede the development of these cancers in women.

337. The available medical monitoring examinations and tests are reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis of epithelial ovarian cancer, fallopian tube cancer, and primary peritoneal cancer.

338. Through appropriate monitoring, diagnostic testing and preventative measures, the Qualifying Talc Users in Subclass 1, will be far less likely to experience death and/or an untreatable form of ovarian cancer, fallopian tube cancer, or primary peritoneal cancer.

339. Therefore, Plaintiffs, the Class and specifically, Subclass 1, seek an injunction creating a Court-supervised, medical monitoring program, which will facilitate the prevention and diagnosis of ovarian cancer, fallopian tube cancer, and primary peritoneal cancer for Qualifying Talc Users. The medical monitoring program should include a fund (overseen by the Court) to pay for the baseline assessments, diagnostic testing, and preventative measures for Subclass 1 members as frequently and appropriately as necessary.

340. Plaintiffs, the Class, and specifically, the members of Subclass 1 have no adequate remedy at law in that monetary damages alone cannot compensate them for the continued risk of developing ovarian cancer, fallopian tube cancer, and primary peritoneal cancer. Without Court-approved medical monitoring as described herein, or established by the Court, the Plaintiffs, Class, and the members of Subclass 1 will continue to face an unreasonable risk of developing (or, failing to promptly diagnose) ovarian cancer, fallopian tube cancer, and primary peritoneal.

COUNT II - STRICT LIABILITY-FAILURE TO WARN
(Against The Johnson & Johnson Defendants)

341. Plaintiffs, individually and on behalf of the Class, incorporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs and the Class plead all Counts of this Class Complaint in the broadest sense, pursuant to all laws that may apply pursuant

to choice-of-law principles, including the laws of the Plaintiffs' and Class members' resident States.

342. The Johnson & Johnson Defendants are liable under a theory of strict products liability as set forth in § 402A of the Restatement of Torts (Second).

343. At all relevant times, the Johnson & Johnson Defendants were engaged in the business of manufacturing, formulating, designing, marketing, testing, promoting, selling, distributing, and otherwise introducing into the stream of interstate commerce the PRODUCTS.

344. At all relevant times, the Johnson & Johnson Defendants knew or should have known that the use of the PRODUCTS in the female perineal area significantly increased the risk of ovarian cancer in women based upon scientific knowledge dating back until at least 1971.

345. At all relevant times, the PRODUCTS, manufactured and supplied by the Johnson & Johnson Defendants, were defective and unreasonably dangerous because, despite the Johnson & Johnson Defendants' knowledge that the PRODUCTS were carcinogenic and lead to an increased risk of ovarian cancer when applied to the female perineal area, a reasonably foreseeable use of the PRODUCTS, the Johnson & Johnson Defendants failed to provide adequate warning or instruction to consumers, including Plaintiffs and Class members, regarding the increased risk of ovarian cancer when the PRODUCTS are applied to the female perineal area.

346. At all relevant times, the Plaintiffs and Class Members used the PRODUCTS to powder their perineal area, a use that was reasonably foreseeable and for which the PRODUCTS were supplied.

347. Had the Plaintiffs and Class members received warning and/or instruction from the Johnson & Johnson Defendants regarding the increased risk of ovarian cancer associated with the

PRODUCTS when applied to the perineal area, they would not have used the PRODUCTS in this manner.

348. Due to the absence of any warning or instruction by the Johnson & Johnson Defendants as to the significant health and safety risks posed by the PRODUCTS as described herein, the Plaintiffs and Class members were unaware that the PRODUCTS created an increased risk of ovarian cancer, as this danger was not known to the general public.

349. As the direct and proximate result of the reasonably foreseeable use of the PRODUCTS as manufactured, formulated, marketed, tested, promoted, sold, distributed and introduced into the stream of commerce by the Defendants, Plaintiff Bynum and the other members of Subclass 1 have an unreasonable, increased risk of developing a Defined Injury in the future. Accordingly, Plaintiff Bynum and the other members of Subclass 1 are entitled to relief in the form of a Court-approved medical monitoring program; and compensatory damages, consequential damages, interest, costs and attorneys' fees to compensate the members of Subclass 1 (and their Representative and/or Derivative Claimants) who may be diagnosed with a Defined Injury in the future.

350. Also, as a direct and proximate result of the reasonably foreseeable use of the PRODUCTS as manufactured, formulated, marketed, tested, promoted, sold, distributed and introduced into the stream of commerce by the Johnson & Johnson Defendants, Plaintiff Robin Coburn and the other members of Subclass 2 have been diagnosed with a Defined Injury and have suffered and will continue to suffer damages for which they (and their Representative and/or Derivative Claimants) are entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs and attorneys' fees.

COUNT III – STRICT LIABILITY –DEFECTIVE MANUFACTURE AND DESIGN
(Against The Johnson & Johnson Defendants)

351. Plaintiffs, individually and on behalf of the Class, incorporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs and the Class plead all Counts of this Class Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles, including the laws of the Plaintiffs' and Class members' resident States.

352. The Johnson & Johnson Defendants are liable under the theory of strict liability as set forth in the Restatement (Second) of Torts § 402A.

353. At all relevant times, the Johnson & Johnson Defendants were engaged in the business of manufacturing, formulating, creating, designing, testing, labeling, packaging, supplying, marketing, promoting, selling, advertising and otherwise introducing the PRODUCTS into the stream of interstate commerce, which they sold and distributed throughout the United States.

354. At all relevant times, the PRODUCTS were expected to and did reach the Plaintiffs and Class members without a substantial change in condition.

355. At all relevant times, the PRODUCTS were defectively and improperly manufactured and designed by the Johnson & Johnson Defendants in that, when the PRODUCTS left the hands of the Johnson & Johnson Defendants, the foreseeable risks of the PRODUCTS far outweighed the benefits associated with their design and formulation.

356. At all relevant times, the PRODUCTS were defectively manufactured and designed by the Johnson & Johnson Defendants in that their design and formulation was more dangerous than an ordinary consumer would expect when used in an intended and reasonably foreseeable manner.

357. At all relevant times, the PRODUCTS created significant risks to the health and safety of consumers that far outweigh the risks posed by other products on the market used for the same cosmetic purpose.

358. At all relevant times, a reasonable and safer alternative design existed, which could have feasibly been employed by the Johnson & Johnson Defendants to manufacture a product with the same cosmetic purpose as the PRODUCTS. Despite knowledge of this reasonable and safer alternative design, the Johnson & Johnson Defendants failed to alter the PRODUCTS' design and formulation. The magnitude of the danger created by the PRODUCTS far outweighs the costs associated with using an alternative, safer design.

359. As a direct and proximate result of the defective design and manufacture of the PRODUCTS, Plaintiff Bynum and the other members of Subclass 1 have an unreasonable, increased risk of developing a Defined Injury in the future. Accordingly, Plaintiff Bynum and the other members of Subclass 1 are entitled to relief in the form of a Court-approved medical monitoring program; and compensatory damages, consequential damages, interest, costs and attorneys' fees to compensate the members of Subclass 1 (and their Representative and/or Derivative Claimants) who may be diagnosed with a Defined Injury in the future.

