



SEEGERWEISS LLP

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July 8, 2015



VIA HAND DELIVERY

Honorable Glenn A. Grant
Acting Administrative Director of the Courts
Attention: MCL Comments – Talc-Based Body Powder Products
Hughes Justice Complex, P.O. Box 037
Trenton, New Jersey 08625-0037

Re: Plaintiffs’ Response to Defendants’ Application for Centralized Management of Certain Cases Involving Talc Based Products

Dear Judge Grant:

Our firm represents Plaintiffs in the talc-based products litigation currently pending in the Superior Court of New Jersey, Atlantic County and Bergen County. The defendants in these cases are Johnson & Johnson, Johnson & Johnson Consumer Companies, Inc., Imerys Talc America, Inc., and Personal Care Products Council (collectively “Defendants”). Plaintiffs do not oppose centralized management of these cases; however, Plaintiffs respectfully request that the cases be consolidated for centralized management before the Honorable Jessica R. Mayer in Middlesex County.

As noted in Defendants’ application, the first of these cases, *Chesteen v. Johnson & Johnson et al.*, was filed in Atlantic County in January 2014. Although Judge Carol E. Higbee initially handled these cases, Judge Nelson C. Johnson assumed all Atlantic County cases shortly thereafter. In September 2014, the parties came before Judge Johnson to discuss the 14 cases pending at that time. Judge Johnson consolidated these 14 cases for discovery purposes and issued CMO 1. (EXHIBIT A). In April 2015, parties met with Judge Johnson via telephone conference and Judge Johnson entered CMO 2 (EXHIBIT B) on May 15, 2015. CMO 2 provided a discovery schedule for a total of 94 cases: the initial fourteen cases filed in Atlantic County, an additional seventy cases filed in Atlantic County, and ten cases filed in Bergen County. Defendants submitted their application for centralized management on May 19, 2015.

BACKGROUND

These cases concern the association between perineal use of cosmetic talcum powder and ovarian cancer in women. Talc is a hydrous magnesium silicate mineral which serves as the primary ingredient in Johnson’s Baby Powder and as one of several ingredients in Shower to Shower. Each of these products has been marketed toward women for many years to increase “freshness” in feminine areas. Plaintiffs have named as defendants Johnson & Johnson and Johnson & Johnson Consumer Companies—the manufacturer of these products and its parent company, Imerys Talc America f/k/a Luzenac America—the company that mines the talc and

distributes it to Johnson & Johnson Consumer Companies, and Personal Care Products Council f/k/a the Cosmetics, Toiletry, and Fragrances Association—the trade association responsible for representing industry interests and lobbying against regulation of talc.

In 1971, a study by Henderson et al. found talc particles “deeply embedded” in ovarian tumors, signifying an indication that there may be an association between talcum powder and ovarian cancer. (EXHIBIT C). Although scientific debate regarding this link continued over the next decade, in 1982 Dr. Daniel Cramer and colleagues conducted the first epidemiological study examining the association. (EXHIBIT D). Cramer’s study demonstrated that women who regularly used talcum powder on their genital areas had a statistically significant 92% increased risk of ovarian cancer. Since Cramer’s 1982 study, more than 20 additional studies have examined the epidemiological relationship between talc and ovarian cancer. Of these studies, all have shown an increased risk of ovarian cancer among women who use talc in the perineal region, and more than half of the studies have shown a significantly increased risk. In early 2015, Dr. Roberta Ness examined all existing epidemiologic evidence and scientific studies and concluded that talc use increased ovarian cancer risk by 30-60% and that “elimination of talc use could protect more than one quarter or more of women who develop ovarian cancer.” (EXHIBIT E).

Despite more than thirty years of scientific evidence demonstrating an increased risk of ovarian cancer associated with perineal use of talc, the Johnson & Johnson Defendants have failed to place any warning on their products. Similarly, Imerys only placed a warning on the talc shipped to Johnson & Johnson beginning in 2006 and continued to sell the talc to Johnson & Johnson when it knew the intended use was for a product which would be applied perineally by consumers. Finally, Personal Care Products Council conspired with the other Defendants to prevent any regulation of talc or recognition of talc as a carcinogenic substance.

ARGUMENT

The Criteria for Designation outlined in the Multicounty Litigation Guidelines (Directive # 08-12) indicate that “the issues of fairness, geographical location of parties and attorneys, and the existing civil and multicounty litigation caseload in the vicinage” should all be considered in determining the appropriate vicinage for centralization. Although Judge Johnson has very ably handled the scheduling and discovery matters for these cases thus far, the geographical location of the parties and attorneys and the MCL caseload in each vicinage indicate that centralized management is proper in Middlesex County.

Middlesex County is a Convenient Geographic Location for the Parties and Attorneys

In examining the location of the parties and attorneys in this litigation, Middlesex County is the proper vicinage for centralized management. The Johnson & Johnson Defendants maintain their principle place of business in Middlesex County, so this vicinage will be particularly convenient for this party and many of their witnesses. Additionally, local counsel for the large majority of cases in this matter, Seeger Weiss, have offices in New York, New York and Newark, New Jersey, so Middlesex County provides a convenient vicinage for these attorneys. The remaining parties and attorneys will travel to New Jersey from various locations outside of New Jersey. For these individuals, Middlesex County is centrally located within the state and

convenient to multiple international airports. Plaintiffs also note that Defendants provided no evidence that Atlantic County is more geographically convenient than the alternative vicinages. In fact, in an earlier memorandum in support of their Motion to Change Venue, Defendants stated "The proper venue of this case is Middlesex or Somerset County, not Atlantic County, New Jersey." (EXHIBIT F).

The Existing Civil and MCL Caseload Supports Centralization in Middlesex County

As noted in Defendants' Application, Middlesex County currently has the lowest caseload of the three MCL vicinages. Although Judge Johnson has successfully managed these cases to date, his mass tort case load is heavier than that of Judge Mayer. While Atlantic County currently has 6,711 cases, Middlesex County has only 5,033 cases (Bergen County has a significantly heavier caseload at 14,159 cases). There is also a pending application for centralized management in Atlantic County which, if allocated to Atlantic County in the Olmesartan Medoxomil/Benicar litigation (EXHIBIT G), will only add to Judge Johnson's case load. In the interest of efficiency and proper allocation of the MCL case load, these cases should be centralized in Middlesex County.

Defendants argue that these cases should remain in Atlantic County due to Judge Johnson's "significant involvement" in the cases to this point. However, this litigation is still in the early stages, and no prejudice or inefficiency will occur by centralizing the cases in a different vicinage. In fact, transfer of these cases to Middlesex County will only further the intentions of the Multicounty Litigation Guidelines (Directive #08-12) by balancing the case load across vicinages.

CONCLUSION

For the foregoing reasons, Plaintiffs through their undersigned counsel, hereby respectfully request that all litigation, pending and subsequently filed, alleging ovarian cancer arising from the perineal use of Johnsons Baby Powder and Shower to Shower, be consolidated as a multicounty litigation and received centralized management before Judge Jessica R. Mayer in Middlesex County.

Respectfully submitted,



Moshe Horn, Esq.

Enclosures

cc: Honorable Nelson C. Johnson, J.S.C.
Honorable Brian R. Martinotti, J.S.C.

Honorable Glenn A. Grant

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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 Counsel for Defendants

EXHIBIT A

JENNY APPLEWHITE,
Plaintiff,
v.
JOHNSON & JOHNSON, et al.,
Defendants.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: ATLANTIC COUNTY

DOCKET NO. ATL-L-1995-14

CIVIL ACTION

FILED

MAY 14 2015

NELSON C. JOHNSON, J.S.C.

BARBARA CALDERON,
Plaintiff,
v.
JOHNSON & JOHNSON, et al.,
Defendants.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: ATLANTIC COUNTY

DOCKET NO. ATL-L-1985-14

CIVIL ACTION

MOLLY CHESTEEN and RANDY CHESTEEN,
Plaintiffs,
v.
JOHNSON & JOHNSON, et al.,
Defendants.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: ATLANTIC COUNTY

DOCKET NO. ATL-L-414-14

CIVIL ACTION

RITZIE DONALD,
Plaintiff,
v.
JOHNSON & JOHNSON, et al.,
Defendants.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: ATLANTIC COUNTY

DOCKET NO. ATL-L-1528-14

CIVIL ACTION

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| <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> |

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| <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> |

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| <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. 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.

EXHIBIT B

FILED

SEP. 23 2014

MELSON C. JOHNSON, J.S.C.

COURT INITIATED

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| <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> |

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| <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> |

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| <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> |

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| <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.

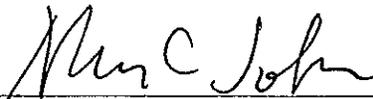
21) This Order has been sent to all parties. Any motions as to discovery or the scheduling of any future proceedings are to be accompanied by a copy of this Order and any other Management Order entered in these proceedings.

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

 5-14-15

Nelson C. Johnson, J.S.C.

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.

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, Marrily 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 Mae 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 |

EXHIBIT C

TALC AND CARCINOMA OF THE OVARY AND CERVIX

BY

W. J. HENDERSON, *Electron Microscopist*
Tenovus Institute for Cancer Research

C. A. F. JOSLIN, *Consultant Radiotherapist*
Velindre Memorial Centre for Cancer Research

A. C. TURNBULL, *Professor of Obstetrics and Gynaecology*
Welsh National School of Medicine

AND

K. GRIFFITHS, *Director*

Tenovus Institute for Cancer Research, Welsh National School of Medicine, Cardiff

Summary

An extraction-replication technique was used to examine tissue from patients with ovarian and cervical tumours. In both conditions talc particles were found deeply embedded within the tumour tissue. The close association of talc to the asbestos group of minerals is of interest.

