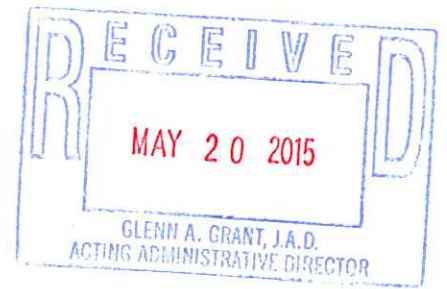


May 19, 2015



VIA FEDERAL EXPRESS

Honorable Glenn A. Grant, J.A.D.
Acting Administrative Director of the New Jersey Courts
Administrative Office of the Courts
Hughes Justice Complex
25 West Market Street
Trenton, New Jersey 08625

**Re: *Application for Centralized Management of Certain Cases
Involving Talc Based Products.***

Dear Judge Grant:

On behalf of the defendants in the talcum powder products cases currently pending in Atlantic and Bergen Counties we write to respectfully request Centralized Management of these cases by Hon. Nelson C. Johnson in Atlantic County.

The first of these cases was filed in January 2014 in Atlantic County before Judge Carol E. Higbee J.S.C. Shortly thereafter, Judge Higbee moved to the Appellate Division, and Judge Nelson C. Johnson, J.S.C. assumed the handling of these cases. The parties appeared before Judge Johnson to discuss the cases in September 2014. At that time, there were 14 cases pending in Atlantic County. Judge Johnson consolidated these cases for discovery purposes only and entered Case Management Order No. 1. (Exhibit A). Since the time of the entry of this Case Management Order, the cases have grown significantly, and there are currently 87 cases pending in Atlantic County. (Exhibit B). Only 3 of the 103 plaintiffs are New Jersey residents. Despite the significant increase in the number of cases, Judge Johnson has ably managed the cases without the need for the formal designation of Multi-County Litigation. However, beginning in February 2015, the Plaintiffs' firm that started the New Jersey litigation and filed the majority of the Atlantic County cases began to selectively file some of its cases in Bergen County, while also continuing to file cases in Atlantic County. As of this date, there are 16 cases now pending in Bergen County, and these Bergen County cases are assigned to 8 different judges. (Exhibit C). Counsel have been advised by the Court that it is not possible to administratively transfer the Bergen County cases to Atlantic County. Defendants therefore respectfully request the Centralized Management of all of these matters before Judge Johnson in Atlantic County to conserve judicial resources and avoid the risks of duplicative discovery and inconsistent rulings.

BACKGROUND

Talc is a raw material that has a wide variety of uses in every-day consumer and cosmetic products, including the products at issue in these cases: talc-based body powders. The talcum powders at issue include Johnson's® Baby Powder and Shower to Shower®, both of which are sold over-the-counter. Plaintiffs have named as Defendants Johnson & Johnson, Johnson & Johnson Consumer Companies, Inc., Imerys Talc America Inc., f/k/a Luzenac America, and Personal Care Products Council ("PCPC") (formerly known as the Cosmetics, Toiletries, and Fragrances Association or CTFA). Plaintiffs claim that their use of these talc based body powders for feminine hygiene purposes caused their ovarian cancer.

Defendants vigorously dispute general causation in this litigation. The most recent, comprehensive relevant scientific studies refute Plaintiffs' claims. See Houghton (UMASS Amherst), Perineal Powder Use and Risk of Ovarian Cancer, Journal of the National Cancer Institute (2014) (concluding that "perineal powder use does not appear to influence ovarian cancer risk") (Exhibit D); see also Robert L. Coleman, MD, Professor, University of Texas M.D. Anderson Cancer Center, Talcum Powder...the 'Pluto' of Prognostic Factors for Ovarian Cancer (stating that the "strength of association, if present at all, is weak" and "it is unlikely that modifying exposure to this 'Pluto of a prognostic factor' will modulate any potential diagnostic risk or mortality from ovarian cancer.") (Exhibit E). These recent scientific papers are consistent with the decades-long history of scientific literature, which has failed to demonstrate a causal link between genital talc use and ovarian cancer, let alone any reliable methodology on which an expert can attribute a particular case of ovarian cancer to cosmetic talc products. In short, the scientific community, with overwhelming consensus, discounts the existence of a causal link between ovarian cancer and talc use.

In sum, Defendants intend to present substantial, scientific evidence contesting general causation. Preeminent scientists from leading institutions located across the country will explain why Plaintiffs' hypothesis is roundly rejected. These scientists will come from a large number of relevant disciplines, including gynecology, gynecologic oncology, epidemiology, and toxicology. Given the resources that the parties and the Court will be required to devote to this complex scientific issue, it is most efficient for the Court and the parties to address this scientific inquiry once, within the confines of an MCL rather than repeatedly by different judges holding multiple *Kemp* hearings.

ARGUMENT

Defendants submit that this litigation meets the criteria required under Directive #8-12 for Centralized Case Management and respectfully requests that these cases be

consolidated for case management in the Atlantic County Superior Court before Judge Nelson C. Johnson, J.S.C.

I. THESE CASES SATISFY THE CRITERIA FOR CENTRALIZED CASE MANAGEMENT

A. The Litigation Involves a Large Number of Parties.

There are currently 103 cases pending in New Jersey, 87 in Atlantic County and 16 in Bergen County, as detailed on Exhibits B and C. These cases involve the claims of more than 156 Plaintiffs. In addition, the Plaintiffs' law firms that have filed these actions have indicated their intentions to file additional cases. Nationwide lawyer advertising soliciting additional claims continues at a high volume. The litigation meets the requirement for a "large number" of parties.

B. The Litigation Involves Many Claims with Common, Recurrent Issues of Law and Fact, All Associated with Common Products.

Each of the pending cases alleges that perineal exposure to the same group of talc products caused ovarian cancer. While each Plaintiff will have an individualized medical history, alleged exposure history, and unique facts, each of the Complaints contains consistent allegations and demands for damages against Defendants. In fact, the Complaints in all of these cases (regardless of the identity of Plaintiffs' counsel) are virtually identical. As such, the recurrent issue of law requirement is met, with the note that Plaintiffs at this time are from thirty different states. Defendants are the same in all the cases.

C. Geographical Dispersement and Remoteness of Counsel Require Centralized Management.

Johnson & Johnson Consumer Companies, Inc. maintains its corporate offices in New Jersey, and its corporate witnesses are located in various domestic and international locations. Imerys Talc America Inc. is a California based company with its corporate witnesses in various locations throughout the United States. Personal Care Products Council is a Washington, D.C. based trade association with its witnesses located primarily in Washington, D.C.

The two Plaintiffs' firms that have filed these actions are Seeger Weiss from Newark, New Jersey (on behalf of multiple Mississippi firms) and Golomb Honik from Philadelphia, Pennsylvania.

In addition, National Counsel for each Defendant is located outside of New Jersey. For the Johnson and Johnson Defendants, Shook, Hardy & Bacon is National Counsel, and their attorneys reside in Texas and Missouri. For Imerys, Gordon and Rees is National Counsel, and its attorneys reside in Oregon, Pennsylvania, and Texas. For Defendant Personal Care Products Council, Seyfarth Shaw is National Counsel, and its attorneys reside in Washington, D.C.

As outlined in the attached case listing at Exhibit B and C, virtually all of the Plaintiffs reside outside of New Jersey. Defendants submit that this geographical diversity meets the geographic dispersement and remoteness requirement.

D. Centralized Management Will Promote Fairness and Provide Convenience to All Parties and their Counsel.

Centralized Management of cases such as these, which involve a significant number of parties, court filings, court hearings, and motion practice, is appropriate. It is not appropriate in the context of this litigation to have the cases proceed in two independent groups in different counties.

Centralized Management in a Multi County litigation venue, with an experienced Judge, will ensure fairness to the parties, provide a streamlined approach to case management, and avoid the possibility of duplicative motion practice and inconsistent discovery rulings between multiple Judges in Bergen and Atlantic Counties.

E. There Are Related Matters Pending.

As is evidenced by the Chart (Exhibit F), there are a number of other matters pending around the Country. At this time, Defendants do not expect the creation of an MDL in any one venue, and, at this time, New Jersey has the most case filings out of any other venue in the United States.

Defendants submit that Centralized Management before one of New Jersey's experienced Multi County litigation Judges, together with their staff, will provide the most efficient and fair forum in which to litigate these matters.

II. ATLANTIC COUNTY IS THE MOST APPROPRIATE VENUE FOR THE CENTRALIZED MANAGEMENT OF THESE CASES

These matters have been pending in Atlantic County for almost 17 months. Judge Johnson has been overseeing this docket of cases as it has grown for almost a year. Case Management Order No. 2 as entered by Judge Johnson (Exhibit G) sets out a comprehensive schedule for discovery, motions, and trial practice that has been agreed to

Judge Grant
May 19, 2015
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by all parties to this litigation. Defendants submit that because of his significant involvement in these matters to date, his knowledge of the litigation and the issues involved therein, and his efficient handling of the cases up to this point, that these matters should be consolidated for management before Judge Johnson in Atlantic County.

Based upon review of the current mass tort caseloads, Atlantic County is the proper venue for this litigation. Atlantic County's active Mass Tort caseload is 6,711 cases, down 64% over the last year. Compared with Bergen County which has seen a 387% increase, with a total caseload of 14,159 cases. And while Middlesex County has a caseload of 5,033 cases, the total increase there is 341% in new matters recently assigned or reassigned to that Court. *See New Jersey Judiciary, CIVIL CASELOAD SUMMARY BY CASETYPE, July, 2014- March, 2015, Middlesex, Atlantic and Bergen Counties.* <http://www.judiciary.state.nj.us/quant/index.htm>.

CONCLUSION

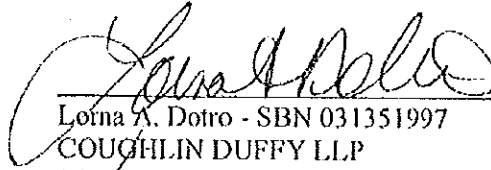
For all of the foregoing reasons, Defendants respectfully request that each of the matters identified in Exhibits B and C and any additional cases filed in New Jersey be consolidated for Centralized Management in Atlantic County.

Respectfully Submitted,

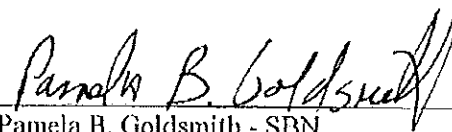


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cc: Honorable Nelson C. Johnson, J.S.C.
Honorable Brian R. Martinotti, J.S.C.
Honorable Estela M. De La Cruz, J.S.C.
Honorable Lisa A. Firko, J.S.C.
Honorable Lisa Perez Friscia, J.S.C.
Honorable Rachelle Lea Harz, J.S.C.
Honorable John J. Langan, Jr., J.S.C.
Honorable Charles E. Powers, Jr., J.S.C.
Honorable Mary F. Thurber, J.S.C.
Honorable Robert C. Wilson, J.S.C.
All Plaintiffs' Counsel

FILED

SEP. 23 2014

MELSON C. JOHNSON, J.S.C.