360. Also, as a direct and proximate result of the defective design and manufacture of the PRODUCTS, Plaintiff Robin Coburn and the other members of Subclass 2 have been diagnosed with a Defined Injury and have suffered and will continue to suffer damages for which they (and their Representative and/or Derivative Claimants) are entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs and attorneys' fees.

COUNT IV- BREACH OF EXPRESS WARRANTIES
(Against The Johnson & Johnson Defendants)

361. Plaintiffs, individually and on behalf of the Class, incorporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs and the Class plead all Counts of this Class Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles, including the laws of the Plaintiffs' and Class members' resident States.

362. The Johnson & Johnson Defendants, through their advertising and promotional materials, expressly warranted and affirmed that the PRODUCTS were safe for the uses for which they were intended and for uses which were reasonably foreseeable. The Johnson & Johnson Defendants' express warranties extended beyond delivery of the PRODUCTS and expressly warranted the future performance of the PRODUCTS. These express warranties include, but are not limited to, the following:

a. The Johnson & Johnson Defendants advertised and labeled the PRODUCTS as safe for application all over the body, including the following: "For you, use every day to help feel soft, fresh, and comfortable;" "A sprinkle a day keeps the odor away;" "Your body perspires in more places than just under your arms;" "Use SHOWER to SHOWER to feel dry, fresh, and comfortable throughout the day;" and "SHOWER to SHOWER can be used all over your body."

b. The Johnson & Johnson Defendants advertised SHOWER to SHOWER to be applied around or on the perineal area. For example, the Johnson & Johnson Defendants advertised that women should use SHOWER to SHOWER to "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."

363. The Johnson & Johnson Defendants, through the advertisements as listed above, made express warranties to the Plaintiffs, the Class, and the general public that the PRODUCTS were safe and effective when applied all over the body, including the female perineal area.

364. At all relevant times, the Johnson & Johnson Defendants breached said express warranties in that the PRODUCTS were unsafe and ineffective for application all over the body, specifically when used in the female perineal area, because the PRODUCTS, when used in this manner for which the Johnson & Johnson Defendants advertised and promoted, significantly increased the risk of developing ovarian cancer among consumers.

365. At all relevant times, the Johnson & Johnson Defendants had knowledge of the hazards and health risks posed by the PRODUCTS when applied to the perineal area.

366. At all relevant times, the Johnson & Johnson Defendants willfully failed to disclose the defects and health risks of the PRODUCTS to Plaintiffs and the consuming public.

367. At all relevant times, in reliance upon the express warranties made by the Johnson & Johnson Defendants as set forth above, Plaintiffs and the Class members purchased and used the PRODUCTS in their perineal area, believing that the PRODUCTS were safe when used in this manner.

368. As a direct and proximate result of the Johnson & Johnson Defendants' breach of their express warranties concerning the PRODUCTS, as described herein, Plaintiff Bynum and the other members of Subclass 1 have an unreasonable, increased risk of developing a Defined Injury in the future. Accordingly, Plaintiff Bynum and the other members of Subclass 1 are entitled to relief in the form of a Court-approved medical monitoring program; and compensatory damages,

consequential damages, interest, costs and attorneys' fees to compensate the members of Subclass 1 (and their Representative and/or Derivative Claimants) who may be diagnosed with a Defined Injury in the future.

369. Also, as a direct and proximate result of the Johnson & Johnson Defendants' breach of their express warranties concerning the PRODUCTS, as described herein, Plaintiff Robin Coburn and the other members of Subclass 2 have been diagnosed with a Defined Injury and have suffered and will continue to suffer damages for which they (and their Representative and/or Derivative Claimants) are entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs and attorneys' fees.

COUNT V – BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY (Against The Johnson & Johnson Defendants)

370. Plaintiffs, individually and on behalf of the Class, incorporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs and the Class plead all Counts of this Class Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles, including the laws of the Plaintiffs' and Class members' resident States.

371. At the time the Johnson & Johnson Defendants manufactured, marketed, labeled, promoted, distributed and/or sold the PRODUCTS, Defendants knew of the uses for which the PRODUCTS were intended, including use by women in the perineal area, and impliedly warranted the PRODUCTS were merchantable and fit for the ordinary purposes for which they were intended.

372. Members of the consuming public, including consumers such as the Plaintiffs and Class members, were intended third-party beneficiaries of the warranty.

373. The PRODUCTS were not merchantable or fit for their ordinary purposes, because they had a propensity to lead to the serious personal injuries described herein.

374. The Plaintiffs and Class members reasonably relied on the Johnson & Johnson Defendants' representations that the PRODUCTS were safe and free of defects.

375. The Johnson & Johnson Defendants' breach of the implied warranty of merchantability was the direct and proximate cause of the Plaintiffs' and Class members' injuries.

376. The Johnson & Johnson Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of the consumers and users of their products, including the Plaintiffs and Class members, with knowledge of the safety and efficacy problems, and suppressed this knowledge from the Plaintiffs, the Class, and the general public. The Johnson & Johnson Defendants made conscious decisions not to redesign, relabel, warn or inform the Plaintiffs, Class members, or the unsuspecting consuming public. The Johnson & Johnson Defendants' outrageous conduct warrants an award of punitive damages.

377. As a direct and proximate result of the Johnson & Johnson Defendants' breach of their implied warranties of merchantability concerning the PRODUCTS, as described herein, Plaintiff Bynum and the other members of Subclass 1 have an unreasonable, increased risk of developing a Defined Injury in the future. Accordingly, Plaintiff Bynum and the other members of Subclass 1 are entitled to relief in the form of a Court-approved medical monitoring program; and compensatory damages, consequential damages, interest, costs and attorneys' fees to compensate the members of Subclass 1 (and their Representative and/or Derivative Claimants) who may be diagnosed with a Defined Injury in the future.

378. Also as a direct and proximate result of the Johnson & Johnson Defendants' breach of their implied warranties of merchantability concerning the PRODUCTS, as described herein,

Plaintiff Robin Coburn and the other members of Subclass 2 have been diagnosed with a Defined Injury and have suffered and will continue to suffer damages for which they (and their Representative and/or Derivative Claimants) are entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs and attorneys' fees.

COUNT VI – BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE
(Against The Johnson & Johnson Defendants)

379. Plaintiffs, individually and on behalf of the Class, incorporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs and the Class plead all Counts of this Class Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles, including the laws of the Plaintiffs' and Class members' resident States.

380. The Johnson & Johnson Defendants manufactured, supplied and sold the PRODUCTS with an implied warranty that they were fit for the particular purpose for which they were warranted.

381. Members of the consuming public, including the Plaintiffs and Class members, were the intended third-party beneficiaries of the warranty.