THE development in this laboratory of an extraction-replication technique (Henderson, 1969) for the study of foreign particles within tissues has allowed the *in situ* identification of crocidolite asbestos within the tissue of various mesotheliomas (Henderson *et al.*, 1969) removed from patients who had been concerned with the manipulation of asbestos in industry. This technique has now been applied to the study of tissue from ovarian and cervical carcinoma.

MATERIALS AND METHODS

Tissue

The tissue studied was obtained from patients with cancer of either the ovary or the cervix, and was first prepared as paraffin sections for normal routine histological examination but was unstained. Sections were then stained for histological assessment in the usual manner, and adjacent unstained tissue prepared for electron microscopy.

Replication Technique

The extraction-replication procedure has been described (Henderson, 1969). Sections of tissue were immersed in xylene and in ethanol, and the dehydrated tissue was then embedded by

impinging the section on to the surface of a thin sheet of acetone-softened cellulose acetate, mounted on a glass slide, and left to harden. On removing the slide, the embedded tissue was left in the cellulose acetate. The tissue was then outlined with thin strips of Scotch tape to form a shallow well, and a 10 per cent (v/v) polyvinyl alcohol (PVA) solution applied. When the PVA had hardened it was stripped from the section providing a replica of the tissue surface. Foreign particles associated with the tissue are often removed with the PVA during this stripping process.

A complete sequential examination through the embedded tissue is possible by taking successive strippings. These surface replicas were then preshadowed with platinum, a carbon film deposited for strength, and the PVA removed by floating the replica in a hot water bath. Replicas were mounted on electron microscope grids for examination, using the AEI-6B microscope.

RESULTS

No asbestos particles were found in any of the tissue studied. Particles of talc were identified in approximately 75 per cent (10 of 13) of the



FIG. 1
Typical decoration pattern on a particle of natural talc. Numerous crystal lattice planes are shown (a). ($\times 30\ 000$.)
Scale refers to $1.0\ \mu$.

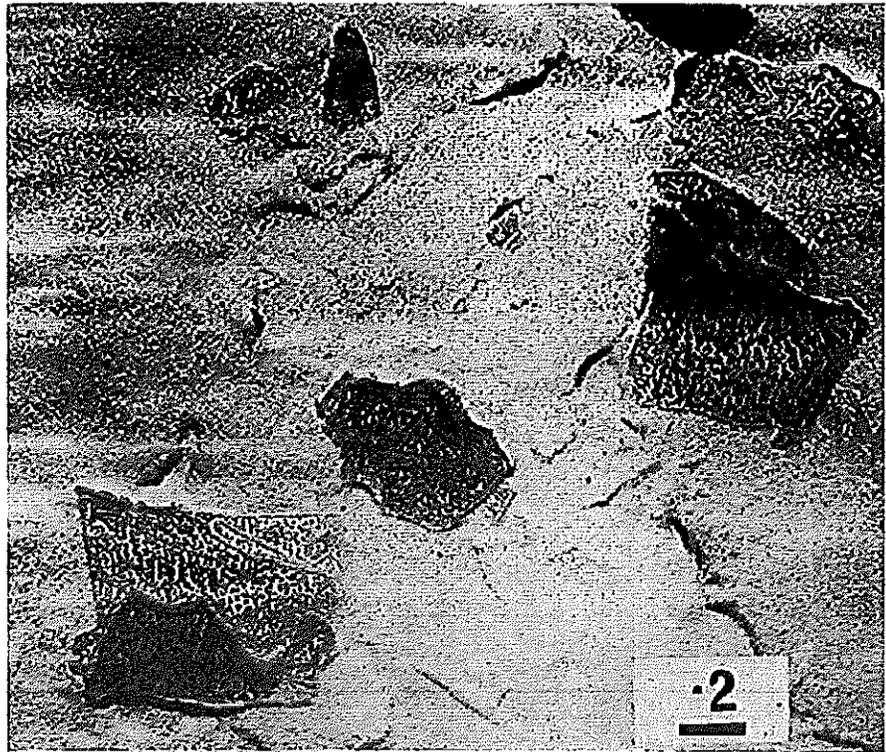


FIG. 2
Commercial talc preparations illustrating the decoration pattern. ($\times 40\ 000$.)



FIG. 3

Micrograph of tissue from a serous papillary cystadenocarcinoma of the ovary removed from a 27-year-old female. No previous abdominal operations had been carried out. The decoration pattern and lattice planes are shown. ($\times 30\,000$.)

ovarian tumours. Using the replication technique identification of talc is possible because of the characteristic "decoration pattern" induced by the evaporation of platinum *in vacuo* on the crystal surface. Figure 1 shows this pattern on a particle of *natural* talc and the distinctive lattice planes of the crystals. Anthophyllite asbestos, which is known to be converted naturally to talc, is the only crystalline material which is at present indistinguishable from talc by using the replication technique. The decoration pattern on material from a commercial talc preparation is also demonstrated in Figure 2.

Material found within the ovarian tumours

and identified as talc is illustrated in Figure 3. The talc particles were found deep within the tumour tissue. Some were as small as 1000\AA in size but they were generally within a range from 1000\AA to $2\ \mu$.

Talc particles were also found embedded within tumours of the cervix. Figure 4 shows one such particle embedded in a capillary wall within the tumour, and Figure 5 illustrates the decoration pattern of the particle at a higher magnification. Crystals as large as $5\ \mu$. were found in tissue from the cervical tumours and were generally larger than those seen in the ovarian tumours. Talc crystals were found in

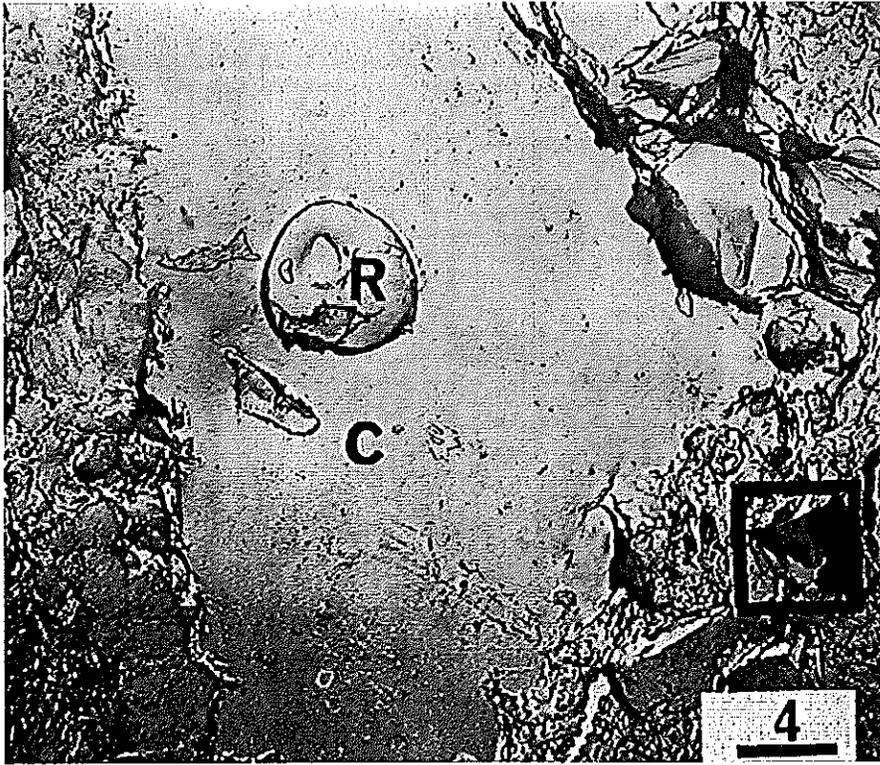


FIG. 4
Micrograph of tissue from a squamous-cell carcinoma of the cervix from a 62-year-old female. C—capillary, R—red cell. The particle of talc can be seen in the wall of the capillary. ($\times 3500$.)

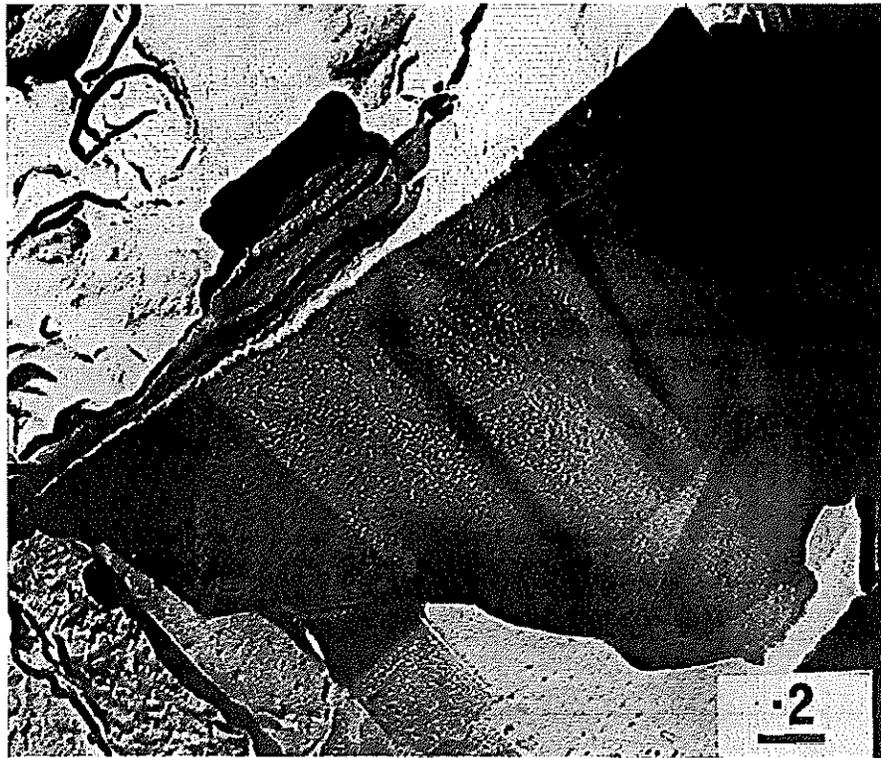


FIG. 5
A higher magnification of the talc particles outlined in Fig. 4. The typical decoration pattern is shown. ($\times 40\ 000$.)