COURT INITIATED

<p>JENNY APPLEWHITE, Plaintiff, v. JOHNSON & JOHNSON, et al., Defendants.</p>	<p>SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY DOCKET NO. ATL-L-1995-14 CIVIL ACTION</p>
<p>BARBARA CALDERON, Plaintiff, v. JOHNSON & JOHNSON, et al., Defendants.</p>	<p>SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY DOCKET NO. ATL-L-1985-14 CIVIL ACTION</p>
<p>MOLLY CHESTEEN and RANDY CHESTEEN, Plaintiffs, v. JOHNSON & JOHNSON, et al., Defendants.</p>	<p>SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY DOCKET NO. ATL-L-414-14 CIVIL ACTION</p>
<p>RITZIE DONALD, Plaintiff, v. JOHNSON & JOHNSON, et al., Defendants.</p>	<p>SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY DOCKET NO. ATL-L-1528-14 CIVIL ACTION</p>

<p>DEBORAH DONALS, Plaintiffs, v. JOHNSON & JOHNSON, et al., Defendants.</p>	<p>SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY DOCKET NO. ATL-L-2394-14 CIVIL ACTION</p>
<p>DORIS JONES, Plaintiff, v. JOHNSON & JOHNSON, et al., Defendants.</p>	<p>SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY DOCKET NO. ATL-L-772-14 CIVIL ACTION</p>
<p>LYNN GAUTHIER, Plaintiff, v. JOHNSON & JOHNSON, et al., Defendants.</p>	<p>SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY DOCKET NO. ATL-L-3568-14 CIVIL ACTION</p>
<p>LATODRA LEE, INDIVIDUALLY AND AS ADMINISTRATOR OF THE ESTATE OF LAVONDA LEE, DECEASED, Plaintiffs, v. JOHNSON & JOHNSON, et al., Defendants.</p>	<p>SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY DOCKET NO. ATL-L-2592-14 CIVIL ACTION</p>

<p>DEBORAH SANDLAUFER and DOUGLAS SANDLAUFER,</p> <p style="text-align: center;">Plaintiffs,</p> <p>v.</p> <p>JOHNSON & JOHNSON, et al.,</p> <p style="text-align: center;">Defendants.</p>	<p>SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY</p> <p>DOCKET NO. ATL-L-2396-14</p> <p style="text-align: center;">CIVIL ACTION</p>
<p>AGNES SPURLOCK,</p> <p style="text-align: center;">Plaintiff,</p> <p>v.</p> <p>JOHNSON & JOHNSON, et al.,</p> <p style="text-align: center;">Defendants.</p>	<p>SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY</p> <p>DOCKET NO. ATL-L-3778-14</p> <p style="text-align: center;">CIVIL ACTION</p>
<p>EMILY SULLIVAN,</p> <p style="text-align: center;">Plaintiffs,</p> <p>v.</p> <p>JOHNSON & JOHNSON, et al.,</p> <p style="text-align: center;">Defendants.</p>	<p>SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY</p> <p>DOCKET NO. ATL-L-5142-14</p> <p style="text-align: center;">CIVIL ACTION</p>
<p>LINDA SYKES, INDIVIDUALLY AND AS ADMINISTRATOR OF THE ESTATE OF BRENDA PHILLIPS, DECEASED,</p> <p style="text-align: center;">Plaintiffs,</p> <p>v.</p> <p>JOHNSON & JOHNSON, et al.,</p> <p style="text-align: center;">Defendants.</p>	<p>SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY</p> <p>DOCKET NO. ATL-L-3330-14</p> <p style="text-align: center;">CIVIL ACTION</p>

<p>CRAIG WERNER, INDIVIDUALLY AND AS ADMINISTRATOR OF THE ESTATE OF BARBARA WERNER, DECEASED,</p> <p>Plaintiffs,</p> <p>v.</p> <p>JOHNSON & JOHNSON, et al.,</p> <p>Defendants.</p>	<p>SUPERIOR COURT OF NEW JERSEY LAW DIVISION; ATLANTIC COUNTY</p> <p>DOCKET NO. ATL-L-1800-14</p> <p>CIVIL ACTION</p>
<p>MICHELLE WHITE,</p> <p>Plaintiffs,</p> <p>v.</p> <p>JOHNSON & JOHNSON, et al.,</p> <p>Defendants.</p>	<p>SUPERIOR COURT OF NEW JERSEY LAW DIVISION; ATLANTIC COUNTY</p> <p>DOCKET NO. ATL-L-2590-14</p> <p>CIVIL ACTION</p>

CASE MANAGEMENT ORDER NO. 1

THIS MATTER having come before the Court with the consent of all Counsel, and for good cause having been shown, the Court hereby enters the following order:

It is on this 23rd day of September, 2014, ORDERED as follows:

1) Pursuant to R. 4:38-1, the Court hereby, *sua sponte*, consolidates the fourteen (14) above captioned matters for purposes of pre-trial discovery only. Unless otherwise requested by counsel or directed by the Court, these matters shall proceed to trial separately.

2) Each Plaintiff shall complete and serve upon Defendants an HIPPA compliant Medical Records Authorization Form for all treaters, providers, hospitals, employers, insurance carriers and government agencies, on or before November 15, 2014.

a. The scope of production of mental health records and government agency records to be conferred on between the parties.

- b. For non – OB/GYN providers, Plaintiffs shall execute authorizations for the release of records during the period from five years prior to the diagnosis of cancer to the present.
- c. For OB/GYN providers, Plaintiff shall execute authorizations for the release of records during the period from ten years prior to the diagnosis of cancer to the present.
- d. Defendants reserve the right to seek additional records beyond these time parameters and will confer with Plaintiffs' Counsel regarding same.

3) Pursuant to R. 4:17 and R. 4:18, each Plaintiff shall respond to Defendants' Interrogatories and First Request for Production of Documents and Tangible Things and any outstanding deficiency letters thereto, by November 15, 2014.

4) Each Defendant shall provide Plaintiffs a proposed Protective Order by October 10, 2014.

5) Each Defendant shall provide Plaintiffs with the complete discovery produced in the *Berg* case within one week from Plaintiffs' execution of the protective order.'

6) Defendants will provide documents in response to Seeger Weiss LLP's Requests for Production of Documents served in Chesteen and Jones on a rolling basis beginning from entry of the Protective Order and completed no later than January 31, 2015.

7) Plaintiffs and Defendants can submit written discovery requests on a rolling basis during fact discovery. These requests should not be duplicative.

8) The Parties shall respond to written discovery requests within forty-five (45) days of the request unless good cause is shown.

9) Parties may depose Plaintiffs, fact witnesses, and Plaintiffs' treating physicians starting on January 2, 2015. This date may be accelerated due to the health of a specific Plaintiff.

10) Discovery motions may not be filed without leave of Court and after Counsel have met and conferred to discuss discovery issues.

11) Corporate Representative Depositions shall occur from January 2, 2015. Custodial records of each employee shall be produced at least 14 days prior to the deposition.

12) Depositions will take place at a mutually agreeable date, place and time and not on less than 45 days notice to any party unless good cause is shown

13) Plaintiffs may depose Defendants' fact witnesses beginning January 2, 2015 and consistent with R. 4:14.

14) A Case Management Conference will be scheduled on *Thursday, July 16, 2015 at 10:00 a.m.* to address status and scheduling of remaining discovery phases.

15) A trial date for the Estate of Molly Chesteen is tentatively set for March 23, 2016.

16) The second trial is tentatively scheduled for July 13, 2016, on a case to be chosen by Defendants.

17) In the event counsel incurs any difficulty in scheduling or completing any of the required discovery proceedings, either attorney may contact the Court and a telephonic management conference shall be promptly scheduled.

18) In the event any party wishes to explore settlement, all counsel grant the undersigned permission to engage in *ex parte* conversations with counsel to determine whether or not an amicable resolution(s) can be achieved.

This Order has been e-mailed to all parties. Any motions as to discovery or the scheduling of any future proceedings are to be accompanied by a copy of this Order and any other Management Order entered in this proceeding.


NELSON C. JOHNSON, J.S.C.

TALCUM POWDER CASES CURRENTLY PENDING IN ATLANTIC COUNTY

No.	Plaintiff(s)	Docket No.
1.	Adkins, Derick, Individually and as Executor of the Estate of Ruth Ann Adkins, Deceased	ATL-L-0083-15
2.	Apperson, Bertha	ATL-L-0239-15
3.	Applewhite, Jenny	ATL-L-1995-14
4.	Bacon-Barnette, Karen	ATL-L-0368-15
5.	Balderrama, Diana and Gilbert	ATL-L-6540-14
6.	Bonanno, Linda	ATL-L-0250-15
7.	Burgos, Angel, Individually and as Administrator of the Estate of Constance Burgos	ATL-L-6384-14
8.	Burke, Aisha L., Individually and as Administrator of the Estate of Sophronia Victoria Burke, Deceased	ATL-L-0241-15
9.	Calderon, Barbara	ATL-L-1985-14
10.	Calloway, Wanda, Individually, and as Sister and Next Friend of Joyce Calloway, Deceased	ATL-L-0473-15
11.	Canuelle, Linda	ATL-L-6756-14
12.	Carl, Brandi and Joel	ATL-L-6546-14
13.	Cherry, Frances and Ronald	ATL-L-6326-14
14.	Chesteen, Randy, Individually and as Administrator of the Estate of Molly Chesteen	ATL-L-414-14
15.	Clugston, Nicole	ATL-L-0813-15
16.	Conley, Annette	ATL-L-6755-14
17.	Cowles, Veronica	ATL-L-6799-14
18.	Craig, Marrayly and Daniel	ATL-L-6504-14
19.	Daniel, Carla, Individually and as Daughter and Next Friend of Bobbie J. Daniel	ATL-L-6621-14
20.	Distefano, Donna	ATL-L-0598-15
21.	Donald, Ritzie	ATL-L-1528-14
22.	Donals, Deborah	ATL-L-2394-14
23.	Fabian, Penny and Michael	ATL-L-0711-15
24.	Faison, Craigory, Individually and as Personal Representative of the Estate of Grace Faison, Deceased, on behalf of himself and the Estate of Grace Faison, Deceased, and the heirs and beneficiaries of the Estate	ATL-L-955-15