382. The PRODUCTS were not fit for the particular purpose for which they were warranted without serious risk of personal injury, which risk is much higher than other products designed to perform the same function.

383. The Plaintiffs and Class members reasonably relied on the Johnson & Johnson Defendants' representations that the PRODUCTS were safe and effective for use by women in the perineal area.

384. The Johnson & Johnson Defendants' breach of the implied warranty of fitness for a particular purpose was the direct and proximate cause of the Plaintiffs' and Class members' injuries.

385. The Johnson & Johnson Defendants' conduct, as described above, was extreme and outrageous. The Johnson & Johnson Defendants risked the lives of the consumers and users of their products, including the Plaintiffs and Class members, by having knowledge of the safety and efficacy problems associated with the PRODUCTS, but suppressing this knowledge from the general public. The Johnson & Johnson Defendants made conscious decisions not to redesign, relabel, warn or inform the unsuspecting consuming public. The Johnson & Johnson Defendants' outrageous conduct warrants an award of punitive damages.

386. As a direct and proximate result of the Johnson & Johnson Defendants' breach of their implied warranties of fitness concerning the PRODUCTS, as described herein, Plaintiff Bynum and the other members of Subclass 1 have an unreasonable, increased risk of developing a Defined Injury in the future. Accordingly, Plaintiff Bynum and the other members of Subclass 1 are entitled to relief in the form of a Court-approved medical monitoring program; and compensatory damages, consequential damages, interest, costs and attorneys' fees to compensate the members of Subclass 1 (and their Representative and/or Derivative Claimants) who may be diagnosed with a Defined Injury in the future.

387. Also, as a direct and proximate result of the Johnson & Johnson Defendants' breach of their implied warranties of fitness concerning the PRODUCTS, as described herein, Plaintiff Robin Coburn and the other members of Subclass 2 have been diagnosed with a Defined Injury and have suffered and will continue to suffer damages for which they (and their Representative

and/or Derivative Claimants) are entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs and attorneys' fees.

COUNT VII - NEGLIGENCE
(Against the Johnson & Johnson Defendants)

388. Plaintiffs, individually and on behalf of the Class, incorporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs and the Class plead all Counts of this Class Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles, including the laws of the Plaintiffs' and Class members' resident States.

389. At all relevant times, the Johnson & Johnson Defendants manufactured, designed, formulated, marketed, tested, promoted, supplied, sold and/or distributed the PRODUCTS in the regular course of business.

390. At all relevant times, the Johnson & Johnson Defendants had a duty to act with reasonable care in the design, development, marketing, labeling, manufacturing, formulating, testing, monitoring, distribution and sale of the PRODUCTS.

391. At all relevant times, the Johnson & Johnson Defendants had a duty to act with reasonable care and to warn Plaintiffs and the consuming public of the risk, dangers and adverse side effects of the PRODUCTS.

392. At all relevant times, the Johnson & Johnson Defendants knew or should have known that the PRODUCTS were unreasonably dangerous and defective when used in a reasonably foreseeable manner.

393. The Johnson & Johnson Defendants breached their duty to the Plaintiffs and Class members and were otherwise negligent in the design, development, marketing, labeling, manufacturing, formulating, testing, monitoring, distribution and/or sale of the PRODUCTS

utilized by Plaintiffs and the Class, which were inherently dangerous and defective, and unfit and unsafe for their intended and reasonably foreseeable uses.

394. The Johnson & Johnson Defendants were further negligent in failing to accompany the PRODUCTS with proper warnings or adequate labeling regarding the dangerous and potentially fatal health risks associated with the use of the PRODUCTS, particularly when used in the perineal area of women, which was their intended or reasonably foreseeable use.

395. As a direct and proximate result of the Johnson & Johnson Defendants' negligence, Plaintiff Bynum and the other members of Subclass 1 have an unreasonable, increased risk of developing a Defined Injury in the future. Accordingly, Plaintiff Bynum and the other members of Subclass 1 are entitled to relief in the form of a Court-approved medical monitoring program; and compensatory damages, consequential damages, interest, costs and attorneys' fees to compensate the members of Subclass 1 (and their Representative and/or Derivative Claimants) who may be diagnosed with a Defined Injury in the future.

396. Also, as a direct and proximate result of the Johnson & Johnson Defendants' negligence, Plaintiff Robin Coburn and the other members of Subclass 2 have been diagnosed with a Defined Injury and have suffered and will continue to suffer damages for which they (and their Representative and/or Derivative Claimants) are entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs and attorneys' fees.

COUNT VIII – NEGLIGENT MISREPRESENTATION
(Against the Johnson & Johnson Defendants)

397. Plaintiffs, individually and on behalf of the Class, incorporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs and the Class plead all Counts of this Class Complaint in the broadest sense, pursuant to all laws that may apply pursuant

to choice-of-law principles, including the laws of the Plaintiffs' and Class members' resident States.

398. At all relevant times, the Johnson & Johnson Defendants were engaged in the business of manufacturing, formulating, marketing, testing, promoting, selling and/or distributing the PRODUCTS.

399. At all relevant times, the Johnson & Johnson Defendants had a duty to disclose to consumers and the public material facts about the PRODUCTS, including the material fact that application of the PRODUCTS to the female perineal area causes a significantly increased risk of ovarian cancer.

400. Through their actions and omissions in advertising, promoting, labeling and otherwise, the Johnson & Johnson Defendants made public misrepresentations of material facts to, and/or concealed material facts from, consumers like the Plaintiffs and Class members concerning the character, safety and effectiveness of the PRODUCTS.

401. At all relevant times, those misrepresentations and omissions included, but were not limited to, the following:

a. The Johnson & Johnson Defendants labeled and advertised the PRODUCTS in the following ways, among others: "For you, use every day to help feel soft, fresh, and comfortable;" "A sprinkle a day keeps the odor away;" "Your body perspires in more places than just under your arms;" "Use SHOWER to SHOWER to feel dry, fresh, and comfortable throughout the day; and "SHOWER to SHOWER can be used all over your body."

b. The Johnson & Johnson Defendants advertised the product SHOWER to SHOWER to be applied "all over," and in particular, urged women to use it to

"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."

c. The Johnson & Johnson Defendants, through the advertisements described above, among others, misrepresented to consumers, including Plaintiffs, that the PRODUCTS were safe for use all over the body, including the female perineal area.

d. The Johnson & Johnson Defendants misrepresented to consumers, including Plaintiffs, that the PRODUCTS did not contain asbestos, heavy metals, or fibrous talc.

e. Despite actual knowledge of the health risks of the PRODUCTS, the Johnson & Johnson Defendants failed to disclose to the consumers and Plaintiffs, through adequate warnings, representations, labeling or otherwise, that the PRODUCTS were inherently dangerous and carcinogenic in nature, which poses serious health risks to consumers.

f. Despite actual knowledge that the use of the PRODUCTS in the perineal area created a significantly increased risk of ovarian cancer, the Johnson & Johnson Defendants failed to disclose to consumers, including Plaintiffs, through adequate warnings, representations, labeling or otherwise, that material fact.