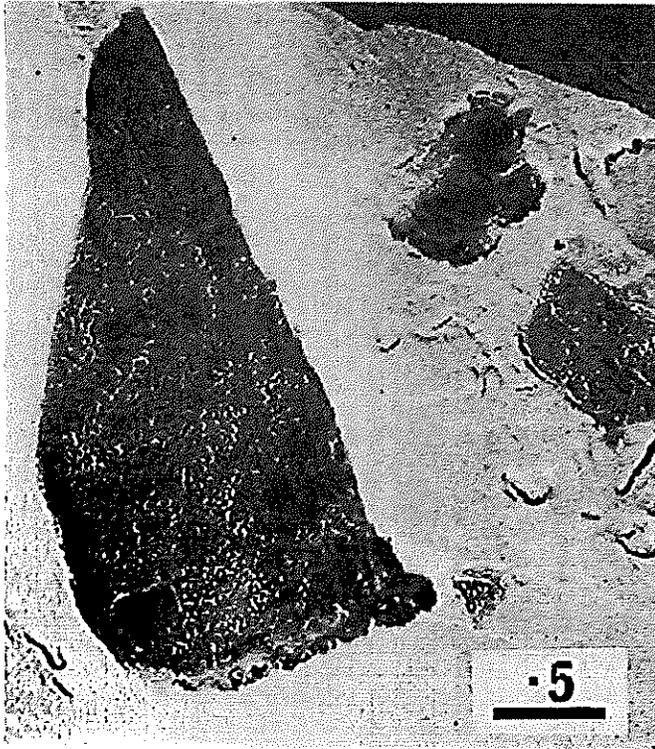


FIG. 6
Talc particles found in tissue from a pneumoconiotic lung. ($\times 30\ 000$.)

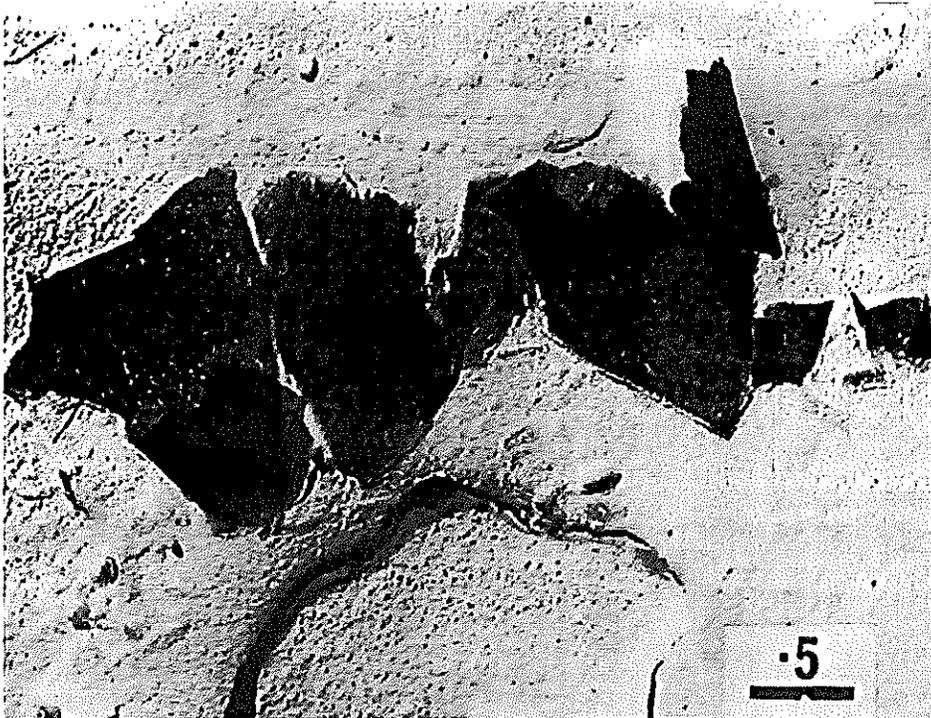


FIG. 7
Micrograph from the deepest part of an extensive papillary adenocarcinoma entirely replacing the endometrium in a 58-year-old woman, 8 years postmenopausal. Both ovaries were enlarged by hilar metastases, showing histological features similar to the primary endometrial lesion. Numerous talc particles were found in the primary endometrial carcinoma, but none in the metastatic ovarian tumours. ($\times 26\ 000$.)

approximately 50 per cent of the cervical tumours examined (12 of 21) but it must be realized that these particles are extremely minute, often with the dimensions of viruses, and only small regions of the tumour tissue could be studied. Approximately ten replication "stripings" for electron-microscope examination are usually taken from each thin section of the tissue. Figure 6 illustrates the use of the technique in the examination of pneumoconiotic lung tissue from a patient whose industrial history indicated long exposure to Norwegian talc.

Many particles of talc were found concentrated in the deeper layers of a primary carcinoma of the endometrium (Fig. 7) whereas extensive studies of a secondary tumour in the ovary in the same patient did not show the presence of talc. Application of the technique to "normal" ovarian tissue removed from patients with breast cancer has also shown talc particles in 5 of 12 such tissues studied. Extensive study at high magnification with the electron microscope is, however, required for evaluation of a replica and particles could easily be missed.

The application of electron-microscope microanalysis (EMMA-ABI, Harlow, England) to the particles extracted by the replication technique has provided preliminary evidence that the crystals contain magnesium and silicon, talc being a magnesium silicate.

DISCUSSION

The possibility that the increasing incidence of carcinoma in western society may be related to a corresponding increase in the use of asbestos (Graham and Graham, 1967) is of interest, especially with regard to pleural and peritoneal mesotheliomas in workers exposed to crocidolite asbestos in industry (Wagner *et al.*, 1960; Elwood and Cochrane, 1964). There have been a number of reports about the relationship between asbestos and carcinogenesis (Smith *et al.*, 1965; Jacob and Anspach, 1965). However, the identification of asbestos fibres within tissue is extremely difficult. Fine particles embedded within tumour tissue are usually beyond the limits of resolution of the optical microscope, and tissue incineration, followed by electron microscopy of the isolated particles, may be unreliable if chemical changes are

induced by the procedure. Using normal light microscopy, identification of asbestos particles is based on the presence of characteristic ferritin bodies on some of the fibres, although these cannot easily be distinguished from similar bodies around elastin fibres (Henderson *et al.*, 1970). This procedure may not, however, be as unreliable as the use of polarized light for the demonstration of brightly illuminated "birefringent crystals of asbestos".

The replication technique (Henderson, 1969) failed to show asbestos fibres in the ovarian neoplasms studied. On the other hand, there was good evidence for the presence of talc, often indistinguishable from anthophyllite asbestos, within the ovarian tissue. (Anthophyllite is converted naturally to talc.) The talc particles were found localized deep within tumour tissues, and not universally dispersed throughout the tumour. The talc particles in the ovary were generally much smaller than those found in the tissue from the tumours of the cervix.

The relationship between asbestos and mesotheliomas appears well established, and the replication technique has provided unequivocal evidence for the presence of fibres within such tumours. This technique has also produced evidence for the presence of talc in tissue from pneumoconiotic lungs of a patient with an industrial history of exposure to Norwegian talc (Henderson *et al.*, 1970). The presence of mica, kaolin and asbestos fibres were also identified in tissue from these pneumoconiotic lung tissue.

Although it is impossible to incriminate talc as a primary cause of carcinomatous changes within either the cervix or the ovary on the preliminary observations described here, the possibility that talc may be related to other predisposing factors should not be disregarded and further investigations are obviously required.

ACKNOWLEDGEMENTS

The authors gratefully acknowledge the generous financial support of the Tenovus Organization. They also thank Dr. J. W. Dobbie, Department of Pathology, Royal Infirmary, Glasgow, for supplying a number of tissue sections, and also Mr. D. E. Evans, Department of Geology, National Museum of Wales, for the natural minerals required for reference purposes.

REFERENCES

- Elwood, P. C., and Cochrane, A. L. (1964): *British Journal of Industrial Medicine*, **21**, 304.
- Graham, J., and Graham, R. (1967): *Environmental Research*, **1**, 115.
- Henderson, W. J. (1969): *Journal of Microscopy*, **89**, 369.
- Henderson, W. J., Gough, J., and Harse, J. (1970): *Journal of Clinical Pathology*, **23**, 104.
- Henderson, W. J., Harse, J., and Griffiths, K. (1969): *European Journal of Cancer*, **5**, 621.
- Jacob, G., and Anspach, M. (1965): *Annals of New York Academy of Sciences*, **132**, 536.
- Keal, E. E. (1960): *Lancet*, **2**, 1211.
- Smith, W. E., Miller, L., Elsasser, R. E., and Hubert, D. D. (1965): *Annals of New York Academy of Sciences*, **132**, 456.
- Wagner, J. C., Sleggs, C. A., and Marchand, P. (1960): *British Journal of Industrial Medicine*, **12**, 260.