No.	Plaintiff(s)	Docket No.
25.	Farrell, Helen	ATL-L-6795-14
26.	Felder, Susan	ATL-L-6807-14
27.	Fordham, Teresa, Individually and as Provisional Administratrix of the Succession of Betty Dennis, Deceased	ATL-L-6753-14
28.	Fountain, Nadia	ATL-L-0028-15
29.	Gauthier, Lynn	ATL-L-3568-14
30.	Gillespie, Saul, Individually, and as Husband, and Next Friend of Alicia Simmons-Gillespie, Deceased	ATL-L-0472-15
31.	Glanton, Luvell, Individually and as Administrator of the Estate of Verbena Glanton, Deceased	ATL-L-0085-15
32.	Goforth, Ronice and David	ATL-L-6327-14
33.	Gray, Yvette M., Individually and Administrator of the Estate of Christine M. Chasing Bear, Deceased	ATL-L-0378-15
34.	Hanson, Rebecca	ATL-L-6752-14
35.	Harris, Robert, Individually and as Husband and Next Friend of Diana Harris	ATL-L-0242-15
36.	Holub, Tamara	ATL-L-6385-14
37.	Howze, Angela, Individually and as Daughter and as Successor in Interest of Carrie McCall, Deceased	ATL-L-0173-15
38.	Jackson, James, Individually and as Administrator of the Estate of Betty Lou Jackson, Deceased	ATL-L-6754-14
39.	Johnson, Lucas, Individually and Personal Representative of the Estate of Kim Johnson, Deceased, and the heirs and Beneficiaries of the Estate	ATL-L-0036-15
40.	Jones, Celestine, Individually and as Administrator of the Estate of Shirley McCall	ATL-L-6450-14
41.	Jones, Doris	ATL-L-772-14
42.	Kilburne, Nathaniel, individually and as Administrator of the Estate of Debra Kilburne	ATL-L-6751-14
43.	Kincade (McCullin), Shelley, Individually and as Independent Executrix of the Succession of Lora Imogene Kincade, Deceased	ATL-L-6808-14
44.	Kincaid, Tonja & Anthony	ATL-L-6195-14
45.	Krauchuk, Paula	ATL-L-6805-14

No.	Plaintiff(s)	Docket No.
46.	Kyker, Maurice, Individually and as Husband and Next Friend of Judith Kyker, Deceased	ATL-L-6806-14
47.	Laprairie, Teresa	ATL-L-6328-14
48.	Lee, Latodra, Individually and as Administrator of the Estate of Lavonda Lee, Deceased	ATL-L-2592-14
49.	Lewis, Frankie A.	ATL-L-0377-15
50.	Lockett, Linda, Individually and as Independent Executrix of the Succession Kenner Cann Lockett, Deceased	ATL-L-0360-15
51.	Lucas, Dianna	ATL-L-6750-14
52.	Machen, Susan K., Individually and as Daughter, and Next Friend of Alta Jane Shannon, Deceased	ATL-L-0134-15
53.	Marcinek, Lorraine and Matthew	ATL-L-956-15
54.	Mathis, Gussie	ATL-L-6793-14
55.	Maxwell, Cheryl and John	ATL-L-0338-15
56.	Minor, Latoya, Individually and Special Administrator of the Estate of Annie Mae Carey, Deceased	ATL-L-0053-15
57.	Morrow-King, Amelia, Individually and as Administrator of the Estate of Nancy Morrow, Deceased	ATL-L-0293-15
58.	Ourso, Robert, Jr., Individually and as Independent Executor of the Succession of Tina Marie Scheffer, Deceased	ATL-L-6749-14
59.	Parker, Venessa	ATL-L-0288-15
60.	Pettway, Tasha	ATL-L-0255-15
61.	Pollard, Deborah	ATL-L-0243-15
62.	Ralph, Patricia	ATL-L-6804-14
63.	Ramseur, Sharon and John	ATL-L-6337-14
64.	Reddell, Renee Ann	ATL-L-6798-14
65.	Riley, Shirley	ATL-L-6797-14
66.	Robbins, Kay	ATL-L-6794-14
67.	Ross, Frances, Individually and as Sister and Next Friend of Lessie McCarthy, Deceased	ATL-L-0474-15
68.	Ryan, Stacey, Individually and as Administrator and the Succession of Sandra Ryan, Deceased	ATL-L-6800-14
69.	Salmans, Julie	ATL-L-6386-14
70.	Sandlaufer, Deborah	ATL-L-2396-14

No.	Plaintiff(s)	Docket No.
71.	Shafer, Linda	ATL-L-0852-15
72.	Sims, Ricky L., Individually and as Husband and Next Friend of, Nancy G. Sims, Deceased	ATL-L-0475-15
73.	Smith, Susan Dell	ATL-L-0244-15
74.	Smith, Tretha, Individually and as Administrator of the Estate of Leatha Smith	ATL-L-6468-14
75.	Spurlock, Agnes	ATL-L-3778-14
76.	Sulkowski, Deborah	ATL-L-6239-14
77.	Sullivan, Emily	ATL-L-5142-14
78.	Svatek, Katheryn and Patrick	ATL-L-6556-14
79.	Sykes, Linda, Individually and as Administrator of the Estate of Brenda Phillips, Deceased	ATL-L-3330-14
80.	Townes, Kathleen	ATL-L-6796-14
81.	Werner, Craig, Individually and as Administrator of the Estate of Barbara Werner, Deceased	ATL-L-1800-14
82.	White, Michelle	ATL-L-2590-14
83.	Williams, Darlene, Individually and as Mother and Next Friend of Tammie Arlene Smith Garza, Deceased	ATL-L-6724-14
84.	Williams, Gail	ATL-L-957-15
85.	Williams, Stacey	ATL-L-0172-15
86.	Wooldridge, Joel, Individually and as a Representative of the Estate of Terri L. Wooldridge	ATL-L-6661-14
87.	Young, Sharon	ATL-L-0306-15

TALCUM POWDER CASES CURRENTLY PENDING IN BERGEN COUNTY

No.	Plaintiff(s)	Docket No.	Judge
1.	Alexander, Paulette	BER-L-2979-15	Judge Harz
2.	Arnold, Barbara, Individually and as Personal Representative of the Estate of Laura Mae Robertson, Deceased	BER-L-2524-15	Judge Thurber
3.	Hood, Patricia	BER-L-3893-15	Judge Perez-Friscia
4.	Humphrey, Claude Individually and as Husband and Next Friend and Claudia Humphrey, Individually and as Daughter and Next Friend of Sandra Humphrey, Deceased	BER-L-2975-15	Judge Harz
5.	Jeromos, Marie	BER-L-2059-15	Judge De La Cruz
6.	Lewis, Carla	BER-L-2980-15	Judge Powers
7.	Lord, Deborah and Kris	BER-L-2982-15	Judge Powers
8.	Lovelace, John, Individually and as Administrator of the Estate of Linda Lovelace, Deceased	BER-L-2724-15	Judge Thurber
9.	Oliver, Rosemarie and John J.	BER-L-1633-15	Judge Langan
10.	Perdue, Hermine, Individually and as Administrator of the Estate of Marquita Winston, Deceased	BER-L-2725-15	Judge Thurber
11.	Ratta, Renee	BER-L-4009-15	Judge De La Cruz
12.	Sams, Scarlett Ann	BER-L-4342-15	Judge Wilson
13.	Thornhill, Martia Individually and as Daughter and Next Friend of Juanita Brown Warren, Deceased	BER-L-2078-15	Judge Harz
14.	Truesdale, Quenna	BER-L-4012-15	Judge Powers
15.	Whisenant, Joyce and John	BER-L-4013-15	Judge Firko
16.	Wilkerson, Dora	BER-L-4015-15	Judge Firko

Perineal Powder Use and Risk of Ovarian Cancer

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- Background** Case-control studies have reported an increased risk of ovarian cancer among talc users; however, the only cohort study to date found no association except for an increase in serous invasive ovarian cancers. The purpose of this analysis was to assess perineal powder use and risk of ovarian cancer prospectively in the Women's Health Initiative Observational Study cohort.
- Methods** Perineal powder use was assessed at baseline by self-report regarding application to genitals, sanitary napkins, or diaphragms and duration of use. The primary outcome was self-reported ovarian cancer centrally adjudicated by physicians. Cox proportional hazard regression was used to estimate risk, adjusting for covariates, including person-time until diagnosis of ovarian cancer ($n = 429$), death, loss to follow-up, or September 17, 2012. All statistical tests were two-sided.
- Results** Among 61 576 postmenopausal women, followed for a mean of 12.4 years without a history of cancer or bilateral oophorectomy, 52.6% reported ever using perineal powder. Ever use of perineal powder (hazard ratio [HR]_{adj} = 1.06, 95% confidence interval [CI] = 0.87 to 1.28) was not associated with risk of ovarian cancer compared with never use. Individually, ever use of powder on the genitals (HR_{adj} = 1.12, 95% CI = 0.92 to 1.36), sanitary napkins (HR_{adj} = 0.95, 95% CI = 0.76 to 1.20), or diaphragms (HR_{adj} = 0.92, 95% CI = 0.68 to 1.23) was not associated with risk of ovarian cancer compared with never use, nor were there associations with increasing durations of use. Estimates did not differ when stratified by age or tubal ligation status.
- Conclusion** Based on our results, perineal powder use does not appear to influence ovarian cancer risk.
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In 2013, it is estimated that there will be 22 240 new cases of ovarian cancer and 14 030 ovarian cancer deaths in the United States (US) alone (1). Since the 1960s, there has been speculation that the use of perineal powder is associated with ovarian cancer. In 2006, the International Agency for Research on Cancer (IARC) reviewed studies examining perineal powder use and ovarian cancer and classified talc as a possible carcinogen (2,3). The proportion of US women ever using talc powder on the perineum was estimated in 2001 to be approximately 40% (4), whereas 52% reported ever use of perineal powder in 1993–1998 within the Women's Health Initiative (WHI) (5).

The primary proposed mechanism linking perineal powder use to ovarian cancer is an inflammatory response (6). Talc particulates from perineal application have been shown to migrate to the ovaries (6), disrupting the surface ovarian epithelial tissue leading to entrapment of the talc particles within inclusion cysts (7). Furthermore, tubal ligation and/or hysterectomy, which would eliminate the pathway of talc particulates to the ovaries, are associated with reduced ovarian cancer risk (6).

A meta-analysis examining the risk of ovarian cancer among ever perineal powder users vs non-users showed odds ratios (ORs)

of 1.40 (95% confidence interval [CI] = 1.29 to 1.52) for population-based case-control, 1.12 (95% CI = 0.92 to 1.36) for hospital based case-control, and 1.35 (95% CI = 1.26 to 1.46) for all case-control studies (2). More recently, a large pooled analysis found that ever use of perineal powder increased epithelial ovarian cancer risk by 24% compared with non-use (OR = 1.24, 95% CI = 1.15 to 1.33) (8). Increased risk was associated with invasive serous, endometrioid, clear cell, and borderline serous subtypes of epithelial ovarian cancer (8). However, when looking at the lifetime number of applications of perineal powder, there was no statistically significant trend for increasing applications, attributed to difficulty in recalling details of frequency and duration of perineal powder use (8).

To date there has only been one prospective study conducted examining perineal powder use and risk of ovarian cancer (9). In the Nurses' Health Study (NHS) cohort, no overall association was found between ever use of perineal powder and epithelial ovarian cancer (relative risk [RR] = 1.09, 95% CI = 0.86 to 1.37) or serous ovarian cancers (RR = 1.26, 95% CI = 0.94 to 1.69) (9). However, there was a 40% (95% CI = 1.02 to 1.91) increase in risk for serous

invasive ovarian cancer with ever perineal powder use, which comprises 86% of serous ovarian cancers in this cohort (9).

Limitations of recall bias and misclassification make it difficult to determine the true relationship between perineal powder (10), a commonly used cosmetic product, and ovarian cancer, a disease with poor survival and few known modifiable risk factors. The prior prospective cohort study, which should not be affected by recall bias, had no information on duration of use limiting interpretation. Here we expand on the available evidence by assessing perineal powder use and risk of ovarian cancer in the Women's Health Initiative Observational Study (WHI-OS). The WHI-OS is a large cohort that collected information on several application areas of perineal powder use and their respective durations of use.