402. At all relevant times, the Johnson & Johnson Defendants 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 the Plaintiffs and Class members and/or concealed relevant facts that were known to them.

403. At all relevant times, the Plaintiffs and Class members were not aware of the falsity of the foregoing misrepresentations, nor were they aware that material facts concerning talc and the PRODUCTS had been concealed or omitted. In reasonable reliance upon the Johnson & Johnson Defendants' misrepresentations and/or omissions, the Plaintiffs and Class members were induced to and did purchase the PRODUCTS and did use the PRODUCTS on their perineal areas. If the Johnson & Johnson Defendants 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 female perineal area, the Plaintiffs and Class members would not have purchased and/or received the PRODUCTS and/or used the PRODUCTS in that manner.

404. The Plaintiffs' and Class members' reliance upon the Johnson & Johnson Defendants' misrepresentations and omissions were 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 the Plaintiffs and Class members were not in a position to know these material facts, and because the Johnson & Johnson Defendants failed to warn or otherwise provide notice to the consuming public as to the risks of the PRODUCTS, thereby inducing the Plaintiffs and Class members to use the PRODUCTS in lieu of safer alternatives and in ways that created unreasonably dangerous risks to their health. At all relevant times, the Johnson & Johnson Defendants' corporate officers, directors and/or managing agents knew of and ratified the acts of the Johnson & Johnson Defendants, as alleged herein.

405. As a direct and proximate result of the Johnson & Johnson Defendants' negligent misrepresentations and/or omissions concerning the risks and benefits of the PRODUCTS, Plaintiff Bynum and the other members of Subclass 1 have an unreasonable, increased risk of developing a Defined Injury in the future. Accordingly, Plaintiff Bynum and the other members of Subclass 1 are entitled to relief in the form of a Court-approved medical monitoring program; and compensatory damages, consequential damages, interest, costs and attorneys' fees to compensate the members of Subclass 1 (and their Representative and/or Derivative Claimants) who may be diagnosed with a Defined Injury in the future.

406. Also, as a direct and proximate result of the Johnson & Johnson Defendants' negligent misrepresentations and/or omissions concerning the risks and benefits of the PRODUCTS, Plaintiff Robin Coburn and the other members of Subclass 2 have been diagnosed with a Defined Injury and have suffered and will continue to suffer damages for which they (and their Representative and/or Derivative Claimants) are entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs and attorneys' fees.

COUNT IX - FRAUD
(Against the Johnson & Johnson Defendants)

407. Plaintiffs, individually and on behalf of the Class, incorporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs and the Class plead all Counts of this Class Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles, including the laws of the Plaintiffs' and Class members' resident States.

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

409. At all relevant times, the Johnson & Johnson Defendants misrepresented and/or concealed material facts concerning the PRODUCTS to consumers, including the Plaintiffs and Class members, with knowledge of the falsity of their misrepresentations.

410. At all relevant times, upon information and belief, the misrepresentations and concealments concerning the PRODUCTS made by the Johnson & Johnson Defendants include, but are not limited to the following:

a. The Johnson & Johnson Defendants falsely labeled and advertised the PRODUCTS in the following ways, among others: "For you, use every day to help feel soft, fresh, and comfortable," "a sprinkle a day keeps the odor away," "your body perspires in more places than just under your arms," "Use SHOWER to SHOWER to feel dry, fresh, and comfortable throughout the day," and "SHOWER to SHOWER can be used all over your body."

b. The Johnson & Johnson Defendants falsely advertised SHOWER to SHOWER to be applied "all over," and in particular, urged women to use it to "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."

c. The Johnson & Johnson Defendants, through the advertisements described above, knowingly misrepresented to Plaintiffs and the public that the PRODUCTS were safe for use all over the body, including the perineal areas of women.

d. The Johnson & Johnson Defendants intentionally failed to disclose that talc and the associated PRODUCTS, when used in the perineal area, increase the risk of ovarian cancer.

e. The Johnson & Johnson Defendants intentionally failed to disclose and actively concealed that talcum powder products contained other carcinogenic constituents such as fibrous talc, asbestos, heavy metals, and fragrance chemicals.

f. The Johnson & Johnson Defendants intentionally failed to include adequate warnings with the PRODUCTS regarding the potential and actual risks of using the PRODUCTS in the perineal area on women and the nature, scope, severity and duration of any serious injuries resulting therefrom.

g. Despite knowing about the carcinogenic nature of talc and its likelihood to increase the risk of ovarian cancer in women, the Johnson & Johnson Defendants 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.

411. At all relevant times, the Johnson & Johnson Defendants actively, knowingly and intentionally concealed and misrepresented these material facts to the consuming public with the intent to deceive the public, the Plaintiffs and Class members, and with the intent that consumers would purchase and use the PRODUCTS in the female perineal area.

412. At all relevant times, the consuming public, including the Plaintiffs and Class members, would not otherwise have purchased the PRODUCTS and/or applied the PRODUCTS in the perineal area if they had been informed of the risks associated with the use of the PRODUCTS in the perineal area.

413. At all relevant times, the Plaintiffs and Class members relied on the Johnson & Johnson Defendants' misrepresentations concerning the safety of the PRODUCTS when

purchasing the PRODUCTS and using the PRODUCTS on their perineal areas, and their reliance was reasonable and justified.

414. As a direct and proximate result of the Johnson & Johnson Defendants' fraudulent conduct concerning the PRODUCTS, as described herein, Plaintiff Bynum and the other members of Subclass 1 have an unreasonable, increased risk of developing a Defined Injury in the future. Accordingly, Plaintiff Bynum and the other members of Subclass 1 are entitled to relief in the form of a Court-approved medical monitoring program; and compensatory damages, consequential damages, interest, costs and attorneys' fees to compensate the members of Subclass 1 (and their Representative and/or Derivative Claimants) who may be diagnosed with a Defined Injury in the future.

415. Also, as a direct and proximate result of the Johnson & Johnson Defendants' fraudulent conduct concerning the PRODUCTS, as described herein, Plaintiff Robin Coburn and the other members of Subclass 2 have been diagnosed with a Defined Injury and have suffered and will continue to suffer damages for which they (and their Representative and/or Derivative Claimants) are entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs and attorneys' fees.

COUNT X – VIOLATION OF CONSUMER PROTECTION LAWS
(Against The Johnson & Johnson Defendants)

416. Plaintiffs, individually and on behalf of the Class, incorporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs and the Class plead all Counts of this Class Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles, including the laws of the Plaintiffs' and Class members' resident States.

417. The Plaintiffs and Class members purchased and used the PRODUCTS primarily for personal use and thereby suffered ascertainable losses as a result of the Johnson & Johnson Defendants' actions in violation of the consumer protection laws applicable to the individual Plaintiffs' and Class members' resident States.