EXHIBIT D

Ovarian Cancer and Talc

A Case-Control Study

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AND CAROL A. WOJCIECHOWSKI, RN‡

Opportunities for genital exposure to talc were assessed in 215 white females with epithelial ovarian cancers and in 215 control women from the general population matched by age, race, and residence. Ninety-two (42.8%) cases regularly used talc either as a dusting powder on the perineum or on sanitary napkins compared with 61 (28.4%) controls. Adjusted for parity and menopausal status, this difference yielded a relative risk of 1.92 ($P < 0.003$) for ovarian cancer associated with these practices. Women who had regularly engaged in both practices had an adjusted relative risk of 3.28 ($P < 0.001$) compared to women with neither exposure. This provides some support for an association between talc and ovarian cancer hypothesized because of the similarity of ovarian cancer to mesotheliomas and the chemical relation of talc to asbestos, a known cause of mesotheliomas. The authors also investigated opportunities for potential talc exposure from rubber products such as condoms or diaphragms or from pelvic surgery. No significant differences were noted between cases and controls in these exposures, although the intensity of talc exposure from these sources was likely affected by variables not assessed in this study.

Cancer 50:372-376, 1982.

THE POSSIBILITY that ovarian cancer may be caused by exposure to certain hydrous magnesium silicates such as talc and asbestos has been raised by several researchers.¹⁻³ The lack of epidemiologic studies regarding this hypothesis prompted us to investigate talc exposure in a case-control study of ovarian cancer.

Methods

The cases studied were women with ovarian cancer, diagnosed between November 1978 and September 1981 and identified through the pathology logs or tumor boards of twelve participating hospitals in the Greater Boston area. The study was restricted to English-speaking residents of Massachusetts ranging in age from 18 to 80 years. During the study period, 297 eligible cases were identified. Physicians denied permission to contact their patients in 13 instances. Fourteen patients declined to participate, and 14 other patients had died or moved before they could be contacted.

For each of the 256 interviewed cases, slides of the surgical specimens were reviewed by two authors (W.R.W. or R.E.S). Eighteen cases were excluded as nonovarian primaries. Each ovarian tumor was classified according to the Histological Classification of Ovarian Tumors of the World Health Organization.⁴ The present analysis was restricted to 215 white women with epithelial cancers, including 39 with tumors of borderline malignancy and their matched controls.

Control cases were identified through the Massachusetts Town Books, annual publications that list residents by name, age, and address. Controls were selected randomly from those women who matched cases by precinct of residence, race, and age within two years. Additionally, it was required that a subject be excluded

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Supported by Grant Number 5-RO1 CA24209, awarded by the National Institutes of Health, DHEW.

Address for reprints: Dr. Cramer, Department of Obstetrics and Gynecology, Brigham and Women's Hospital, Boston, MA 02115.

This study could not have occurred without the generous participation of many clinicians and institutions in the greater Boston area including: Dr. Emanuel Friedman of the Beth Israel Hospital, Drs. Robert Knapp and Thomas Griffiths of the Brigham and Women's Hospital and Sidney Farber Cancer Institute, Dr. Arthur Hasset of the Brockton Hospital, Dr. Joel Rankin of the Framingham Union Hospital, Dr. Edward Copenhaver of the Lahey Clinic Foundation, Dr. James Nelson of the Massachusetts General Hospital, Dr. Clement Yahia of the New England Deaconess Hospital, Dr. Lalita Gandhir of the Pondville Hospital, Dr. James Whelton of Saint Elizabeth's Hospital, Dr. Stephen Alpert of the Salem Hospital, Dr. Richard Hunter of the University of Massachusetts Medical School. The superb clerical and technical assistance of Ms. Eileen McManus, Ms. Sally Cassells, and Ms. Christine Peters is also gratefully acknowledged.

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as a control if she had had a bilateral salpingo-oophorectomy, but subjects were not excluded because of prior hysterectomy or other types of pelvic operations. Women who had had pelvic operations were generally confident in their knowledge of whether their ovaries had been removed, but the nature of the operations could not be verified by hospital records in each instance. Women whose statements could not be verified were included or excluded on the basis of their recollection of the surgery. The 215 controls in this study were eventually obtained from a total of 475 potential controls identified through the Town Books. Fifty-six (12%) of the total could not be reached because they had moved, died, or had disconnected or unlisted phones. Twenty-nine (6%) of the total were ineligible because of a history of bilateral salpingo-oophorectomy, while 20 (4%) were of the wrong age or race or did not speak English. Of the total potential controls, 155 (33%) refused to participate. If the 215 cases are characterized as to ease of matching, 121 (56%) cases were matched with no refusals, 58 (27%) were matched after one refusal, and 36 (17%) were matched only after two or more refusals.

Interviews were conducted personally to assess a number of factors from the menstrual and reproductive history, medical and family history, and environmental exposures. This report will deal only with the results of several questions related to potential or definite talc exposure by way of contraceptive practices, operations, or perineal hygiene. Subjects were stratified by potential confounders described below, and adjusted relative risks associated with these exposures were calculated by the Mantel-Haenszel procedure as adapted by Rothman and Boice.⁵ To accommodate other confounders as well as the matched design in the data collection, logistic analysis for matched data as described by Breslow *et al.*⁶ was also employed.

Results

The average age (and standard error of the mean, SEM) for cases was 53.2 (1.0) years and for controls,

| Characteristic | Cases (Total = 215) | | Controls (Total = 215) | |
|--|------------------------|------|---------------------------|------|
| | No. | % | No. | % |
| Educational level (completed college) | 48 | 22.3 | 49 | 22.8 |
| Religion (Roman Catholic) | 126 | 58.6 | 128 | 59.5 |
| Marital status (never married) | 46 | 21.4 | 24 | 11.2 |
| Nulliparous | 78 | 36.3 | 39 | 18.1 |
| Menopausal status (postmenopausal*) | 137 | 63.7 | 129 | 60.0 |

* Postmenopausal at time of diagnosis for cases or for interview for controls.

53.5 (1.0) years. Table 1 shows other characteristics of subjects. Controls were comparable to cases in educational level and religion. Cases and controls differed significantly in marital status and parity with parity being the more important discriminator between them. Sixty-four percent of the cases were postmenopausal at the time of diagnosis, whereas 60% of controls were postmenopausal. Of these, 15 cases and 20 controls had had an artificial menopause. Parity and menopausal status were considered important potential confounders in this analysis and were adjusted for as described above.

Relative risks associated with potential talc exposure from contamination on rubber products are explored in Table 2. Although surgical gloves of recent vintage are dusted with starch, talc contamination may still be found.⁷ Thus, a history of pelvic operations (appendectomy, cesarean section, hysterectomy, and other operations on internal genital organs other than bilateral salpingo-oophorectomy) was determined in cases and controls. Excluding operations associated with the diagnosis or treatment of the ovarian cancer among the cases, no excess in the occurrence of pelvic operations was noted. The greatest opportunity for talc exposure from surgery occurred before 1950, when talc was the

TABLE 2. Relative Risks (RR) for Common Epithelial Ovarian Cancers Associated with Potential Talc Exposure from Contamination on Rubber Products

| Exposure | Cases | | Controls | | Crude RR | Adjusted RR* | 95% Confidence limits |
|--------------------------------|-------|-----------------------|----------|-----------------------|----------|--------------|-----------------------|
| | Total | No. (%) with exposure | Total | No. (%) with exposure | | | |
| Pelvic surgery | 215 | 78 (36.3) | 215 | 75 (34.9) | 1.06 | 1.17 | (0.76-1.79) |
| Pelvic surgery (prior to 1950) | 215 | 51 (23.7) | 215 | 48 (22.3) | 1.08 | 1.12 | (0.69-1.82) |
| Use of condom† | 169 | 19 (11.2) | 191 | 30 (15.7) | 0.68 | 0.77 | (0.41-1.44) |
| Use of diaphragm† | 169 | 37 (21.9) | 191 | 35 (18.3) | 1.24 | 1.19 | (0.69-2.05) |

* Adjusted for parity (nulliparous, parous) and menopausal status (pre- and postmenopausal).

† Restricted to subjects who had ever been married.

TABLE 3. Relative Risks (RR) Associated with Using Talc for Storage Among Diaphragm Users* by Duration of Use of Diaphragm

| Duration of diaphragm use | Total | Cases | | Controls | | Crude RR | Adjusted RR† | 95% Confidence limits |
|--|-------|------------------------------------|-------|------------------------------------|-------|----------|--------------|-----------------------|
| | | No. (%) who used talc on diaphragm | Total | No. (%) who used talc on diaphragm | Total | | | |
| Total diaphragm use less than five years | 13 | 6 (46.2) | 21 | 8 (38.1) | 21 | 1.39 | 1.82 | (0.42-8.00) |
| Total diaphragm use five or more years | 27 | 16 (59.3) | 19 | 11 (57.9) | 19 | 1.06 | 1.23 | (0.36-4.17) |
| All users | 40 | 22 (55.0) | 40 | 19 (47.5) | 40 | 1.35 | 1.56 | (0.62-3.88) |

* Includes all women who used diaphragm regardless of marital status.

† Adjusted for parity and menopausal status.

predominantly used dusting powder for surgical gloves. However, no significant excess of pelvic operations prior to 1950 was observed for cases.

The patients (cases) who, at sometime, had been married, chose condoms less frequently and diaphragms more frequently for contraception than the control group, but neither difference was statistically significant. Condom use is not necessarily associated with talc exposure. Not all brands of condoms are dusted with talc, and lubricants could affect the shedding of talc from the condom. Unfortunately, details on specific brands of condoms were not obtained. Similarly, talc exposure is not a necessary consequence of diaphragm use. We inquired specifically about the practice of dusting the diaphragm with talc for storage after use (Table 3). Among all subjects who had used a diaphragm, there was no significant excess of cases who regularly stored their diaphragm using talc, nor was any greater risk associated with this practice observed among women who had used the diaphragm for longer durations. Before the risk from this exposure can be adequately assessed, greater detail is needed including frequency of use and whether the powder was washed off prior to use. Furthermore, contraceptive jellies used with the diaphragm could affect the transport of talc in the genital tract.