Methods

Study Population

The WHI-OS enrolled 93 676 women from 40 clinical centers across the United States from 1993 to 1998 (11). Women were eligible if they were aged 50 to 79 at enrollment, postmenopausal, and planned to reside in the area for at least three years (11). Women were excluded from the WHI-OS if they were participating in another clinical trial, unlikely to survive three years due to medical conditions, or had conditions that would interfere with study participation (11). Participants completed annual mailed questionnaires to update information on risk factors and outcomes, including ovarian cancer (11). Written informed consent was obtained from participants, and all clinical centers were approved by their respective institutional review boards (11). The current analysis was approved by the University of Massachusetts, Amherst Human Subjects Review Committee.

For this analysis, participants were additionally excluded if they reported a bilateral oophorectomy or an unknown number of ovaries at baseline ($n = 20\,960$), a history of any cancer at baseline except nonmelanoma skin cancer ($n = 10\,622$), or were missing exposure or follow up information ($n = 516$). After applying the exclusion criteria, 61 576 participants with 429 adjudicated incident ovarian cancer cases remained.

Exposure Ascertainment

Perineal powder use was assessed via self-report at baseline. Participants were asked, "Have you ever used powder on your private parts (genital areas)?" Those who responded yes further indicated the duration of use with the following possible responses: less than 1 year, 1–4 years, 5–9 years, 10–19 years, or 20 or more years. For persons that reported ever use of a diaphragm, participants were asked, "Did you ever use powder on your diaphragm?" and those who responded yes further indicated duration. The third category evaluated was "Did you ever use powder on a sanitary napkin or pad?" with those responding yes also reporting duration. Each area of application variable was assessed dichotomously and the duration of use, collapsed into fewer categories because of small numbers, was assessed categorically as never, 9 years or less, or 10 or more years. A combined ever perineal powder variable and duration variable for any powder use was created; where ever use was defined as report of ever use of any of the three application categories, never was report of never use for all three categories,

and duration was the maximum duration reported of any single area of application, because we could not exclude the possibility that applications were concurrent. Lastly, all possible combinations of the three application areas were assessed.

Outcome Ascertainment

Ovarian cancer cases were initially self-reported by participants in the WHI-OS on annual questionnaires. Medical records, including hospital discharge summaries and pathology reports, were requested for each self-reported case and adjudicated by a physician at the local Clinical Center and then centrally by the WHI's Clinical Coordinating Center (11).

Covariate Ascertainment

Potential covariates considered included age, race, education, alcohol servings per week, smoking status, metabolic equivalent (MET) hours per week of recreational physical activity, Body Mass Index (BMI), and self-reported family history of ovarian or breast cancer. Reproductive factors considered were age at menarche, age at menopause, age at first birth, age at last birth, parity, breastfeeding duration, history of tubal ligation, history of hysterectomy, history of irregular cycles, history of endometriosis, duration of oral contraceptive use, and duration of postmenopausal hormone use. All covariates were from baseline and were not updated.

Statistical Analysis

To estimate the association between perineal powder use and ovarian cancer, proportional hazard regression models were used. Participants contributed person-time until diagnosis of ovarian cancer, death, loss to follow-up, or September 17, 2012, whichever came first. Participants with other cancers were still considered at risk for ovarian cancer and were not censored at the time of other cancer diagnoses. Information on incident oophorectomy during follow-up was not available and thus participants were not censored in this analysis. The proportional hazards assumption was tested using weighted Schoenfeld residuals.

Covariates were included in the adjusted model according to purposeful selection, where covariates with Wald P values of .25 or less in age-adjusted models were entered into an initial multivariable model and then each covariate was subsequently tested individually via likelihood ratio tests in order of decreasing Wald P values. Variables that had P values of .10 or less during the backwards elimination were kept in the model until a parsimonious model was obtained. Additional variables shown in previous literature (8,9) but not statistically significant in our population were also included in the final multivariable model. Lastly, family history of breast cancer and personal history of endometriosis did not change estimates and were not included in the final multivariable model.

Models fitted included the following independent variables: 1) combined ever perineal powder use, 2) ever powder use by application area (ie, applied to genitals, applied to diaphragm, or applied to sanitary napkins), 3) duration of use by application area, and 4) application area combinations (ie, genital only, diaphragm only, sanitary napkin only, genital and sanitary napkin, genital and diaphragm, diaphragm and sanitary napkin, and all three areas of application). For duration models, test for trend was used to evaluate linear trends across duration categories by modeling the

categories as a continuous variable in the multivariable regression models.

Because powder particles may not reach the ovaries due to tubal ligation and because previous studies have shown a stronger association between powder use and ovarian cancer in women without tubal ligation (4), we separately examined women without tubal ligation. We also stratified by age at baseline, because older women may have had more potential for exposure to talc contaminated with asbestos. Additionally, associations by ovarian cancer histological subtype were evaluated. All analyses were performed using Stata v.12.1 (StataCorp, College Station, TX) and two-sided *P* values of .05 or less were considered statistically significant.

Results

The average age of the participants at baseline was 63.3 years. Participants were followed for a mean of 12.4 years; never powder users were followed for a mean of 12.2 years (range = 0.12 to 17.9 years) and ever powder users were followed for a mean of 12.6 years (range = 0.03 to 18.0). The majority of the participants were white (83.7%), had less than a college degree (56.1%), and were overweight/obese (57.2%). Approximately half (52.6%) of the population reported ever use of perineal powder. Ever powder users were heavier (27.5 kg/m² vs 26.5 kg/m², *P* < .0001) and were more likely to have used oral contraceptives (44% vs 36%, *P* < .0001) and/or diaphragms (50.8% vs 37.3%, *P* < .0001) than never users (Table 1).

Use of powder on the genitals was associated with a 12% increase in the multivariable-adjusted hazard ratio of ovarian cancer (HR_{adj} = 1.12, 95% CI = 0.92 to 1.36), though this was not statistically significant (Table 2). Use of powder on sanitary napkins (HR_{adj} = 0.95, 95% CI = 0.76 to 1.20) or diaphragms (HR_{adj} = 0.92, 95% CI = 0.68 to 1.23) also was not associated with risk. Duration of powder use on the genitals, sanitary napkins, or on the diaphragm was not associated with ovarian cancer; *P*_{trend} for years of use: .67, .69, and .67 respectively. Combined ever powder use from any of the three application areas did not show an association with ovarian cancer risk (HR_{adj} = 1.06, 95% CI = 0.87 to 1.28). For combined duration of use, which was the longest duration of use among the three areas of application, there was no evidence of an association with risk of ovarian cancer [*P*_{trend} for years of use: .77]. Use of powder on genitals, the most common application area, for 20 or more years was not associated with increased risk of ovarian cancer compared with never users (HR_{adj} = 1.10, 95% CI = 0.82 to 1.48). In a sensitivity analysis, invasive serous ovarian cancer risk was not increased (HR_{adj} = 0.96, 95% CI = 0.65 to 1.41), even in women reporting durations of use greater than 10 years.

There was no evidence of an association between perineal powder use and ovarian cancer risk by category of application (Table 3). Combined ever powder use was not associated with individual subtypes of ovarian cancer (Table 4). The multivariable-adjusted hazard ratio for serous ovarian cancer was 1.16 (95% CI = 0.88 to 1.53). Additionally, duration of combined ever powder use was also not shown to be associated with any subtype of ovarian cancer (results not shown).

The associations of combined ever powder use and ovarian cancer did not statistically differ by tubal ligation status (results not shown). When stratified by age group at baseline, hazard estimates also did not statistically differ (*P*_{interaction} = .37); HR_{adj} for younger than

Table 1. Characteristics of postmenopausal women according to perineal powder use status (n = 61 285): Women's Health Initiative Observational Study, 1993–2012

Characteristic, n (%)	Never perineal powder use	Ever perineal powder use
	n = 29 066	n = 32 219
Race		
White	24 006 (82.6)	27 336 (84.8)
Nonwhite	4 991 (17.2)	4 811 (14.9)
Body mass index category, kg/m ²		
<25.0	13 056 (44.9)	12 461 (38.7)
25.0–29.9	9 734 (33.5)	10 799 (33.5)
30.0 +	5 935 (20.4)	8 571 (26.6)
Smoking status		
Never	15 347 (52.8)	15 621 (48.5)
Past	11 481 (39.5)	14 339 (44.5)
Current	1 912 (6.6)	1 881 (5.8)
Duration of oral contraceptive use, y		
Never	17 877 (61.5)	17 954 (55.7)
<5	6 241 (21.5)	7 858 (24.4)
5 to <10	2 528 (8.7)	3 270 (10.2)
10 to <15	1 650 (5.7)	2 125 (6.6)
15+	760 (2.6)	1 005 (3.1)
Diaphragm use	10 826 (37.3)	16 353 (50.8)
Tubal ligation	4 929 (17.0)	5 901 (18.3)
Hysterectomy	6 878 (23.7)	8 285 (25.7)
Family history of ovarian cancer	606 (2.1)	660 (2.1)
Parity		
0	3 687 (12.7)	3 769 (11.7)
1–2	9 773 (33.6)	11 585 (36.0)
3–4	11 101 (38.2)	12 609 (39.1)
5+	4 365 (15.0)	4 098 (12.7)
Age at last birth, y		
Never had term pregnancy	6 219 (21.4)	6 260 (19.4)
< 20	210 (0.7)	324 (1.0)
20–29	9 143 (31.5)	11 480 (35.6)
30+	13 011 (44.8)	13 668 (42.4)
Duration of postmenopausal hormone use, y		
Never	13 381 (46.0)	13 880 (43.1)
<5	6 498 (22.4)	7 546 (23.4)
5 to <10	3 783 (13.0)	4 567 (14.2)
10 to <15	2 688 (9.3)	3 128 (9.7)
15+	2 716 (9.3)	3 097 (9.6)

50 to 59 years = 1.29, 95% CI = 0.91 to 1.82; HR_{adj} for those 60 to 69 years = 0.94, 95% CI = 0.70 to 1.26; and HR_{adj} for those 70 to 79 years = 1.01, 95% CI = 0.68 to 1.48. When restricted to only whites or to those who had never used oral contraceptives, results were again unchanged.

Discussion

In this large prospective study, ever perineal powder use was not associated with ovarian cancer risk, nor was it associated with ovarian cancer when assessed by area of application, duration of use, or ovarian cancer subtype. While many case-control studies have shown an approximately 24–40% increase in risk of ovarian cancer (2,8) for powder users, we did not find evidence of this association in our large, prospective analysis.