418. Unfair methods of competition or deceptive acts or practices that were proscribed by law, include the following:

a. Representing that goods or services have characteristics, ingredients, user benefits or qualities that they do not have;

b. Advertising goods or services with the intent not to sell them as advertised;

c. Over-promotion of the PRODUCTS, including but not limited to over-promotion of their safety and efficacy; and

d. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

419. The Johnson & Johnson Defendants violated consumer protection laws through their use of false and misleading misrepresentations or omissions of material fact relating to the safety of the PRODUCTS.

420. The Johnson & Johnson Defendants uniformly communicated the purported benefits of the PRODUCTS while failing to disclose the serious and dangerous risk of ovarian cancer related to the use of the PRODUCTS, especially use in the perineal area, and of the true state of the PRODUCTS' safety, efficacy and usefulness. The Johnson & Johnson Defendants made these representations to consumers, including the Plaintiffs and Class members, in the marketing and advertising described herein. The Johnson & Johnson Defendants' conduct in connection with the PRODUCTS was also impermissible and illegal in that it created a likelihood

of confusion and misunderstanding, because the Johnson & Johnson Defendants misleadingly, falsely and/or deceptively misrepresented and omitted numerous material facts regarding, among other things, the utility, benefits, safety, efficacy and advantages of the PRODUCTS.

421. As a result of these violations of consumer protection laws, the Plaintiffs and Class members have incurred damage and other expenses, for which the Johnson & Johnson Defendants are liable.

422. As a direct and proximate result of the Johnson & Johnson Defendants' violation of consumer protection laws concerning the PRODUCTS, as described herein, Plaintiff Bynum and the other members of Subclass 1 have suffered economic losses and have an unreasonable, increased risk of developing a Defined Injury in the future. Accordingly, Plaintiff Bynum and the other members of Subclass 1 are entitled to relief in the form of a Court-approved medical monitoring program; and compensatory damages, consequential damages, interest, costs and attorneys' fees to compensate the members of Subclass 1 (and their Representative and/or Derivative Claimants) who may be diagnosed with a Defined Injury in the future.

423. Also, as a direct and proximate result of the Johnson & Johnson Defendants' violation of consumer protection laws concerning the PRODUCTS, as described herein, Plaintiff Robin Coburn and the other members of Subclass 2 have been diagnosed with a Defined Injury and have suffered and will continue to suffer damages (including economic damages) for which they (and their Representative and/or Derivative Claimants) are entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs and attorneys' fees.

COUNT XI – FRAUDULENT CONCEALMENT
(Against The Johnson & Johnson Defendants)

424. Plaintiffs, individually and on behalf of the Class, incorporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs and the Class plead all

Counts of this Class Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles, including the laws of the Plaintiffs' and Class members' resident States.

425. Prior to the Plaintiffs' and Class members' use of the PRODUCTS and during the period in which the Plaintiffs and Class members actually used the PRODUCTS, the Johnson & Johnson Defendants fraudulently suppressed material information regarding the safety and efficacy of the PRODUCTS and the availability of an alternative feasible safer design, including but not limited to, information regarding the safe use of cornstarch-based products for the same purposes. Furthermore, the Johnson & Johnson Defendants fraudulently concealed the safety information about the use of the PRODUCTS, generally, and on the perineal area, specifically. The fraudulent misrepresentations and fraudulent concealment described throughout this Class Complaint were intentional so as to maintain the sales volume of the PRODUCTS.

426. The Johnson & Johnson Defendants intentionally concealed safety issues with the PRODUCTS in order to induce consumers, including the Plaintiffs and Class members, to purchase the PRODUCTS.

427. At the time the Johnson & Johnson Defendants concealed the fact that the PRODUCTS were not safe as designed and marketed, the Johnson & Johnson Defendants were under a duty to communicate this information to the general public in such a manner that the general public could appreciate the risks associated with using the PRODUCTS, generally.

428. The Plaintiffs and Class members relied upon the Defendants' false and fraudulent misrepresentations and concealments regarding the safety of the PRODUCTS.

429. As a direct and proximate result of the Johnson & Johnson Defendants' malicious and intentional concealment of material and information, the Johnson & Johnson Defendants caused or significantly contributed to the Plaintiffs' and Class members' injuries.

430. The Johnson & Johnson Defendants furthered this fraudulent concealment through a continued and systematic failure to disclose information to the Plaintiffs, Class members, and the consuming public.

431. The Johnson & Johnson Defendants' acts before, during and/or after the act causing the Plaintiffs' and Class members' injuries prevented them from discovering the injury or cause thereof.

432. The Johnson & Johnson Defendants' conduct, as described in the preceding paragraphs, amounts to conduct purposely committed, which the Johnson & Johnson Defendants must have realized was dangerous, needless and reckless, without regard to the consequences or the rights and safety of the Plaintiffs and Class members.

433. As a direct and proximate result of the Johnson & Johnson Defendants' fraudulent concealment concerning the PRODUCTS, as described herein, Plaintiff Bynum and the other members of Subclass 1 have an unreasonable, increased risk of developing a Defined Injury in the future. Accordingly, Plaintiff Bynum and the other members of Subclass 1 are entitled to relief in the form of a Court-approved medical monitoring program; and compensatory damages, consequential damages, interest, costs and attorneys' fees to compensate the members of Subclass 1 (and their Representative and/or Derivative Claimants) who may be diagnosed with a Defined Injury in the future.

434. Also, as a direct and proximate result of the Johnson & Johnson Defendants' fraudulent concealment concerning the PRODUCTS, as described herein, Plaintiff Robin Coburn

and the other members of Subclass 2 have been diagnosed with a Defined Injury and have suffered and will continue to suffer damages for which they (and their Representative and/or Derivative Claimants) are entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs and attorneys' fees.

COUNT XII – CIVIL CONSPIRACY
(Against The Johnson & Johnson Defendants)

435. Plaintiffs, individually and on behalf of the Class, incorporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs and the Class plead all Counts of this Class Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles, including the laws of the Plaintiffs' and Class members' resident States.

436. At all relevant times, the Defendants and/or their predecessors-in-interest knowingly agreed, contrived, combined, confederated, acted in concert, aided and abetted and/or conspired to cause the Plaintiffs' and Class members' injuries by exposing Plaintiffs and the Class to the PRODUCTS, which are harmful and dangerous.

437. Further, at all relevant times, the Defendants knowingly agreed, contrived, confederated, acted in concert, aided and abetted and/or conspired to defraud the Plaintiffs, Class members, and the consuming public regarding the PRODUCTS and the true nature of the PRODUCTS and their potential to cause ovarian cancer when used in a reasonably foreseeable manner.

438. At all relevant times, the Defendants knowingly agreed, contrived, confederated, acted in concert, aided and abetted and/or conspired to defraud the Plaintiffs, Class members, and the consuming public regarding the PRODUCTS with the purpose of maintaining the popularity

and reputation of the PRODUCTS and, therefore, maintaining high sales of the PRODUCTS, at the expense of consumer safety.