Hygienic practices involving talc were also studied. Specifically, we inquired whether women had regularly used talc as a dusting powder on the perineum or regularly dusted sanitary napkins with talc (Table 4). Ninety-two (42.8%) of the cases had talc exposure by either or both of these routes compared with 61 (28.4%) of the controls. The adjusted relative risk was 1.92 ($P < 0.003$) with 95% confidence limits of 1.27-2.89 compared to subjects who had neither exposure. Sixty (27.9%) cases and 48 (22.3%) controls had either used talc for dusting or on napkins but not both. This difference yielded an adjusted relative risk of 1.55, which was of borderline significance ($P = 0.06$). The greatest risk occurred in women who had both exposures (use on the perineum and on napkins) compared to women who had neither exposure. Thirty-two (14.9%) of cases were in this category compared with 13 (6.0%) controls, for an adjusted relative risk of 3.28 ($P < .001$) and 95% confidence limits of 1.68-6.42. The histologic characteristics of tumors developing in women with perineal exposure to talc did not differ significantly from those in women without perineal exposure to talc (Table 5). In addition, the proportion of cases with tumors of borderline malignancy was identical among those with and without perineal exposure to talc. Twenty-two (18%) of 123 cases without the exposure had tumors of bor-

TABLE 4. Relative Risks (RR) for Common Epithelial Ovarian Cancers Associated with Talc Exposure in Perineal Hygiene

| | No perineal exposure | Any perineal exposure | Types of perineal exposure | | |
|------------------------|----------------------|-----------------------|--------------------------------------|--------------------------------------|---------------------------------------|
| | | | As dusting powder but not on napkins | On napkins but not as dusting powder | Both on napkins and as dusting powder |
| Cases (Total = 215) | 123 (57.2%) | 92 (42.8%) | 43 (20.0%) | 17 (7.9%) | 32 (14.9%) |
| Controls (Total = 215) | 154 (71.6%) | 61 (28.4%) | 34 (15.8%) | 14 (6.5%) | 13 (6.0%) |
| Crude rr | 1 | 1.89 | 1.58 | 1.52 | 3.08 |
| Adjusted RR* | — | 1.92 | 1.55 | | 3.28 |
| 95% confidence limits | — | (1.27-2.89) | (0.98-2.47) | | (1.68-6.42) |

* Adjusted for parity and menopausal status.

derline malignancy compared to 17 (18%) of 92 with the talc exposure.

Discussion

The argument linking talc and ovarian cancer includes four elements: the chemical relationship between talc and asbestos, asbestos as a cause of pleural and peritoneal mesotheliomas, the possible relation between epithelial ovarian cancers and mesotheliomas, and the ability of talc to enter the pelvic cavity. The mineral talc is a specific hydrous magnesium silicate chemically related to several asbestos group minerals and occurring in nature with them. Generic "talc" is seldom pure and may be contaminated with asbestos, particularly in powders formulated prior to 1976.^{8,9}

Epidemiologic studies have clearly linked lung cancer and pleural and peritoneal mesotheliomas with asbestos exposure.¹⁰ An excess of similar pulmonary lesions has been reported in talc workers and seems to be correlated with the amount of asbestos contamination in the talc deposits worked.¹¹ Graham and Graham¹ were able to induce ovarian neoplasms in guinea pigs with asbestos and suggested that ovarian cancer could be related to asbestos exposure, noting the similarity between mesotheliomas and ovarian cancers. Parmley and Woodruff¹² further emphasized this similarity and popularized the pelvic contamination theory, which proposed that environmental carcinogens might enter the pelvic cavity via the genital tract. Years earlier it had been observed that inert carbon particles placed in the vagina immediately prior to hysterectomy could be recovered from the fallopian tubes.¹³ Although greeted with skepticism, the finding of talc particles embedded in normal and abnormal ovaries suggests that talc is a substance that can enter the pelvic cavity via the vagina.²

Although no consensus concerning the risks of talc has emerged from letters, editorial and articles,^{1,14-16} participants in the discussion have agreed upon the need for epidemiologic studies of ovarian cancer and talc exposure. In this case-control study of ovarian cancer of the epithelial variety, we investigated several sources of potential talc exposure. Among these, the only significant finding was an association between ovarian cancer and hygienic practices involving the use of talc on the perineum. It is especially notable that women who regularly had both dusted their perineum with talc and had used it on sanitary napkins had more than a three-fold increase in risk compared to women with neither exposure. Several potential biases must be considered in interpreting this association.

The observation by Wynder *et al.*¹⁷ that menstrual characteristics may differ between women with ovarian cancer and controls might suggest that such differences may confound the association between perineal use of

TABLE 5. Characteristics of Ovarian Cancer in Women with and without Perineal Exposure to Talc

| | No perineal use of talc | Any perineal use of talc |
|-----------------------------|-------------------------|--------------------------|
| | No. (%) | No. (%) |
| Serous | 66 (53.7) | 45 (48.9) |
| Mucinous | 16 (13.0) | 14 (15.2) |
| Endometrioid and clear cell | 32 (26.0) | 24 (26.1) |
| Other and undifferentiated | 9 (7.3) | 9 (9.8) |
| Total | 123 (100) | 92 (100) |

talc and ovarian cancer. We found that menstrual characteristics of cases and controls were virtually identical in this study. Fifty-three (24.7%) cases complained of moderate or severe dysmenorrhea compared to 56 (26.0%) controls. Twenty-five (11.6%) cases complained of irregular periods compared to 32 (14.9%) controls. The average numbers (and SEM) of days of flow and cycle length were, respectively, 4.9 (0.1) and 28.9 (0.3) days for cases and 4.9 (0.1) and 29.6 (0.3) days for controls.

Since entry of talc into the pelvic cavity is prevented by hysterectomy or tubal ligation, it might also be argued that the inclusion of subjects with pelvic surgery in the analysis may obviate any association between talc and ovarian cancer. It should be noted that such surgery generally occurred near the end of reproductive life for both cases and controls, probably after most significant talc exposure had already occurred. The exclusion of such subjects from the analysis did not substantially alter the observed associations. For example, the adjusted relative risk for the use of talc both on the perineum and sanitary napkins was 2.79 ($P < 0.003$) in the group without pelvic surgery compared to 3.28 observed for the entire group.

In terms of other confounders, the association persisted after adjustment for menopausal status and parity. We also applied multivariate logistic regression for paired observations.⁶ The maximum likelihood estimate of relative risk associated with any perineal use of talc was 1.61 ($P = 0.03$) with 95% confidence limits of 1.04-2.49 after simultaneous adjustment for religion, marital status, educational level, ponderal index, age at menarche, exact parity, oral contraceptive or menopausal hormone use, and smoking.

Our sample of cases represents more than 50% of ovarian cancer cases diagnosed in Boston residents in the study period. Therefore, it is difficult to conceive of a plausible bias in the selection of cases that would yield this excess use of talc. There is reason for concern that the high refusal rate among the controls may have introduced a selection bias among the controls. But,

when we restricted the analysis to the 121 cases who were matched without a control refusal, we again found a significant association between talc use and ovarian cancer. For women who had used talc both in dusting and on the perineum we found an adjusted relative risk of 2.44 ($P < 0.05$). Interviewer bias is also unlikely to explain the association. Of the 18 women who were initially interviewed as ovarian cancer cases but later excluded as having metastatic tumors to the ovary, only one (5.6%) had both perineal and napkin exposure as compared with 15% in cases and 6% in controls.

Experimental data which might bear on the carcinogenicity of talc come primarily from models using pleural implantation of various minerals in rats.¹⁸ These data suggest that carcinogenicity is dependent primarily upon the shape of the particles with long thin fibers such as those occurring in crocidolite asbestos being most carcinogenic. Talc consists primarily of plates but may contain fibers, although voluntary guidelines to limit the content of asbestiform fibers in consumer talcums were proposed by the cosmetics industry in 1976.¹⁹

If talc is involved in the etiology of ovarian cancer, it is not clear whether this derives from the asbestos content of talc or from the uniqueness of the ovary which might make it susceptible to carcinogenesis from both talc and other particulates. With ovulation entrapment of the surface epithelium of the ovary into the ovarian stroma occurs. If present, talc or other particulates might be incorporated into these inclusion cysts. Apparently implantation of foreign bodies into the lumens of epithelial lined organs provides a favorable environment for carcinogenesis.²⁰ Alternatively, talc might serve to stimulate entrapment of the surface epithelium and act in the same way that "incessant ovulation" has been proposed as an etiologic factor for ovarian cancer.²¹ Given the histologic and clinical diversity of ovarian cancer, talc exposure is unlikely to be the only cause. Undoubtedly, reproductive experiences such as pregnancies and, perhaps, oral contraceptive use play a role in its etiology.²¹⁻²³ The possibility that talc exposure interacts with these variables deserves further investigation.

It is hoped that this report will stimulate further study of talc exposure in relation to ovarian cancer. Animal studies would be helpful to determine whether and under what circumstances ovarian tumors may be induced by various talc preparations. Epidemiologic studies should focus on opportunities for excessive vaginal contamination with talc such as when it is repeatedly used in perineal dusting powders or sprays and in or on tampons, sanitary napkins, or other products intended for

intravaginal use. More precise details on the exact nature and frequency of the exposure and the amount and specific brand of powder used are essential. Opportunities for talc exposure are widespread and pervasive,²⁴ but that should not discourage epidemiologists from studying this potentially important exposure in relation to ovarian cancer.