The meta-analysis of 20 case-control studies by Langseth and colleagues found a 35% increase in the odds of epithelial ovarian

Table 2. Age and multivariable-adjusted hazard ratios of ovarian cancer by area of perineal powder application (n = 61576): Women's Health Initiative Observational Study, 1993–2012

Variable	No. of cases	Person-years	Age-adjusted HR		Multivariable HR*	
			(95% CI)	<i>P</i> _{trend} †	(95% CI)	<i>P</i> _{trend} †
Powder use on genitals						
Never	247	457855	1.0 (referent)	.63	1.0 (referent)	.67
Ever‡	181	304867	1.13 (0.93 to 1.37)		1.12 (0.92 to 1.36)	
Less than 9 years	112	173118	1.24 (0.99 to 1.55)		1.23 (0.98 to 1.54)	
10 or more years	68	129647	0.98 (0.75 to 1.29)		0.98 (0.75 to 1.29)	
Powder use on sanitary napkins						
Never	336	590351	1.0 (referent)	.70	1.0 (referent)	.69
Ever‡	93	172712	0.96 (0.76 to 1.21)		0.95 (0.76 to 1.20)	
Less than 9 years	62	114305	0.98 (0.75 to 1.28)		0.96 (0.73 to 1.26)	
10 or more years	30	56174	0.93 (0.64 to 1.35)		0.95 (0.65 to 1.37)	
Powder use on diaphragm						
Never	373	661239	1.0 (referent)	.78	1.0 (referent)	.67
Ever‡	52	97714	0.94 (0.70 to 1.25)		0.92 (0.68 to 1.23)	
Less than 9 years	35	67468	0.93 (0.66 to 1.32)		0.91 (0.64 to 1.30)	
10 or more years	17	29202	0.99 (0.61 to 1.60)		0.95 (0.58 to 1.56)	
Combined ever powder use§						
Never	197	361583	1.0 (referent)	.67	1.0 (referent)	.77
Ever‡	232	404983	1.07 (0.89 to 1.30)		1.06 (0.87 to 1.28)	
Less than 9 years	135	228931	1.12 (0.90 to 1.39)		1.09 (0.88 to 1.36)	
10 or more years	97	173307	1.03 (0.81 to 1.31)		1.02 (0.80 to 1.30)	

* Adjusted for: Age (continuous), race (white, nonwhite, missing), oral contraceptive duration in years (never, <5, 5 to <10, 10 to <15, 15+, missing), hormone replacement therapy duration in years (never, <5, 5 to <10, 10 to <15, 15+, missing), family history (yes, no, missing), age (y) at last birth (never, <20, 20 to <30, 30+, missing), body mass index in kg/m² (<25.0, 25.0 to <30.0, 30.0+, missing), smoking (never, past, current, missing), tubal ligation (yes, no, missing), and parity (0, 1 to 2, 3 to 4, 5+, children, missing).

† Hazard ratios (HRs) and 95% confidence intervals (CIs) were estimated in cox proportional hazard regression models; *P*_{trend} was estimated by modeling categories as continuous. All statistical tests were two-sided.

‡ Person-years may not add up; duration information was missing for some.

§ Combined ever powder use is the longest duration of use among the applications to genitals, sanitary napkins, and diaphragms.

Table 3. Age and multivariable-adjusted hazard ratios for ovarian cancer by combined categories of powder use (n = 61576): Women's Health Initiative Observational Study, 1993–2012

Variable	No. of cases	Person-years	Age-adjusted HR*	Multivariable HR*
			(95% CI)	(95% CI)
Powder Type Used				
No powder	193	355523	1.0 (referent)	1.0 (referent)
Only genital powder	96	158130	1.14 (0.90 to 1.46)	1.13 (0.88 to 1.45)
Only diaphragm powder	19	42367	0.82 (0.51 to 1.32)	0.80 (0.50 to 1.29)
Only sanitary napkin powder	28	50051	1.04 (0.70 to 1.54)	1.01 (0.68 to 1.50)
Genital and sanitary napkin powder	55	96173	1.09 (0.80 to 1.47)	1.08 (0.80 to 1.46)
Genital and diaphragm powder	24	29858	1.49 (0.98 to 2.28)	1.45 (0.95 to 2.23)
Diaphragm and sanitary napkin powder	4	6858	1.06 (0.40 to 2.86)	1.02 (0.38 to 2.74)
Genital, diaphragm, and sanitary napkin powder	5	18331	0.51 (0.21 to 1.24)	0.50 (0.21 to 1.22)

* Hazard ratios (HRs) and 95% confidence intervals (CIs) were estimated in cox proportional hazard regression models. All statistical tests were two-sided. Multivariable HR adjusted for: age (continuous), race (white, nonwhite, missing), oral contraceptive duration in years (never, <5, 5 to <10, 10 to <15, 15+, missing), hormone replacement therapy duration in years (never, <5, 5 to <10, 10 to <15, 15+, missing), family history (yes, no, missing), age (y) at last birth (never, <20, 20 to <30, 30+, missing), body mass index in kg/m² (<25.0, 25.0 to <30.0, 30.0+, missing), smoking (never, past, current, missing), tubal ligation (yes, no, missing), and parity (0, 1 to 2, 3 to 4, 5+, children missing).

cancer among ever perineal powder users compared to never-users (2), and the pooled analysis of eight case-control studies by Terry and colleagues found a 24% increase in the same group (8). Langseth and colleagues did not assess dose-response or risk among subtypes of ovarian cancer (2). Terry and colleagues assessed lifetime applications of perineal powder and found no statistically significant trend with increasing lifetime applications (8). This corroborates our results that there was no statistically significant risk with increasing duration

of perineal powder use, though they were able to capture both frequency and duration (8), whereas we only had duration. Terry and colleagues found elevated risks for invasive serous, borderline serous, endometrioid, and clear cell subtypes of ovarian cancer (8), which we did not observe. One potential reason that case-control studies have found slight increases in risk is the potential for an overestimation of the true association due to recall bias, because the participants are aware of their ovarian cancer status when reporting powder

Table 4. Age and multivariable-adjusted hazard ratios for combined ever powder use by subtype of ovarian cancer (n = 61 576): Women's Health Initiative Observational Study, 1993–2012

Variable	No. of cases	Person-years	Age-adjusted HR*	Multivariable HR*
			(95% CI)	(95% CI)
Serous†				
Never	87	355 523	1.0 (referent)	1.0 (referent)
Ever	117	404 983	1.18 (0.89 to 1.56)	1.16 (0.88 to 1.53)
Serous Invasive				
Never	80	355 523	1.0 (referent)	1.0 (referent)
Ever	105	404 983	1.16 (0.87 to 1.55)	1.13 (0.84 to 1.51)
Mucinous				
Never	12	355 523	1.0 (referent)	1.0 (referent)
Ever	13	404 983	0.98 (0.44 to 2.14)	1.03 (0.47 to 2.27)
Endometrioid				
Never	13	355 523	1.0 (referent)	1.0 (referent)
Ever	20	404 983	1.39 (0.69 to 2.79)	1.29 (0.64 to 2.61)
Other				
Never	47	355 523	1.0 (referent)	1.0 (referent)
Ever	54	404 983	1.04 (0.71 to 1.54)	1.04 (0.70 to 1.54)

* Hazard ratios (HRs) and 95% confidence intervals (CIs) were estimated in cox proportional hazard regression models. All statistical tests were two-sided. Multivariable HR adjusted for: age (continuous), race (white, nonwhite, missing), oral contraceptive duration in years (never, <5, 5 to <10, 10 to <15, 15+, missing), hormone replacement therapy duration in years (never, <5, 5 to <10, 10 to <15, 15+, missing), family history (yes, no, missing), age (y) at last birth (never, <20, 20 to <30, 30+, missing), body mass index in kg/m² (<25.0, 25.0 to <30.0, 30.0+, missing), smoking (never, past, current, missing), tubal ligation (yes, no, missing), and parity (0, 1 to 2, 3 to 4, 5+, children missing).

† Includes borderline cancers.

exposure. The prospective nature of our study would eliminate the potential for recall bias. Additionally, the case-control studies tended to have a younger population than our study, which included both premenopausal and postmenopausal ovarian cancers (2,8), whereas the WHI cohort consisted only of postmenopausal ovarian cancers. Ovarian cancer that occurs prior to menopause may have a different etiology than ovarian cancer occurring afterwards.

We found similar results to that of the NHS, the only other prospective cohort, which had a similar sample size and number of ovarian cancer cases to our study. Ever use of perineal powder did not appear to be associated with ovarian cancer in the NHS (9), similar to our findings. The results of Gertig and colleagues were also null for use on the genitals and for use on sanitary napkins (9). Additionally, neither our study nor the NHS found associations with serous ovarian cancer, endometrioid, or mucinous ovarian cancers, although subgroup sample size may have reduced statistical power to test these associations. In contrast to our results, the study by Gertig and colleagues found a 40% increase in invasive serous ovarian cancer among ever powder users compared with never powder users (9).

Strengths of our study included large sample size with a substantial number of ovarian cancer cases, a prospective cohort design, good case ascertainment, and detailed information on most ovarian cancer risk factors. We also had information on duration of powder use, qualifiers not available in several earlier studies, including the previous cohort study (2,8,9).

One potential limitation of our analyses includes a lack of information regarding oophorectomy after baseline, which would result in the inclusion of some women not at risk for ovarian cancer in the analytical cohort. However, the impact was likely to be minor, as a previous study in the WHI-OS had reported the number of persons with incident bilateral oophorectomies to be less than 250 (out of more than 90 000 participants) during nearly eight years of follow-up (12). While the prospective nature of the study design

eliminates recall bias, it does not eliminate potential for nondifferential misclassification of the exposure. Women still needed to recall past perineal powder use and duration and thus may have trouble recollecting specifics regarding the use of perineal powder, leading to a bias toward the null. Information regarding powder use was not collected after baseline, and there is potential for never users to begin using powder; however, this is unlikely because the women are postmenopausal, reducing need to use perineal powder on diaphragms or sanitary napkins. We also had no specific data regarding the frequency of powder use in our sample. Frequency of use, as well as duration may influence ovarian cancer risk. We may have been comparing long-term infrequent users with short-term frequent users. If we had frequency of use in addition to the duration, we could have looked at intensity of use, which may be more accurate, and shown a dose response relationship. However, Terry and colleagues did not find a dose response relationship either when taking into account frequency and duration (8).

When restricted to women without tubal ligation status, the estimates for the association between combined ever perineal powder use and ovarian cancer were not increased. While some studies have found stronger associations between powder use and ovarian cancer in women that have not undergone a tubal ligation (4), the results from our study did not support this previous finding. The pooled analysis (8) and the NHS cohort (9) also did not find evidence of stronger associations in women without tubal ligations.

While we had information on duration of use, it is unknown during which years the perineal powder was used. Talc powder had potential for asbestos contamination (13) until 1976, when the Cosmetic, Toiletry, and Fragrance Association required all cosmetic talc products to be free of asbestos (14). Therefore, those using powder prior to 1976 may have been potentially exposed to asbestos, a known carcinogen. The pooled analysis and meta-analysis also included case-control studies not within the United States

(2,8), which potentially have different regulations regarding perineal powder and earlier studies that may have been more likely to include exposure to contaminated perineal powder (2). However, risk estimates in more recent studies are similar to earlier studies (2), reducing the likelihood that confounding by asbestos is driving the findings. Additionally, assuming older women in the cohort could have been exposed longer to perineal powder with potential contamination compared with younger women, we did not see statistically significant differences in risk when stratified by age group, further suggesting asbestos contamination is not a likely explanation.