439. At all relevant times, pursuant to and in furtherance of said conspiracies, the Defendants performed the following overt and unlawful acts:

a. For many decades, upon information and belief, Defendants, individually, jointly, and in conspiracy with each other, have been in possession of medical and scientific data, literature and test reports which indicate that, when applied to the perineal area, an ordinary and foreseeable use by women, talc-based body powder and the PRODUCTS are unreasonably dangerous, hazardous, deleterious to human health, carcinogenic and potentially deadly;

b. Upon information and belief, despite the medical and scientific data, literature and test reports possessed by and available to the Defendants, Defendants individually, jointly and in conspiracy with each other, fraudulently, willfully and maliciously:

i. Withheld, concealed and suppressed said medical information regarding the increased risk of ovarian cancer from consumers, including Plaintiffs;

ii. Withheld, concealed and suppressed information regarding the presence of fibrous talc, asbestos, heavy metals, and fragrance chemicals in the PRODUCTS;

iii. Through the TIPTF, Defendants instituted a "defense strategy" to defend talc-based body powder at all costs. Admittedly, the Defendants, through the TIPTF, used their influence over the NTP Subcommittee, and the threat

of litigation against the NTP, to prevent the NTP from classifying talc as a carcinogen on its 10th RoC;

iv. Defendants, through the TIPTF, used their influence over local, state and federal agencies to control material facts disclosed to consumers, including Plaintiffs; and

v. Caused to be released, published and disseminated medical and scientific data, literature, and test reports containing information and statements regarding the risks of ovarian cancer, which Defendants knew were incorrect, incomplete and misleading.

c. Upon information and belief, by these false and fraudulent representations, omissions and concealments, Defendants intended to induce consumers, including the Plaintiffs and Class members, to rely upon said false and fraudulent representations, omissions and concealments, and to continue to expose themselves to the dangers inherent in the use of talc-based body powders and the PRODUCTS.

440. Plaintiffs and the Class reasonably relied upon the aforementioned fraudulent representations, omissions and concealments made by the Defendants regarding the nature of talc-based body powder and the PRODUCTS.

441. PCPC engaged in, coordinated or facilitated conduct with no legitimate purpose, and used various improper means to achieve unlawful ends, such that its conduct constituted a sham and therefore takes PCPC outside the purview of *Noerr-Pennington* immunity or similar immunities.

442. As a direct and proximate result of Defendants' overt unlawful acts regarding the nature of talc-based baby powder and the PRODUCTS which were made pursuant to and in furtherance of a common scheme, and the Plaintiffs' and Class members' reliance thereon, Plaintiff Bynum and the other members of Subclass 1 have an unreasonable, increased risk of developing a Defined Injury in the future. Accordingly, Plaintiff Bynum and the other members of Subclass 1 are entitled to relief in the form of a Court-approved medical monitoring program; and compensatory damages, consequential damages, interest, costs and attorneys' fees to compensate the members of Subclass 1 (and their Representative and/or Derivative Claimants) who may be diagnosed with a Defined Injury in the future.

443. Also, as a direct and proximate result of Defendants' overt unlawful acts regarding the nature of talc-based baby powder and the PRODUCTS which were made pursuant to and in furtherance of a common scheme, and the Plaintiffs' and Class members' reliance thereon, Plaintiff Robin Coburn and the other members of Subclass 2 have been diagnosed with a Defined Injury and have suffered and will continue to suffer damages for which they (and their Representative and/or Derivative Claimants) are entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs and attorneys' fees.

COUNT XIII - LOSS OF CONSORTIUM
(Against The Johnson & Johnson Defendants)

444. Plaintiffs, individually and on behalf of the Class, incorporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs and the Class plead all Counts of this Class Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles, including the laws of the Plaintiffs' and Class members' resident States.

445. At all relevant times hereto, the Plaintiffs and Class members had spouses (hereafter referred to as "Spouse Plaintiffs") and/or family members (hereafter referred to as "Family Member Plaintiffs") who have suffered injuries and losses as a result of the PRODUCTS and the Plaintiffs' and Class members' injuries.

446. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have necessarily paid and have become liable to pay (or may in the future pay) for medical aid, treatment, medications and other expenditures and will necessarily incur (or may incur) further expenses of a similar nature in the future as a proximate result of Defendants' misconduct.

447. For the reasons set forth herein, Plaintiff James Coburn and the Spouse Plaintiffs and/or Family Member Plaintiffs of Subclass 2 have suffered and will continue to suffer the loss of their loved one's support, companionship, services, society, love and affection.

448. All Spouses of members of Subclass 2, allege that their marital relationship was impaired and depreciated, and the marital association between husband and wife has been altered.

449. Further, the Spouses of members of Subclass 1, will suffer the loss of their loved one's support, companionship, services, society, love and affection in the future if they should be diagnosed with a Defined Injury.

450. Spouse Plaintiffs and/or Family Member Plaintiffs have suffered (or will suffer) great emotional pain and mental anguish.

451. As a direct and proximate result of Defendants' wrongful conduct, Spouse Plaintiffs, Family Member Plaintiffs and/or intimate partners of Subclass 1 and Subclass 2 members, like Plaintiff James Coburn, have sustained (or will sustain) severe emotional distress, economic losses and other damages for which they are entitled to compensatory and punitive damages in an amount to be proven at trial. Defendants are liable to Spouse Plaintiffs, Family

Member Plaintiffs and intimate partners of Subclass 1 and Subclass 2 members, like James Coburn, jointly and severally for all general, special and other relief to which Spouse Plaintiffs, Family Member Plaintiffs and intimate partners of Subclass 1 and Subclass 2 members are entitled by law.

COUNT XIV - PUNITIVE DAMAGES
(Against The Johnson & Johnson Defendants)

452. Plaintiffs, individually and on behalf of the Class, incorporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs and the Class plead all Counts of this Class Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles, including the laws of the Plaintiffs' and Class members' resident States.

453. Defendants sold the PRODUCTS to the Plaintiffs, Class members, and other consumers throughout the United States without doing adequate testing to ensure that the PRODUCTS were reasonably safe for their intended use.

454. Defendants sold the PRODUCTS to the Plaintiffs, Class members, and other consumers throughout the United States in spite of their knowledge that the PRODUCTS cause the problems heretofore set forth in this Class Complaint, thereby causing the severe and debilitating injuries suffered by the Plaintiffs and Class members.

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

456. At all times material hereto, 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 are used in the perineal area.

457. Defendants' misrepresentations included knowingly withholding material information from the consumers, including the Plaintiffs and Class members, concerning the safety and efficacy of the PRODUCTS.

458. At all times material hereto, 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.

459. At all times material hereto, 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.

460. At all times material hereto, 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.

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

462. 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 the Plaintiffs and Class members, in conscious and/or reckless disregard of the foreseeable harm caused by the PRODUCTS.