REFERENCES

1. Graham J, Graham R. Ovarian cancer and asbestos. *Environ Res* 1967; 1:115-128.
2. Henderson WJ, Joslin CAF, Turnbull AC, Griffiths K. Talc and carcinoma of the ovary and cervix. *J Obstet Gynaecol Br Commonw* 1971; 78:266-272.
3. Longo DL, Young RC. Cosmetic talc and ovarian cancer. *Lancet* 1979; ii:349-351.
4. Serov SF, Scully RE, Sobin LH. International Histological Classification of Tumours, No. 9. Histological Typing of Ovarian Tumours. Geneva, World Health Organization, 1973.
5. Rothman KJ, Boice JD. Epidemiologic analysis with a programmable calculator. NIH Publication No. 79-1649, 1979.
6. Breslow NE, Day NE, Halvorsen KT, Prentice RL, Sabai C. Estimation of multiple relative risk functions in matched case-control studies. *Am J Epidemiol* 1978; 108:299-307.
7. Henderson WJ, Hamilton TC, Griffiths K. Talc in normal and malignant ovarian tissue. *Lancet* 1979; i:499.
8. Cralley LJ, Key MM, Groth DH, Lainhart WS, Ligo RM. Fibrous and mineral content of cosmetic talcum products. *Am Ind Hyg Assoc J* 1968; 350-354.
9. Rohl AN, Langer AM, Selikoff IJ, Tordini A, Klimentidis R. Consumer talcums and powders: Mineral and chemical characterization. *J Toxicol Environ Health* 1976; 2:255-284.
10. Selikoff IJ, Hammond EC (eds.). Health hazards of asbestos exposure. *Ann NY Acad Sci* 1979; 330:1-179.
11. Kleinfeld M, Messite J, Zaki MH. Mortality experiences among talc workers: A follow-up study. *J Occup Med* 1974; 16:345-349.
12. Parmley TH, Woodruff JD. The ovarian mesothelioma. *Am J Obstet Gynecol* 1974; 120:234-241.
13. Egli GE, Newton M. The transport of carbon particles in the human female reproductive tract. *Fertil Steril* 1961; 12:151-155.
14. Anonymous. Cosmetic talc powder. *Lancet* 1977; i:1348.
15. Newhouse ML. Cosmetic talc and ovarian cancer. *Lancet* 1979; ii:528.
16. Roe FJC. Controversy: Cosmetic talc and ovarian cancer. *Lancet* 1979; ii:744.
17. Wynder EL, Dodo H, Barber HRK. Epidemiology of cancer of the ovary. *Cancer* 1969; 23:352-370.
18. Stanton MF, Layard M, Tegeris A, et al. Relation of particle dimension to carcinogenicity in amphibole asbestoses and other fibrous minerals. *J Natl Cancer Institute* 1981; 67:965-975.
19. C.T.F.A. Specification. Talc, cosmetic: Cosmetic, toiletry, and fragrance association, Inc. Issue 10-17, 1976.
20. Brand KG, Johnson KH, Buoen LC. Foreign body tumorigenesis. *CRC Crit Rev Toxicol* 1976; 4(Oct):353-394.
21. Casagrande JT, Pike MC, Ross RK, Louie EW, Roy S, Henderson BE. Incessant ovulation and ovarian cancer. *Lancet* 1979; ii:170-172.
22. Newhouse ML, Pearson RM, Fullerton JM, Boesen EAM, Shannon HS. A case control study of carcinoma of the ovary. *Br J Prev Soc Med* 1977; 31:148-153.
23. McGowan L, Parent L, Lednar W, Norris HJ. The woman at risk for developing ovarian cancer. *Gynecol Oncol* 1979; 7:325-344.
24. Blejer JP, Arlon R. Talc: A possible occupational and environmental carcinogen. *J Occup Med* 1973; 15:92-97.

EXHIBIT E

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Articles

DOES TALC EXPOSURE CAUSE OVARIAN CANCER?: IGCS-0015 Ovarian Cancer

Ness, R.

CONTENT NOT FOR REUSE

Although relatively uncommon, some women had substantial lifetime risk based on reported risk factors and lack of behaviorally modifiable choices.

**IGCS-0015
Ovarian Cancer**

DOES TALC EXPOSURE CAUSE OVARIAN CANCER?

R. Ness

Epidemiology, University of Texas School of Public Health, Houston, USA

Background and Aims:

Controversy surrounds the question of whether talc use causes ovarian cancer.

Design:

Formal systematic analysis of talc use and ovarian cancer.

Methods:

All accumulated epidemiologic evidence (23 case-control studies, 5 meta-analyses, and 3 analyses of a single cohort) and basic science studies were reviewed and graded for quality. Data were considered overall and by histologic subtype. Attributable Risk estimates were calculated. Factors favoring causality were the well-accepted Hill's criteria.

Results:

Talc use increased ovarian cancer risk by 30-60% in almost all well-designed studies. The Attributable Risk was 29%, meaning that elimination of talc use could protect more than one quarter or more of women who develop ovarian cancer. Risk elevations were found consistently among good case-control studies, 2 of 3 cohort analyses, and all meta-analyses/pooled analyses. Well-designed studies that considered dose-response by both duration and frequency all found higher risk among women exposed to more applications. A plausible biologic mechanism is inflammation, known to cause other epithelial cancers. The talc association is more specific to serous ovarian cancer. Systematic bias is excluded because talc use is a durable behavior unlikely to be subject to recall bias; good case-control studies were all population-based or cohorts averting selection bias; and multiple adjustment for other risk factors limited confounding.

Conclusion:

Hill's tenets suggest that talc use causes ovarian cancer. Several, but not all, baby powder manufacturers have already replaced talc with corn starch.

EXHIBIT F

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CRAIG WERNER, Individually and as
Administrator of the Estate of BARBARA
WERNER, deceased,

Plaintiff,

v.

JOHNSON & JOHNSON; JOHNSON
CONSUMER COMPANIES, INC.;
IMERYS TALC AMERICA, INC., F/K/A
LUZENAC AMERICA, INC., PERSONAL
CARE PRODUCTS COUNSEL
FOUNDATION F/K/A COSMETIC,
TOILETRY, AND FRAGRANCE
ASSOCIATION (CTFA); JOHN
DOES/JANE DOES 1-30; UNKNOWN
BUSINESSES AND/OR CORPORATIONS
1-50,

Defendants.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: ATLANTIC COUNTY

DOCKET NO. ATL-L-1800-14

CIVIL ACTION

**NOTICE OF MOTION
TO CHANGE VENUE**

TO: Christopher A. Seeger, Esq.
Seeger Weiss LLP
550 Broad Street
Suite 920
Newark, New Jersey 07102
Attorneys for Plaintiff

COUNSEL:

PLEASE TAKE NOTICE that on Friday, July 11, 2014, at 9:00 a.m. or as soon
thereafter as counsel may be heard, Drinker Biddle & Reath LLP, counsel for defendants

Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc. will move before the Honorable Julio L. Mendez, A.J.S.C., in the Superior Court of New Jersey, Law Division, Atlantic County, for an order changing venue to Middlesex or Somerset County.

In support of this application, defendants shall rely upon their supporting Memorandum of Law, and Certification of Counsel submitted herewith.

PLEASE TAKE FURTHER NOTICE that defendants hereby request oral argument if a timely opposition is filed.

A proposed Order is enclosed.

DRINKER BIDDLE & REATH LLP
Attorneys for Defendants Johnson & Johnson and
Johnson & Johnson Consumer Companies, Inc.

By:  _____
Susan M. Sharko

Dated: June 24, 2014

CRAIG WERNER, Individually and as
Administrator of the Estate of BARBARA
WERNER, deceased,

Plaintiff,

v.

JOHNSON & JOHNSON; JOHNSON
CONSUMER COMPANIES, INC.;
IMERYS TALC AMERICA, INC., F/K/A
LUZENAC AMERICA, INC., PERSONAL
CARE PRODUCTS COUNSEL
FOUNDATION F/K/A COSMETIC,
TOILETRY, AND FRAGRANCE
ASSOCIATION (CTFA); JOHN
DOES/JANE DOES 1-30; UNKNOWN
BUSINESSES AND/OR CORPORATIONS
1-50,

Defendants.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: ATLANTIC COUNTY
DOCKET NUMBER ATL-L-1800-14

CIVIL ACTION

**BRIEF IN SUPPORT OF DEFENDANTS' MOTION TO CHANGE VENUE TO
MIDDLESEX OR SOMERSET COUNTY**

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Johnson & Johnson Consumer Companies, Inc.

On the Brief:

Susan M. Sharko, Esq.
Zoha Barkeshli, Esq.

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PRELIMINARY STATEMENT

The plaintiff in this products liability case is from New York. None of the defendants have any ties to Atlantic County related to this litigation. The two New Jersey based defendants, Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc. are located in Middlesex County and Somerset County, respectively. The other defendants are from out-of-state. This motion presents a simple question: Is Atlantic County the appropriate venue for a products liability case brought by a New York resident concerning the alleged purchase and use of an over-the-counter product in New York, where the key documents and witnesses of the only New Jersey based defendants are located in Middlesex and Somerset Counties, New Jersey? The answer is “no.” The proper venue of this case is Middlesex or Somerset County, not Atlantic County, New Jersey. The motion to change venue to one of these two counties should be granted.