The WHI-OS queried general perineal powder use rather than talc powder use, and we had no specific information regarding the content of talc in products used, which the previous literature reviewed by IARC suggested to be the possible carcinogen of concern (2). However, the NHS cohort and most studies included within the pooled analyses asked about general perineal powder use as well (2,8,9). In summary, perineal powder use did not appear to be associated with ovarian cancer risk in this large sample of postmenopausal women, even with use for long durations.

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Notes

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January 1, 2015

Talcum Powder...the 'Pluto' of Prognostic Factors for Ovarian Cancer

Special Feature

By Robert L. Coleman, MD Professor, University of Texas; M.D. Anderson Cancer Center, Houston
Dr. Coleman reports no financial relationships relevant to this field of study.

Talcum Powder...the 'Pluto' of Prognostic Factors for Ovarian Cancer

Synopsis: A large prospective cohort study of perineal talc use demonstrated no increased risk of ovarian cancer overall or within any histological subtype. In addition, no association with talc application method was observed.

Source: Houghton SC, et al. Perineal powder use and risk of ovarian cancer. *J Natl Cancer Inst* 2014;106:dju208 doi:10.1093/jnci/dju208.

Risk for ovarian cancer has been linked to talcum powder use for several years. Its structural properties and its historical link to asbestos have driven the biological plausibility. The preponderance of data to support this association has come from case-control studies; however, the only prospective cohort study from the Nurse's Health Study did not show this effect, with the exception of serous invasive ovarian cancers. The current analysis from the Women's Health Initiative Observational Study cohort prospectively assessed perineal powder use and risk of ovarian cancer. In this study, perineal powder use was assessed at baseline by self-report regarding application to genitals, sanitary napkins, or diaphragms and duration of use. The primary outcome was self-reported ovarian cancer centrally adjudicated by physicians. Cox proportional hazard regression was used to estimate risk, adjusting for covariates, including person-time until diagnosis of ovarian cancer (n = 429), death, loss to follow-up, or September 17, 2012. A total of 61,576 postmenopausal women without a history of cancer or bilateral oophorectomy were followed for a mean of 12.4 years. Fifty-three percent reported ever using perineal powder. Ever use of perineal powder (hazard ratio [HR] 1.06; 95% confidence interval [CI], 0.87-1.28) was not associated with risk of ovarian cancer compared with never use. Individually, ever use of powder on the genitals (HR = 1.12; 95% CI, 0.92-1.36), sanitary napkins (HR, 0.95; 95% CI, 0.76-1.20), or diaphragms (HR, 0.92; 95% CI, 0.68-1.23) was not associated with risk of ovarian cancer compared with never use, nor were there associations with increasing durations of use. There was no association between ever use and ovarian cancer histology, including invasive serous cancer. Estimates did not differ when stratified by age or tubal ligation status. Based on these findings, perineal powder use does not appear to influence ovarian cancer risk.

Commentary

The discovery of prognostic factors in any disease serves not only to provide insight into disease pathogenesis, such as obesity and endometrial cancer with the implication of estrogen, but also to explore potential preventive interventions that can modulate risk, such as use of coagulation and cardiovascular disease with aspirin. In ovarian cancer, the most lethal of all the gynecologic cancers, prognostic factors carry added value as they highlight potential modifiable habits that might also impact mortality.

As most are aware, ovarian cancer usually presents when the disease is widespread, causing symptoms of bloating, pelvic pressure, early satiety, and bladder dysfunction. 2 Although these symptoms are frequently reported by patients in whom the diagnosis is ultimately made, the disconnection between a specific set of symptoms and stage of disease challenges any attempt to use this approach to modify mortality. Screening of otherwise normal women has also presented significant challenges for ovarian cancer. The disease is rare and has low prevalence even in menopausal women. This places substantial pressure on the performance of testing that would be utilized in a triage algorithm. The most frequently used screening modalities are the combination of examination, biomarkers such as CA125, and imaging such as transvaginal ultrasound. While these approaches have value in identifying women with the disease, the way in which they are implemented in an asymptomatic population, including recognition of abnormality (what's abnormal?), frequency of testing (yearly? every 6 months? every 3 months?), and intervention of aberration (repeat assessment? referral? surgery?), is critical to the goal of identifying disease that is different from a non-screened population. In a disease like ovarian cancer, in which a clearly defined preinvasive state is not universally recognized or identifiable, the ultimate endpoint of a screening program is "stage shifting," or the alteration in the proportion of women diagnosed with earlier stage disease relative to the general population. Since stage I ovarian cancer is highly curable, this is a reasonable strategy to reduce mortality.

Unfortunately, stage I ovarian cancer is usually diagnosed by serendipity. Indeed, a report from the Prostate, Lung, Colorectal and Ovarian cancer screening trial demonstrated once-a-year screening with CA125 and transvaginal ultrasound not only did not increase the number of early-stage cases, but it increased morbidity due to complications from unnecessary surgery. 3 The United Kingdom Collaborative Trial of Ovarian Cancer Screening (UKCTOCS) randomized screening trial of more than 200,000 menopausal women assessing two different diagnostic triage algorithms (vs standard of care) in asymptomatic menopausal women has completed accrual and is expected to report in 2015. This trial's primary endpoint is overall survival. An initial report of the prevalence data from the two screening algorithms demonstrated an efficiency and precision difference among women undergoing referral and surgical intervention. 4 A separate prospective cohort study utilizing a two-step risk of ovarian cancer algorithm (ROCA), which, incidentally, is similar to one of the two screening strategies being utilized in the UKCTOCS trial, showed promise of the stage migration effect. 5 In this trial, 4051 asymptomatic menopausal women underwent annual CA125 and utilized a ROCA mathematical algorithm to provide risk estimates of ovarian cancer. The resulting "low-," "intermediate-," and "high-risk" designation proscribed the next intervention, namely, repeat annual CA125, repeat CA125 in 3 months, and transvaginal ultrasound and gynecologic oncology referral, respectively. Ten women ultimately underwent surgical intervention, and four invasive ovarian cancers were found (40% positive predictive value; one stage IA, two stage IC and one stage IIC). While promising, proper evaluation of this approach will require the sample size, follow-up, and design (control group) of the UKCTOCS trial to assess the ultimate merit of screening in this disease.

Thus, in the absence of effective screening, attention has focused on prevention strategies. Many of these interventions, such as oral contraceptives, aspirin, salpingectomy, salpingo-oophorectomy, and tubal ligation, were identified as significant prognostic factors associated with reduced odds of diagnosis. 1 As intuitive as these factors may seem and as easy as they are to identify, the business of properly assigning risk and the directionality of effect (positive, negative, or neutral) is much more difficult. In addition, the leap from identification of a prognostic factor to the effect of modulating risk by doing some sort of intervention (medication, surgery, habit alteration) based on that factor is a substantial gamble. Prognostic factors that accurately reflect the risk of developing a disease in a population require careful assessment of exposures. Most of the trials that serve to identify risk and the associated factors are done in retrospect and are subject to a profound effect of recall bias. 6 It's not hard to imagine that a woman with advanced stage ovarian cancer following surgery and chemotherapy might attribute blame to a specific habit, such as talcum powder use, and the amount of exposure differently relative to a woman without disease. Studies of oral contraceptive use, a noted prognostic factor associated with reduced risk of ovarian cancer, where centralized records of prescriptive practice exist, highlight this recall bias effect. In addition, accuracy of intended exposure, such as prescriptions made and actual use, provide another element of bias that is difficult to control. So while retrospective case-control trials are the primary resource from which prognostic factors are developed, they are often fraught with substantial bias hurdles that can lead to inconclusive or even disparate findings.

Such is the case with talcum powder. Talc is a water-absorbing mineral composed of magnesium silicate that has structural similarities and co-occurs with asbestos. The link of asbestos and cancer is relatively strong, so the implication of talc and cancer has been long suspected. The mechanism through which asbestos causes cancer is not completely understood, but its induction of a chronic inflammatory response and alteration in local immunogenicity to antigens in the microenvironment have been documented. Both of these factors have also been implicated in the carcinogenesis of ovarian cancer. Talc is a frequent component of genital powders and is usually applied directly on the perineal skin in a variety of ways. Historically, talcum powders used in cosmetics were not purified talc and had contamination with asbestos factors. However, in 1976, the Cosmetic, Toiletry and Fragrance Association (now known as the Personal Care Products Council) issued stringent purity standards for talc used in cosmetics, including specifications that talc must contain no detectable fibrous asbestos mineral. Nevertheless, talc fibers have been identified in the vagina, cervix, uterus, and ovaries in women who have reported perineal talc use. The quantity of these fibers is substantially reduced in ovarian tissue relative to the vagina and, while granulomatous inclusions have also been identified, the direct association of these foreign body reactions and cancer has not been observed. A comprehensive analysis of the safety assessment of talc used in cosmetics was conducted in 2006 by the International Agency for Research on Cancer's Cosmetic Ingredient Review Expert Panel and released for public consumption 2010. ⁷ In this report, toxicokinetics, preclinical and clinical toxicology, reproductive and developmental toxicity, genotoxicity, and carcinogenicity were extensively reviewed. Their concluding statement is summarized:

In 2010, the IARC Working Group determined that there is limited evidence in experimental animals for the carcinogenicity of talc not containing asbestos or asbestiform fibers.... For humans, the evaluation of the IARC working group was that perineal use of talc-based body powder is possibly carcinogenic to humans (Group 2B) , and that inhaled talc not containing asbestos or asbestiform fibers is not classifiable as to its carcinogenicity (Group 3) . In evaluating the carcinogenicity of talc in humans, the Working Group reviewed cohort studies of talc miners and millers, cohort and case-controlled studies examining the association of cosmetic talc use and the risk of ovarian cancer in humans, and the animal data and evidence regarding the potential mechanisms through which talc might cause cancer in humans. The Working Group found there is inadequate evidence in humans for the carcinogenicity of inhaled talc not containing asbestos or asbestiform fibers and there is limited evidence in humans for the carcinogenicity of perineal use of talc-based body powder.

The strength of their Group 2B conclusion rested on the volumes of retrospective reports, including a meta-analysis of 20 case-control studies and a pooled analysis of eight other population-based, case-control studies implicating a risk of up to 35% between talc use in perineal powders and ovarian cancer. However, the only two prospective cohort studies, including the current trial from the Women's Health Initiative Observational Study, provided no association. ⁸ The current trial is the largest prospective trial to assess the implied risk and is strengthened by its low risk of recall bias. However, only data on duration of use (vs duration and frequency of use) were available. To date, a dose-response relationship has not been made.

In again...out again...what conclusions/recommendations can be made about talc and ovarian cancer? One clear assurance is that talcum powder used in cosmetics is regulated to be asbestos free. Second, evidence of migration of talc fibers from the perineum to the fallopian tubes and ovaries is present, but is devoid of the asbestos-inducing inflammatory response, disrupting the biological plausibility of talc exposure and cancer. Third, the strength of association, if present at all, is weak and the current study's design and conclusions should be reassuring to users. Finally, it is unlikely that modifying exposure to this "Pluto of a prognostic factor" will modulate any potential diagnostic risk or mortality from ovarian cancer.