463. Defendants continue to intentionally conceal and/or recklessly and/or grossly negligently fail to disclose to the public, including the Plaintiffs and Class members, the serious side effects of the PRODUCTS in order to ensure continued and increased sales.

464. Defendants' intentional, reckless and/or grossly negligent failure to disclose information deprived the Plaintiffs and Class members of necessary information to enable them to weigh the true risks of using the PRODUCTS against their benefits.

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

466. Defendants have engaged in conduct entitling Plaintiffs and the Class to an award of punitive damages pursuant to Common Law principles and the statutory provisions of the Plaintiffs' and Class members' respective states.

467. 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.

COUNT XV - WRONGFUL DEATH
(Against The Johnson & Johnson Defendants)

468. Plaintiffs, individually and on behalf of the Class, incorporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs and the Class plead all Counts of this Class Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles, including the laws of the Plaintiffs' and Class members' resident States.

469. The Defendants' conduct has caused some members of Subclass 1 to die and may cause some members of Subclass 2 to die in the future. The Decedents' spouses, beneficiaries and/or lawful representatives of Decedents' Estates for Subclass 1 and Subclass 2 members bring this claim on behalf of themselves and as the Decedents' lawful beneficiaries.

470. As a direct and proximate result of the conduct of the Defendants and the defective nature of the PRODUCTS as outlined above, Subclass 1 and Subclass 2 Decedents suffered (or will in the future suffer) bodily injury resulting in pain and suffering, disability, disfigurement, mental anguish, loss of capacity of the enjoyment of life, shortened life expectancy, expenses for hospitalization, medical and nursing treatment, loss of earnings, loss of ability to earn, funeral expenses and death.

471. As a direct and proximate cause of the conduct of Defendants, Subclass 1 and Subclass 2 Decedents' beneficiaries have incurred (or will in the future incur) hospital, nursing and medical expenses, and estate administration expenses as a result of Decedents' deaths. Administrators of Subclass 1 and Subclass 2 Decedents' estates, bring this claim on behalf of Decedents' lawful beneficiaries for these damages and for all pecuniary losses sustained by said beneficiaries pursuant to any and all relevant statutes.

472. As a direct and proximate result of Defendants' overt unlawful acts regarding the nature of the PRODUCTS, the Administrators and/or Representatives of Subclass 1 and Subclass 2 Decedents, demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, damages for wrongful death, together with interest, costs of suit, attorneys' fees, punitive damages and such further relief as the Court deems equitable and just.

COUNT XVI - SURVIVAL ACTION
(Against The Johnson & Johnson Defendants)

473. Plaintiffs, individually and on behalf of the Class, incorporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs and the Class plead all Counts of this Class Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles, including the laws of the Plaintiffs' and Class members' resident States.

474. The Defendants' conduct has caused some members of Subclass 1 to die and may cause some members of Subclass 2 to die in the future. As a direct and proximate result of the conduct of Defendants, Subclass 1 and Subclass 2 Decedents, prior to their deaths, were obligated (or became obligated) to spend various sums of money to treat their injuries, which debts have been assumed by their estates. As a direct and proximate cause of the aforesaid, Subclass 1 and Subclass 2 Decedents were caused (or may be caused) pain and suffering, mental anguish and impairment of the enjoyment of life, until the date of their deaths and, as a direct and proximate result of the aforesaid, Subclass 1 and Subclass 2 Decedents suffered (or may in the future suffer) a loss of earnings and earning capacity. Subclass 1 and Subclass 2 members' spouses, as Administrators of the Estates of Subclass 1 and Subclass 2 Decedents, bring this claim on behalf of the estates for damages under any and all applicable statute or common law.

475. As a direct and proximate result of the conduct of Defendants, Subclass 1 and Subclass 2 Decedents and their spouses, until the time of Decedents' deaths, suffered (or may in the future suffer) a disintegration and deterioration of the family unit and the relationships existing therein, resulting in enhanced anguish, depression and other symptoms of psychological stress and disorder. This claim is brought on behalf of the Estates of Subclass 1 and Subclass 2 Decedents pursuant to any and all applicable statutes or common law.

476. As a direct and proximate result of the conduct of Defendants and including the observances of the suffering (or future suffering) of the Subclass 1 and Subclass 2 Decedents, until the date of their deaths, they suffered permanent and ongoing psychological damage.

477. As a direct and proximate result of the aforesaid and including the observance of the suffering and physical deterioration of Subclass 1 and Subclass 2 Decedents until the date of their deaths, Plaintiffs have and will continue to suffer (or may in the future suffer) permanent and ongoing psychological damage which may require future psychological and medical treatment. The spouses, as Administrators of the Estates of the Subclass 1 and Subclass 2 Decedents, bring the claims on behalf of the Estates for damages pursuant to any and all applicable statutes or common law and in their own right.

478. Defendants' actions, as described above, were performed willfully, intentionally, and with reckless disregard for the rights of the Plaintiffs, Class members, and the public.

479. As a result of the Defendants' conduct, the families and/or representatives of Subclass 1 and Subclass 2 Decedents suffered (or may in the future suffer) the injuries and damages specified herein.

480. Accordingly, the families and/or representatives of Subclass 1 and Subclass 2 Decedents seek and are entitled to compensatory and punitive damages in an amount to be determined at trial.

481. As a direct and proximate result of Defendants' overt unlawful acts regarding the nature of the PRODUCTS, the families and/or representatives of Subclass 1 and Subclass 2 Decedents demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, damages for wrongful death, together

with interest, costs of suit, attorneys' fees, punitive damages and such further relief as the Court deems equitable and just.

COUNT XVII – ASSUMPTION OF DUTY
(Against Defendant Johnson & Johnson)

481. Plaintiffs, individually and on behalf of the Class, incorporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs and the Class plead all Counts of this Class Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles, including the laws of the Plaintiffs' and Class members' resident States.

482. At all times relevant hereto, Johnson & Johnson as the parent company of Windsor Minerals, Inc., New JJCI, Old JJCI, and other affiliated subsidiaries negligently failed to exercise the standard of care and skill it was obliged to exercise by reason of its aforesaid undertaking and assumption of duty regarding the testing and safety profile of the talcum powder that it sold, distributed, manufactured and/or marketed, including but not limited to the failure to properly test for asbestos contamination; failure to properly communicate test results of positive asbestos tests. and issue and implement appropriate recommendations regarding the removal of talcum powder from Johnson's Baby Powder; the failure to warn customers it knew or should have known would come into contact with its asbestos contaminated products; and the failure to expeditiously discontinue use and remove asbestos-contaminated products from the market, thereby causing and creating or permitting dangerous conditions where Plaintiffs and the Class sustained exposure to asbestos.

483. Johnson & Johnson's failure to exercise the standard of care and skill it was obliged to exercise by reason of its aforesaid undertaking and assumption of duty increased the risk of harm to Plaintiffs and the Class.