FACTUAL BACKGROUND

Plaintiff Craig Werner, resident of the State of New York, filed this products liability case individually and as administrator of the estate of Barbara Werner, against Johnson & Johnson, Johnson & Johnson Consumer Companies, Inc., Imerys Talc America, Inc. (“Imerys”) f/k/a Luzenac America, Inc., Personal Care Products Council Foundation (“PCPCF”) f/k/a Cosmetic, Toiletry, and Fragrance Association (CTFA), and various unnamed defendants, claiming wrongful death as a result of Barbara Werner’s use of Johnson & Johnson Baby Powder and Shower to Shower in New York. The moving defendants here, Johnson & Johnson (“J&J”) and Johnson & Johnson Consumer Companies Inc. (“JJCC”), filed their answer on June 16, 2014. Although the defendants served discovery requests with their answer, no discovery has been taken to date. No motions have been filed and there is no trial date.

This case has nothing to do with Atlantic County. There is no allegation that Barbara Werner purchased or used the products in question in New Jersey, nor did she receive her medical treatment in Atlantic County specifically or New Jersey generally. By contrast, any of the J&J or JJCC employees who might be witnesses in the case are in Middlesex and or Somerset County. None are located in Atlantic County. No documents exist in Atlantic County. (Certification of Zoha Barkeshli, Esq., hereinafter "Barkeshli Cert." Paragraph 2). J&J and JJCC now move to change venue to Middlesex County or Somerset County pursuant to R. 4:3-3.

The alleged connections of the other defendants to this forum relevant to this litigation are even further attenuated. Plaintiff himself concedes that defendant Imerys is a Delaware corporation, has its principal place of business in California, and Plaintiff does not allege that any Imerys activities *related to* JJCC's Baby Powder and Shower to Shower occurred in Atlantic County. (Compl., ¶ 15). The same is true with respect to Plaintiff's allegations concerning defendant PCPCF, which is alleged to have its principal place of business in the District of Columbia (Compl., ¶ 17).

The claims at issue here have nothing to do with Atlantic County and for the convenience of the parties and the interests of justice, the motion to change venue should be granted.

LEGAL ARGUMENT

I. VENUE SHOULD BE CHANGED FROM ATLANTIC COUNTY TO MIDDLESEX COUNTY OR SOMERSET COUNTY

Once venue has properly been laid in accordance with R. 4:3-2, any request for a change in venue is governed by R. 4:3-3(a). Doyle v. Schroeter, 191 N.J. Super. 120, 125 (Law Div. 1983). Pursuant to R. 4:3-3(a)(3), this Court may change venue, in its sound discretion, "for the convenience of parties and witnesses in the interest of justice."

Here, both the convenience of the parties and witnesses, and the interests of justice compel a venue change. Middlesex County and Somerset County are more accessible to the parties and the witnesses than Atlantic County is. The New Jersey based defendants and their witnesses and documents are located in Middlesex and Somerset Counties. They are not in Atlantic County. Plaintiff, a New York resident, will be traveling from New York to New Jersey to litigate this case, and New Brunswick, Middlesex County and Somerville, Somerset County are both closer to New York than Atlantic City, Atlantic County is. (Barkeshli Cert. Paragraph 3). Plaintiff cannot argue that he will be inconvenienced by traveling to Middlesex or Somerset County instead of Atlantic County. If anything, it will be more convenient for him to travel to Middlesex or Somerset County than to Atlantic County.

The interests of justice will be promoted by transferring this matter to either Middlesex or Somerset County. The Atlantic County court docket is already inundated with cases. Atlantic County has far more cases than Middlesex County or Somerset County. There are approximately 21,000 civil cases pending in Atlantic County, as compared with 10,163 for Middlesex, and 1,611 in Somerset County. (Barkeshli Cert., Paragraph 4). Based on the above statistics, the case distribution for each judge in Atlantic County is 3,630 per judge, as compared with 725 per judge in Middlesex, and 268 per judge in Somerset County. Id. These numbers alone provide compelling reason to transfer venue in this products liability case. It is simply unfair to the Atlantic County judicial system, including its staff and personnel, to single-handedly shoulder the resources that are needed for the administration, filing, processing, management and adjudication of this case. Atlantic County residents who are seeking access to their court for fair trial will be inevitably forced to endure delays due to the over-burdened docket of Atlantic County and will continue to be forced to stand in line behind out-of-state

residents in order to have their cases heard. For all of these reasons, the motion to change venue should be granted.

II. DEFENDANTS' MOTION TO CHANGE VENUE IS FURTHER SUPPORTED BY A FORUM NON CONVENIENS ANALYSIS

The doctrine of *forum non conveniens* allows the court to decline jurisdiction when litigation in plaintiff's selected forum is contrary to the convenience of the parties and to the interests of justice. Gore v. U.S. Steel Corp., 15 N.J. 301, 305, cert. denied, 348 U.S. 861 (1954). The doctrine is intended to prevent a court from being burdened with lawsuits that should more properly be tried in forums where the relevant events and circumstances giving rise to the claims occurred. Id. at 313. Proper judicial administration requires that local courts not be burdened with extensive litigation of foreign matters to the impediment of the expeditious determination of local matters. Id.

In considering a motion to change venue based on *forum non conveniens*, courts generally apply a three step process. Varo v. Owens-Illinois, Inc., 400 N.J. Super. 508, 519 (App. Div. 2008). At the outset, the court determines whether an adequate alternative forum exists to adjudicate the parties' dispute. If an alternative forum is available, the court considers the degree of deference accorded to the plaintiff's choice of forum. Finally, the Private and Public Interest factors as set forth in Gulf Oil Corp. v. Gilbert, 330 U.S. 501 (1947) are taken into consideration. In Kurzke, 164 N.J. 159, 168 (2000), the New Jersey Supreme Court noted its continuing reliance and adoption of the Public and Private Interest factors enumerated in Gulf Oil. In addition to the change-of-venue analysis set forth above, application of the "Gulf Oil factors" provides additional compelling support for transfer of this case to Middlesex or Somerset County.

Here, an adequate alternative forum exists here in both Middlesex and Somerset Counties. And, no basis exists in this case for the traditional deference to a domiciliary plaintiff's choice of forum because Plaintiff is not a New Jersey citizen. Kurzke v. Nissan Motor Corp., 164 N.J. 159, 171 (2000).

1. The Private Interest Factors Enumerated by the Kurzke Court Support a Change of Venue.

Viewed objectively, the "private interest" factors discussed in Kurzke support J&J and JJCC's motion to change venue. The private-interest factors look to the impact of the forum on the parties' presentation of proofs:

(1) the relative ease of access to sources of proof; (2) the availability of compulsory process for attendance of unwilling witnesses and the cost of obtaining the attendance of willing witnesses, (3) whether a view of the premises is appropriate to the action and (4) all other practical problems that make trial of a case easy, expeditious and inexpensive, including the enforceability of the ultimate judgment.

Kurzke, 164 N.J. at 166 (quoting Gulf Oil, 330 U.S. 501, 508-09 (1947)) (internal quotations omitted).

Application of the "private interest" factors supports a change of venue from Atlantic County to Middlesex County or Somerset County. Ease of access to sources of proof leads away from Atlantic County, which has not even a single connection to this case, to Middlesex County or Somerset County, where J&J and JJCC's relevant documents and witnesses are located.

2. The Public Interest Factors Set Forth in Kurzke Support Defendants' Motion for a Change of Venue.

Likewise, the "public interest" factors that should be considered on a motion to dismiss on the ground of *forum non conveniens* support a change in venue here, for the reasons set forth above.

(1) the administrative difficulties which follow from having litigation pile up in congested centers rather than be handled at its origin, (2) the imposition of jury duty on members of a community having no relation to the litigation, (3) the local interest in the subject matter such that affected members of the community may wish to view the trial, and (4) the local interest in having localized controversies decided at home.

Kurzke, 164 N.J. at 165 (quoting Gulf Oil, 330 U.S. at 508-09) (internal quotations omitted).

This is not a localized controversy to be decided in Atlantic County. Application of the “public interest” factors points to a change of venue to Middlesex County or Somerset County.

CONCLUSION

For the foregoing reasons, J&J and JJCC respectfully request that this Court enter an Order changing the venue of this matter to Middlesex County or Somerset County.

Respectfully submitted,

DRINKER BIDDLE & REATH LLP
Attorneys for Johnson & Johnson and Johnson & Johnson
Consumer Companies, Inc.

By: _____

Susan M. Sharko

Dated: June 24, 2014

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CRAIG WERNER, Individually and as
Administrator of the Estate of BARBARA
WERNER, deceased,

Plaintiff,

v.

JOHNSON & JOHNSON; JOHNSON
CONSUMER COMPANIES, INC.;
IMERYS TALC AMERICA, INC., F/K/A
LUZENAC AMERICA, INC., PERSONAL
CARE PRODUCTS COUNSEL
FOUNDATION F/K/A COSMETIC,
TOILETRY, AND FRAGRANCE
ASSOCIATION (CTFA); JOHN
DOES/JANE DOES 1-30; UNKNOWN
BUSINESSES AND/OR CORPORATIONS
1-50,

Defendants.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: ATLANTIC COUNTY

DOCKET NUMBER ATL-L-1800-14

CIVIL ACTION

**CERTIFICATION OF
ZOHA BARKESHLI, ESQ. IN SUPPORT
OF DEFENDANTS' MOTION TO
CHANGE VENUE TO MIDDLESEX OR
SOMERSET COUNTY**

ZOHA BARKESHLI, of full age, certifies as follows:

1. I am an Attorney-at-Law of the State of New Jersey and an associate of the firm of Drinker Biddle & Reath LLP, attorneys for defendants Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc. ("J&J and JJCC"). This Certification is submitted in support of the J&J and JJCC's Motion to Change Venue to Middlesex or Somerset County, New Jersey.