References

---- Index References ----

News Subject: (Health & Family (1HE30); Health & Wellness (1HE60))

Industry: (Financial Services (1FI37); Healthcare (1HE06); Healthcare Practice Specialties (1HE49); Insurance (1IN97); Insurance Liability (1IN26); Internal Medicine (1IN54); Lead Paint & Asbestos (1LE49); Oncology & Hematology (1ON95); Women's Health (1WO30))

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NewsRoom

TALCUM POWDER CASES PENDING THROUGHOUT THE COUNTRY

No.	PLAINTIFF(S)	COURT & CAUSE No.
FEDERAL COURT CASES-4, with 1 pending dismissal		
1.	BISHOP, LINDA	USDC, So. Dist. of IL; 3:14-cv-01081-MJR-SCW
2.	BLAES, MICHAEL (Shawn Blaes, dec'd)	USDC E.D. MO, Eastern Div; 4:14-cv-00213-RLW
3.	CEBULSKE, LYNNE (Notice of Dismissal Pending)	USDC, So. IL; 14-627-MJR-SCW
4.	CHAKALOS, JAMES (JANICE CHAKALOS, DEC'D)	USDC, NJ; 3:14-cv-07079-AET-LHG
5.	HARLAN, JUDYTH	USDC, IL, East St. Louis Division; 3:15-cv-00418
DC SUPERIOR COURT-1 CASE		
6.	OULES, LORI	District of Columbia Superior Court, DC 2014 CA 008327 B (Civil Calendar 12 – Judge Brian Holeman)
ILL STATE COURT-1 CASE		
7.	LEWIS, CANDACE	Madison County Circuit Ct, IL; Edwardsville 2015L-0409
MO STATE COURT CASES – 9 CASES		
8.	DUNN, PEGGY, ET AL (56 Plaintiffs)	MO Circuit Court, 22 nd Judicial Circuit, City of St. Louis; 1422-CC10042, Division 17
9.	DYSART, PATRICIA J. (53 Plaintiffs)	MO Circuit Court, 22 nd Judicial Circuit, City of St. Louis; 1522-CC00167, Division 16
10.	FARRAR, TENESHA, ET AL (98 Plaintiffs)	MO Circuit Court, 22 nd Judicial Circuit, City of St. Louis; 1422-CC09964, Division 17
11.	FORREST, VICKIE, ET AL (83 Plaintiffs)	MO Circuit Court, 22 nd Judicial Circuit, City of St. Louis; 1522-CC00419

No.	PLAINTIFF(S)	COURT & CAUSE No.
12.	HOGANS, TIFFANY, ET AL (65 Plaintiffs)	MO Circuit Court, 22 nd Judicial Circuit, City of St. Louis; 1422-CC09012, Division 17
13.	LIVAUDAIS, SHARON (77 Plaintiffs)	MO Circuit Court, 22 nd Judicial Circuit, City of St. Louis; 1522-CC00613
14.	LOYD, LEEWING, SR., ET AL (64 Plaintiffs)	MO Circuit Court, 22 nd Judicial Circuit, City of St. Louis; 1422-CC09821, Division 17
15.	MCCULLEN, ALICE (73 Plaintiffs)	MO Circuit Court, 22 nd Judicial Circuit, City of St. Louis; 1522-CC00811
16.	SWANN, VALERIE (62 Plaintiffs)	MO Circuit Court, 22 nd Judicial Circuit, City of St. Louis; 1422-CC09326-01, Division 17

<p>JENNY APPLEWHITE, Plaintiff,</p> <p>v.</p> <p>JOHNSON & JOHNSON, et al., Defendants.</p>	<p>SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY</p> <p>DOCKET NO. ATL-L-1995-14</p> <p>CIVIL ACTION</p> <p>FILED MAY 14 2015 NELSON C. JOHNSON, J.S.C.</p>
<p>BARBARA CALDERON, Plaintiff,</p> <p>v.</p> <p>JOHNSON & JOHNSON, et al., Defendants.</p>	<p>SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY</p> <p>DOCKET NO. ATL-L-1985-14</p> <p>CIVIL ACTION</p>
<p>MOLLY CHESTEEN and RANDY CHESTEEN, Plaintiffs,</p> <p>v.</p> <p>JOHNSON & JOHNSON, et al., Defendants.</p>	<p>SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY</p> <p>DOCKET NO. ATL-L-414-14</p> <p>CIVIL ACTION</p>
<p>RITZIE DONALD, Plaintiff,</p> <p>v.</p> <p>JOHNSON & JOHNSON, et al., Defendants.</p>	<p>SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY</p> <p>DOCKET NO. ATL-L-1528-14</p> <p>CIVIL ACTION</p>

<p>DEBORAH DONALS, Plaintiffs,</p> <p>v.</p> <p>JOHNSON & JOHNSON, et al., Defendants.</p>	<p>SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY</p> <p>DOCKET NO. ATL-L-2394-14</p> <p>CIVIL ACTION</p>
<p>DORIS JONES, Plaintiff,</p> <p>v.</p> <p>JOHNSON & JOHNSON, et al., Defendants.</p>	<p>SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY</p> <p>DOCKET NO. ATL-L-772-14</p> <p>CIVIL ACTION</p>
<p>LYNN GAUTHIER, Plaintiff,</p> <p>v.</p> <p>JOHNSON & JOHNSON, et al., Defendants.</p>	<p>SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY</p> <p>DOCKET NO. ATL-L-3568-14</p> <p>CIVIL ACTION</p>
<p>LATODRA LEE, INDIVIDUALLY AND AS ADMINISTRATOR OF THE ESTATE OF LAVONDA LEE, DECEASED, Plaintiffs,</p> <p>v.</p> <p>JOHNSON & JOHNSON, et al., Defendants.</p>	<p>SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY</p> <p>DOCKET NO. ATL-L-2592-14</p> <p>CIVIL ACTION</p>

<p>DEBORAH SANDLAUFER and DOUGLAS SANDLAUFER,</p> <p>Plaintiffs,</p> <p>v.</p> <p>JOHNSON & JOHNSON, et al.,</p> <p>Defendants.</p>	<p>SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY</p> <p>DOCKET NO. ATL-L-2396-14</p> <p>CIVIL ACTION</p>
<p>AGNES SPURLOCK,</p> <p>Plaintiff,</p> <p>v.</p> <p>JOHNSON & JOHNSON, et al.,</p> <p>Defendants.</p>	<p>SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY</p> <p>DOCKET NO. ATL-L-3778-14</p> <p>CIVIL ACTION</p>
<p>EMILY SULLIVAN,</p> <p>Plaintiffs,</p> <p>v.</p> <p>JOHNSON & JOHNSON, et al.,</p> <p>Defendants.</p>	<p>SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY</p> <p>DOCKET NO. ATL-L-5142-14</p> <p>CIVIL ACTION</p>
<p>LINDA SYKES, INDIVIDUALLY AND AS ADMINISTRATOR OF THE ESTATE OF BRENDA PHILLIPS, DECEASED,</p> <p>Plaintiffs,</p> <p>v.</p> <p>JOHNSON & JOHNSON, et al.,</p> <p>Defendants.</p>	<p>SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY</p> <p>DOCKET NO. ATL-L-3330-14</p> <p>CIVIL ACTION</p>

<p>CRAIG WERNER, INDIVIDUALLY AND AS ADMINISTRATOR OF THE ESTATE OF BARBARA WERNER, DECEASED,</p> <p style="text-align: center;">Plaintiffs,</p> <p>v.</p> <p>JOHNSON & JOHNSON, et al.,</p> <p style="text-align: center;">Defendants.</p>	<p>SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY</p> <p>DOCKET NO. ATL-L-1800-14</p> <p style="text-align: center;">CIVIL ACTION</p>
<p>MICHELLE WHITE,</p> <p style="text-align: center;">Plaintiffs,</p> <p>v.</p> <p>JOHNSON & JOHNSON, et al.,</p> <p style="text-align: center;">Defendants.</p>	<p>SUPERIOR COURT OF NEW JERSEY LAW DIVISION: ATLANTIC COUNTY</p> <p>DOCKET NO. ATL-L-2590-14</p> <p style="text-align: center;">CIVIL ACTION</p>

CASE MANAGEMENT ORDER NO. 2

THIS MATTER having come before the Court with the consent of all Counsel, and for good cause having been shown, the Court hereby enters the following order:

It is on this 14th day of May, 2015, ORDERED as follows:

- 1) Pursuant to Rule 4:38-1, the Court hereby, *sua sponte*, consolidates the fourteen above captioned matters, and all matters listed on the attached Exhibit A for purposes of pre-trial discovery only. Unless otherwise requested by counsel or directed by the Court, these matters shall proceed to trial separately.

Plaintiff Discovery

2) In the 14 matters listed above, each Plaintiff shall complete and serve upon Defendants all outstanding discovery deficiencies and HIPAA compliant Medical Records Authorization Form for all treaters, providers, hospitals, employers, insurance carriers and government agencies, on or before May 22, 2015.

- a. The scope of production of mental health records and government agency records to be conferred on between the parties.
- b. For Non-OB/GYN providers, Plaintiffs shall execute authorizations for the release of records during the period from five years prior to the diagnosis of cancer to the present.
- c. For OB/GYN providers, Plaintiff shall execute authorizations for the release of records during the period from ten years prior to the diagnosis of cancer to the present.
- d. Defendants reserve the right to seek additional records beyond these time parameters and will confer with Plaintiffs' Counsel regarding same.

3) For those matters listed on Exhibit A hereto, each Plaintiff shall complete and serve upon Defendants complete discovery responses and HIPAA compliant Medical Records Authorization Form for all treaters, providers, hospitals, employers, insurance carriers and government agencies, for the time periods listed in Paragraph 2 above, on or before June 12, 2015 or the time period permitted under paragraph 4, whichever is later. Any outstanding discovery served by the Plaintiffs shall also be due on or before June 12, 2015.

4) For any additional matters filed after this date, Plaintiff shall serve complete discovery responses and HIPAA compliant medical authorizations, for the time periods listed

in Paragraph 2 above, within sixty days of receipt of discovery demands from Defendants. The Defendants shall additionally have within sixty days of receipt of discovery demands from Plaintiffs to provide complete discovery responses.

Defendants' Document Productions

5) The parties are to meet and confer and agree on an ESI Protocol with regard to these productions. If same cannot be agreed to, the issue shall be submitted to the Court no later than May 15, 2015. Defendants shall begin a rolling production of their documents within ten (10) days of finalizing the ESI protocol and shall have their document productions substantially complete on or before July 15, 2015.

Fact Discovery

6) Before the trial pool selection date, the defense may take up to a total of ten depositions of plaintiffs, fact witnesses and/or treating physicians.

7) Corporate Representative Depositions/Defendants' current and former employees - fact witness. These depositions consistent with R. 4:14, shall occur from June 12, 2015 to January 11, 2016 for the trial cases. Custodial records of each employee shall be produced at least 14 days prior to the deposition.

8) All depositions will take place at a mutually agreeable date, place and time and not on less than 45 days' notice to any party unless good cause is shown as to depositions of the defense witnesses.

9) On July 29, 2015 each side shall pick 3 cases for trial. Those selections shall be exchanged via email with copies to the Court. Discovery below shall proceed in these 6 matters only. Discovery in the remaining cases shall be stayed, except that plaintiffs are required to complete and serve full and complete discovery responses within sixty days of receipt of

discovery demands from Defendants.