484. As a direct and proximate result of Defendant Johnson & Johnson's failure to exercise the standard of care and skill it was obliged to exercise by reason of its aforesaid undertaking and assumption of duty, Plaintiff Bynum and the other members of Subclass 1 have an unreasonable, increased risk of developing a Defined Injury in the future. Accordingly, Plaintiff Bynum and the other members of Subclass 1 are entitled to relief in the form of a Court-approved medical monitoring program; and compensatory damages, consequential damages, interest, costs and attorneys' fees to compensate the members of Subclass 1 (and their Representative and/or Derivative Claimants) who may be diagnosed with a Defined Injury in the future.

485. Also, as a direct and proximate result of Defendant Johnson & Johnson's failure to exercise the standard of care and skill it was obliged to exercise by reason of its aforesaid undertaking and assumption of duty, Plaintiff Robin Coburn and the other members of Subclass 2 have been diagnosed with a Defined Injury and have suffered and will continue to suffer damages for which they (and their Representative and/or Derivative Claimants) are entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs and attorneys' fees.

COUNT XVIII – AIDING AND ABETTING
(Against Defendant Johnson & Johnson)

486. Plaintiffs, individually and on behalf of the Class, incorporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs and the Class plead all Counts of this Class Complaint in the broadest sense, pursuant to all laws that may apply pursuant to choice-of-law principles, including the laws of the Plaintiffs' and Class members' resident States.

487. Upon information and belief, Defendant Johnson & Johnson knowingly and willfully aided and abetted the fraudulent marketing and sales described herein.

488. Defendant Johnson & Johnson aided and abetted this fraudulent scheme by providing substantial assistance to Old JJCI. This substantial assistance is described, among other places, in the "Facts" section of this pleading.

489. Without Defendant Johnson & Johnson's substantial assistance, involvement, and participation; the fraudulent scheme would not have been possible.

490. As a direct and proximate result of Defendant Johnson & Johnson's substantial assistance, involvement, and participation in this fraudulent scheme, Plaintiff Bynum and the other members of Subclass 1 have an unreasonable, increased risk of developing a Defined Injury in the future. Accordingly, Plaintiff Bynum and the other members of Subclass 1 are entitled to relief in the form of a Court-approved medical monitoring program; and compensatory damages, consequential damages, interest, costs and attorneys' fees to compensate the members of Subclass 1 (and their Representative and/or Derivative Claimants) who may be diagnosed with a Defined Injury in the future.

491. Also, as a direct and proximate result of Defendant Johnson & Johnson's substantial assistance, involvement, and participation in this fraudulent scheme, Plaintiff Robin Coburn and the other members of Subclass 2 have been diagnosed with a Defined Injury and have suffered and will continue to suffer damages for which they (and their Representative and/or Derivative Claimants) are entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs and attorneys' fees.

COUNT XIX – ACTING IN CONCERT
(Against The Johnson & Johnson Defendants)

492. Plaintiffs, individually and on behalf of the Class, in corporate by reference each preceding and succeeding paragraph as if set forth fully herein. Plaintiffs and the Class plead all Counts of this Class Complaint in the broadest sense, pursuant to all laws that may apply pursuant

to choice-of-law principles, including the laws of the Plaintiffs' and Class members' resident States.

493. At all pertinent times, the Johnson & Johnson Defendants knew that the PRODUCTS should contain warnings on the risk of ovarian cancer posed by women using the product to powder the perineal region, but purposefully sought to suppress such information and omit such information from talc-based products so as not to negatively affect sales and maintain the profits of the Johnson & Johnson Defendants, and the members of the PCPC.

494. Additionally, and/or alternatively, the Defendants acted in concert with one another in the negligence, gross negligence, and reckless misconduct. Pursuant to the Restatement (Second) of Torts Section 876, each of the Defendants is liable for the conduct of the other Defendants for whom they aided and abetted.

495. As a direct and proximate result of the Defendants' concerted actions in the negligent, grossly negligent, and reckless misconduct alleged hereinabove, Plaintiff Bynum and the other members of Subclass 1 have an unreasonable, increased risk of developing a Defined Injury in the future. Accordingly, Plaintiff Bynum and the other members of Subclass 1 are entitled to relief in the form of a Court-approved medical monitoring program; and compensatory damages, consequential damages, interest, costs and attorneys' fees to compensate the members of Subclass 1 (and their Representative and/or Derivative Claimants) who may be diagnosed with a Defined Injury in the future.

496. Also, as a direct and proximate result of the Defendants' concerted actions in the negligent, grossly negligent, and reckless misconduct alleged hereinabove, Plaintiff Robin Coburn and the other members of Subclass 2 have been diagnosed with a Defined Injury and have suffered and will continue to suffer damages for which they (and their Representative and/or Derivative

Claimants) are entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs and attorneys' fees.

DISCOVERY RULE AND TOLLING

497. Plaintiffs and the Class assert all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment.

498. Plaintiffs and the Class plead that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiffs and the Class knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiffs and the Class had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

499. Despite diligent investigation by Plaintiffs and the Class into the cause of their injuries, the nature of their injuries and damages and their relationship to the PRODUCTS was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing their claims. Therefore, under appropriate application of the discovery rule, the Plaintiffs' and Class members' suit was filed well within the applicable statutory limitations period.

500. The running of the statute of limitations in this cause is tolled due to equitable tolling. Defendant(s) are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from the Plaintiffs, Class members, and/or the consuming public, of the true risks associated with the PRODUCTS. As a result of the Defendants' fraudulent concealment, the Plaintiffs, Class

members and/or their physicians were unaware, and could not have known or have learned through reasonable diligence that Plaintiffs and the Class had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendant(s).

PRAYER FOR RELIEF

WHEREFORE, Plaintiff and the other members of the Class demand judgment against Defendants on each of the above-referenced claims and causes of action, jointly and severally, as follows:

a. Certification of the Class under Fed. R. Civ. P. 23 and appointment of Plaintiffs as Class representatives for the individual subclasses and the undersigned counsel as Class Counsel;

b. With respect to Count I (Medical Monitoring), certification of the Class and Subclass 1 as proposed in this Complaint pursuant to Fed. R. Civ. P. 23(a)(1-4) & 23(b)(2) (with a right to opt out), or alternatively pursuant to 23(b)(3);

c. With respect to the remaining Counts in this Complaint, certification of the Class and proposed Subclass 1 and Subclass 2 pursuant to Fed. R. Civ. P. 23(b)(3) and an award of Compensatory damages to be determined at trial by a jury.

d. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public, Plaintiffs, and the other members of the Class in an amount sufficient to punish Defendants and deter future similar conduct;

e. Prejudgment interest;

f. Post-judgment interest;

g. Reasonable Class attorneys' fees;

h. Reasonable Class representative participation fees;

i. Awarding the costs of these proceedings; and

j. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs and the Class demand a trial by jury on all matters so triable.

Dated: June 17, 2024

RESPECTFULLY SUBMITTED,

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