10) Except for the depositions of current and former employees of the defendants (which shall be completed by January 11, 2016), fact discovery in the initial six trial pool cases shall be completed by January 31, 2016.

11) The deposition of any Plaintiff, including the Plaintiff in a stayed case, may be completed due to the health of the Plaintiff. If the Plaintiff is unable to travel, the deposition may occur in the Plaintiff's home state. The parties will work together to ensure that adequate discovery and records are provided before any such deposition.

Dispositive Motions

12) Any dispositive motions that the parties believe are not dependent on expert testimony shall be filed on or before January 31, 2016. A briefing schedule will be set by the Court at that time.

Trial Selections

13) On December 16, 2015 each side shall pick 1 initial trial case to go forward. Those selections shall be exchanged via email with copies to the Court. The first trial, to be selected by the Plaintiffs, will proceed on July 13, 2016. The second case, to be selected by the Defendants, will proceed to trial on January 4, 2017. [NOTE: Both such trial dates shall proceed as near to the trial date as is practical under the circumstances.]

Expert Discovery

14) For the two trial cases, the parties shall follow the following expert discovery schedule:

- a. Plaintiffs Generic Expert Disclosures shall due December 18, 2015 and Case Specific Experts shall be due January 18, 2016. Such disclosures shall contain

proposed deposition dates between February 22 and March 11, 2016.

c. Defendants' Generic Expert Disclosures shall be due February 19, 2016, and Case Specific Experts shall be due March 16, 2016. Such disclosures shall contain proposed deposition dates between March 16 and April 15, 2016.

d. Expert Depositions completed by: April 15, 2016

Dispositive/Kemp Motions

15) For the two trial cases, the parties shall follow the following Dispositive Motions/Kemp schedule:

a. All Dispositive Motions/Kemp Motions filed by April 29, 2016

b. All Responsive briefs filed by May 20, 2016

c. All Reply briefs by June 3, 2016

d. Hearings begin June 13, 2016

Case Management

16) The next Case Management Conference will be held on July 16, 2015, 10:00 a.m. Future management conferences will be scheduled at that time.

17) The Court is informed that defense counsel wishes those matters listed on the attached Exhibit B and filed in the Bergen County Superior Court be transferred to this Court. This court takes no action as to said matters. Counsel is free to make the appropriate application.

18) Discovery motions may not be filed without leave of Court and after Counsel have met and conferred to discuss discovery issues.

19) In the event counsel incurs any difficulty in scheduling or completing any of the required discovery proceedings, either attorney may contact the Court and a telephonic

management conference shall be promptly scheduled.

20) In the event any party wishes to explore settlement, all counsel grant the undersigned permission to engage in ex parte conversations with counsel to determine whether or not an amicable resolution can be achieved.

21) This Order has been sent to all parties. Any motions as to discovery or the scheduling of any future proceedings are to be accompanied by a copy of this Order and any other Management Order entered in these proceedings.

22) The discovery end dates in all cases listed above and on the attached Exhibit be and hereby are suspended.

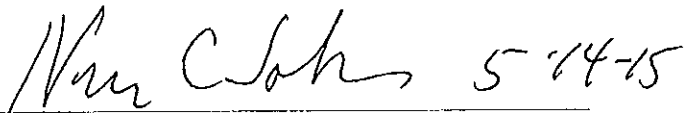

Nelson C. Johnson, J.S.C.

EXHIBIT A

No.	Plaintiff(s)	Docket No.
1.	Adkins, Derick, Individually and as Executor of the Estate of Ruth Ann Adkins, Deceased	ATL-L-0083-15
2.	Apperson, Bertha	ATL-L-0239-15
3.	Bacon-Barnette, Karen	ATL-L-0368-15
4.	Balderrama, Diana and Gilbert	ATL-L-6540-14
5.	Bonanno, Linda	ATL-L-0250-15
6.	Burgos, Angel, Individually and as Administrator of the Estate of Constance Burgos	ATL-L-6384-14
7.	Burke, Aisha L., Individually and as Administrator of the Estate of Sophronia Victoria Burke, Deceased	ATL-L-0241-15
8.	Calloway, Wanda, Individually, and as Sister and Next Friend of Joyce Calloway, Deceased	ATL-L-0473-15
9.	Canuelle, Linda	ATL-L-6756-14
10.	Carl, Brandi and Joel	ATL-L-6546-14
11.	Cherry, Frances and Ronald	ATL-L-6326-14
12.	Clugston, Nicole	ATL-L-0813-15
13.	Conley, Annette	ATL-L-6755-14
14.	Cowles, Veronica	ATL-L-6799-14
15.	Craig, Mairily and Daniel	ATL-L-6504-14
16.	Daniel, Carla, Individually and as Daughter and Next Friend of Bobbie J. Daniel	ATL-L-6621-14
17.	Distefano, Donna	ATL-L-0598-15
18.	Fabian, Penny and Michael	ATL-L-0711-15
19.	Farrell, Helen	ATL-L-6795-14
20.	Felder, Susan	ATL-L-6807-14
21.	Fordham, Teresa, Individually and as Provisional Administratrix of the Succession of Betty Dennis, Deceased	ATL-L-6753-14
22.	Fountain, Nadia	ATL-L-0028-15
23.	Gillespie, Saul, Individually, and as Husband, and Next Friend of Alicia Simmons-Gillespie, Deceased	ATL-L-0472-15
24.	Glanton, Luvell, Individually and as Administrator of the Estate of Verbena Glanton, Deceased	ATL-L-0085-15

No.	Plaintiff(s)	Docket No.
25.	Goforth, Ronice and David	ATL-L-6327-14
26.	Gray, Yvette M., Individually and Administrator of the Estate of Christine M. Chasing Bear, Deceased	ATL-L-0378-15
27.	Hanson, Rebecca	ATL-L-6752-14
28.	Harris, Robert, Individually and as Husband and Next Friend of Diana Harris	ATL-L-0242-15
29.	Holub, Tamara	ATL-L-6385-14
30.	Howze, Angela, Individually and as Daughter and as Successor in Interest of Carrie McCall, Deceased	ATL-L-0173-15
31.	Jackson, James, Individually and as Administrator of the Estate of Betty Lou Jackson, Deceased	ATL-L-6754-14
32.	Johnson, Lucas, Individually and Personal Representative of the Estate of Kim Johnson, Deceased, and the heirs and Beneficiaries of the Estate	ATL-L-0036-15
33.	Jones, Celestine, Individually and as Administrator of the Estate of Shirley McCall	ATL-L-6450-14
34.	Kilburne, Nathaniel, individually and as Administrator of the Estate of Debra Kilburne	ATL-L-6751-14
35.	Kincade (McCullin), Shelley, Individually and as Independent Executrix of the Succession of Lora Imogene Kincade, Deceased	ATL-L-6808-14
36.	Kincaid, Tonja & Anthony	ATL-L-6195-14
37.	Krauchuk, Paula	ATL-L-6805-14
38.	Kyker, Maurice, Individually and as Husband and Next Friend of Judith Kyker, Deceased	ATL-L-6806-14
39.	Laprairie, Teresa	ATL-L-6328-14
40.	Lewis, Frankie A.	ATL-L-0377-15
41.	Lockett, Linda, Individually and as Independent Executrix of the Succession Kenner Cann Lockett, Deceased	ATL-L-0360-15
42.	Lucas, Dianna	ATL-L-6750-14
43.	Machen, Susan K., Individually and as Daughter, and Next Friend of Alta Jane Shannon, Deceased	ATL-L-0134-15
44.	Mathis, Gussie	ATL-L-6793-14
45.	Maxwell, Cheryl and John	ATL-L-0338-15
46.	Minor, Latoya, Individually and Special Administrator of the Estate of Annie Mac Carey, Deceased	ATL-L-0053-15

No.	Plaintiff(s)	Docket No.
47.	Morrow-King, Amelia, Individually and as Administrator of the Estate of Nancy Morrow, Deceased	ATL-L-0293-15
48.	Ourso, Robert, Jr., Individually and as Independent Executor of the Succession of Tina Marie Scheffer, Deceased	ATL-L-6749-14
49.	Parker, Venessa	ATL-L-0288-15
50.	Pettway, Tasha	ATL-L-0255-15
51.	Pollard, Deborah	ATL-L-0243-15
52.	Ralph, Patricia	ATL-L-6804-14
53.	Ramseur, Sharon and John	ATL-L-6337-14
54.	Reddell, Renee Ann	ATL-L-6798-14
55.	Riley, Shirley	ATL-L-6797-14
56.	Robbins, Kay	ATL-L-6794-14
57.	Ross, Frances, Individually and as Sister and Next Friend of Lessie McCarthy, Deceased	ATL-L-0474-15
58.	Ryan, Stacey, Individually and as Administrator and the Succession of Sandra Ryan, Deceased	ATL-L-6800-14
59.	Salmans, Julie	ATL-L-6386-14
60.	Shafer, Linda	ATL-L-0852-15
61.	Sims, Ricky L., Individually and as Husband and Next Friend of, Nancy G. Sims, Deceased	ATL-L-0475-15
62.	Smith, Susan Dell	ATL-L-0244-15
63.	Smith, Tretha, Individually and as Administrator of the Estate of Leatha Smith	ATL-L-6468-14
64.	Sulkowski, Deborah	ATL-L-6239-14
65.	Svatek, Katheryn and Patrick	ATL-L-6556-14
66.	Townes, Kathleen	ATL-L-6796-14
67.	Williams, Darlene, Individually and as Mother and Next Friend of Tammie Arlene Smith Garza, Deceased	ATL-L-6724-14
68.	Williams, Stacey	ATL-L-0172-15
69.	Wooldridge, Joel, Individually and as a Representative of the Estate of Terri L. Wooldridge	ATL-L-6661-14
70.	Young, Sharon	ATL-L-0306-15

EXHIBIT B

No.	Plaintiff(s)	Docket No.	Judge
1.	Alexander, Paulette	BER-L-2979-15	Judge Harz
2.	Arnold, Barbara, Individually and as Personal Representative of the Estate of Laura Mae Robertson, Deceased	BER-L-2524-15	Judge Thurber
3.	Humphrey, Claude Individually and as Husband and Next Friend and Claudia Humphrey, Individually and as Daughter and Next Friend of Sandra Humphrey, Deceased	BER-L-2975-15	Judge Harz
4.	Jeromos, Marie	BER-L-2059-15	
5.	Lewis, Carla	BER-L-2980-15	Judge Marczyk
6.	Lord, Deborah and Kris	BER-L-2982-15	
7.	Lovelace, John, Individually and as Administrator of the Estate of Linda Lovelace, Deceased	BER-L-2724-15	Judge Thurber
8.	Oliver, Rosemarie and John J.	BER-L-1633-15	Judge Langan
9.	Perdue, Hermine, Individually and as Administrator of the Estate of Marquita Winston, Deceased	BER-L-2725-15	Judge Thurber
10.	Thornhill, Martia Individually and as Daughter and Next Friend of Juanita Brown Warren, Deceased	BER-L-2078-15	Judge Harz