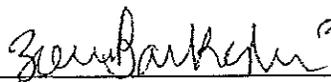
2. Defendant J&J is located in Middlesex County. Defendant JJCC is located in Somerset County. J&J and JJCC employees who would serve as potential relevant witnesses in this lawsuit are located in J&J and JJCC's offices in Middlesex and Somerset Counties, New Jersey, and the documents are located there as well. The employees and documents are not located in Atlantic County.

3. A computerized mapping of the distance from State of New York to Atlantic City, New Jersey and from the State of New York to New Brunswick, Middlesex County and to Somerville, Somerset County shows that the State of New York is closer to both New Brunswick and Somerville than it is to Atlantic City.

4. According to the Superior Court Caseload Reference Guide on the New Jersey Judiciary website, Atlantic County has substantially more cases than Middlesex and Somerset Counties. Total active civil cases pending in Atlantic County for 2014 numbered 21,780, compared with 10,163 for Middlesex and 1,611 for Somerset County. The case distribution for each judge in Atlantic County is 3,630 cases per judge, 725 cases per judge in Middlesex, and 268 cases per judge in Somerset County.

5. J&J and JJCC recently served written Interrogatories, a Request for Production of Documents and Notice of Deposition, but no discovery has taken place in this case to date. No trial date has been set, and no motions have been filed.

I certify that the foregoing statements made by me are true. I am aware that if any of these statements are willfully false, I may be subject to punishment.



Zoha Barkeshli

Dated: June 24, 2014

DRINKER BIDDLE & REATH LLP
A Delaware Limited Liability Partnership
600 Campus Drive
Florham Park, NJ 07932
(973) 549-7000
Attorneys for Defendants Johnson & Johnson
and Johnson & Johnson Consumer Companies, Inc.

CRAIG WERNER, Individually and as
Administrator of the Estate of BARBARA
WERNER, deceased,

Plaintiff,

v.

JOHNSON & JOHNSON; JOHNSON
CONSUMER COMPANIES, INC.;
IMERYS TALC AMERICA, INC., F/K/A
LUZENAC AMERICA, INC.,
PERSONAL CARE PRODUCTS
COUNSEL FOUNDATION F/K/A
COSMETIC, TOILETRY, AND
FRAGRANCE ASSOCIATION (CTFA);
JOHN DOES/JANE DOES 1-30;
UNKNOWN BUSINESSES AND/OR
CORPORATIONS 1-50,

Defendants.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: ATLANTIC COUNTY

DOCKET NO. ATL-L-1800-14

CIVIL ACTION

**ORDER CHANGING VENUE TO
MIDDLESEX OR SOMERSET COUNTY**

THIS MATTER having been opened to the Court by Drinker Biddle & Reath LLP,
attorneys for defendants Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc.
on a Motion for an Order Changing Venue to Middlesex or Somerset County pursuant to R. 4:3-
3(a), and for good cause shown:

IT IS on this _____ day of July, 2014

ORDERED that defendants' Motion for a Change of Venue to Middlesex or Somerset
County be and hereby is granted.

A copy of this Order is to be served on counsel for all interested parties within _____
days from the date of receipt of Order.

Julio L. Mendez, A.J.S.C.

This Motion was:

_____ Opposed

_____ Unopposed

DRINKER BIDDLE & REATH LLP
A Delaware Limited Liability Partnership
600 Campus Drive
Florham Park, NJ 07932-1047
(973) 579-7000
Attorneys for Defendants Johnson & Johnson and
Johnson & Johnson Consumer Companies, Inc.

CRAIG WERNER, Individually and as
Administrator of the Estate of BARBARA
WERNER, deceased,

Plaintiff,

v.

JOHNSON & JOHNSON; JOHNSON
CONSUMER COMPANIES, INC.;
IMERYS TALC AMERICA, INC., F/K/A
LUZENAC AMERICA, INC.,
PERSONAL CARE PRODUCTS
COUNSEL FOUNDATION F/K/A
COSMETIC, TOILETRY, AND
FRAGRANCE ASSOCIATION (CTFA);
JOHN DOES/JANE DOES 1-30;
UNKNOWN BUSINESSES AND/OR
CORPORATIONS 1-50,

Defendants.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: ATLANTIC COUNTY

DOCKET NO. ATL-L-1800-14

CIVIL ACTION

CERTIFICATION OF SERVICE

I, Debra L. Green, of full age, hereby certify as follows:

1. I am a legal assistant employed by Drinker Biddle & Reath LLP, attorneys for Defendants Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc. (collectively "Defendants").

2. On June 24, 2014, I caused an original and one true and correct copy of Defendants' Notice of Motion to Change Venue, Brief in Support of Defendants' Motion to Change Venue to Middlesex or Somerset County, Certification of Zoha Barkeshli, Esq. in

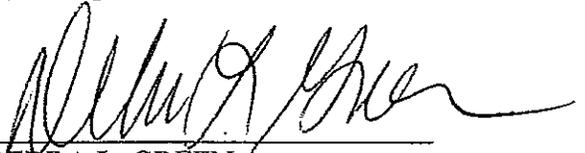
Support of Defendants' Motion to Change Venue to Middlesex or Somerset County and a Proposed Form of Order, together with this Certification of Service to be filed with the Clerk, Superior Court of New Jersey, Atlantic County Civil Courthouse, 1201 Bacharach Boulevard, Atlantic City, New Jersey 08401 via Federal Express.

3. On June 24, 2014, I caused a courtesy copy of the above-referenced papers to be sent via Federal Express to: Honorable Julio L. Mendez, Atlantic County Civil Courthouse, 1201 Bacharach Blvd., Atlantic City, New Jersey 08401.

4. On June 24, 2014, I caused a true and correct copy of the above-referenced papers to be served via Federal Express upon:

Christopher A. Seeger, Esq.
Seeger Weiss LLP
550 Broad Street, Suite 920
Newark, NJ 07102-4573
Attorneys for Plaintiff

I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.


DEBRA L. GREEN

Dated: June 24, 2014

EXHIBIT G

NOTICE TO THE BAR

MULTICOUNTY LITIGATION APPLICATION FOR DESIGNATION OF NEW JERSEY CASES INVOLVING OLMESARTAN MEDOXOMIL MEDICATIONS

The Supreme Court has received an application pursuant to Directive #08-12, "Revised Multicounty Litigation Guidelines," for Multicounty Litigation (MCL) designation of New Jersey state-court litigation involving alleged personal injuries resulting from treatment with medications containing Olmesartan Medoxomil. The litigation is against Daiichi Sankyo, Inc., Daiichi Sankyo U.S. Holdings, Inc., Daiichi Sankyo Company, Limited, Forest Laboratories, Inc., Forest Pharmaceuticals, Inc., and Forest Research Institute, Inc.

Anyone wishing to comment on or object to this application should provide such comments or objections in writing, with relevant supporting documentation, by **June 26, 2015** to:

Hon. Glenn A. Grant
Acting Administrative Director of the Courts
Attention: MCL Comments – Olmesartan Medoxomil Litigation
Hughes Justice Complex, P.O. Box 037
Trenton, New Jersey 08625-0037

A copy of the application submitted to the Court is posted with this Notice on the Judiciary's Internet Website at (www.njcourts.com) in the Multicounty Litigation Information Center (<http://www.judiciary.state.nj.us/mass-tort/index/htm>).



Glenn A. Grant, J.A.D.
Acting Administrative Director of the Courts

Dated: May 26, 2015

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A Delaware Limited
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CALIFORNIA
DELAWARE
ILLINOIS
NEW JERSEY
NEW YORK
PENNSYLVANIA
WASHINGTON DC
WISCONSIN

Andrew B. Joseph
Partner responsible for
Florham Park Office

Established 1849

May 18, 2015

VIA FEDERAL EXPRESS

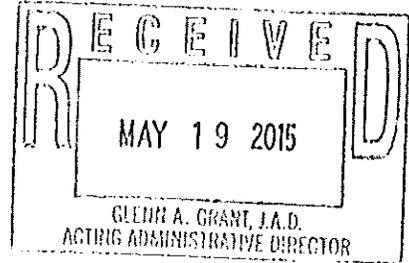
Honorable Glenn A. Grant, J.A.D.
Acting Administrative Director of the New Jersey Courts
Administrative Office of the Courts
Hughes Justice Complex
25 West Market Street
Trenton, New Jersey 08625

Re: **Application for Centralized Management of Cases
Involving Olmesartan Medoxomil Medications.**

Dear Judge Grant:

We represent Defendants Daiichi Sankyo, Inc., Daiichi Sankyo U.S. Holdings, Inc., Daiichi Sankyo Company, Limited, Forest Laboratories, Inc., Forest Pharmaceuticals, Inc., and Forest Research Institute, Inc. in 58 cases consolidated in Atlantic County and one case recently filed in Hudson County. All 59 cases allege sprue-like enteropathy and related personal injuries as a result of plaintiff's treatment with medications containing Olmesartan Medoxomil. We write to respectfully request Centralized Management before the Hon. Nelson C. Johnson, J.S.C., in Atlantic County of products liability cases involving sprue-like enteropathy as a result of taking Olmesartan-containing products.

The New Jersey state court products liability actions relating to Olmesartan were first filed in February 2014 by Rayna Kessler, Esq., then with the Lopez McHugh firm, now with Robins Kaplan. Defendants moved for a change of venue on April 15, 2014 in connection with the first filed case, as none of the Plaintiffs were from Atlantic County.



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That motion was denied by the Hon. Julio Mendez, A.J.S.C. on June 25, 2014, after Ms. Kessler located an Atlantic County resident and filed suit on her behalf.

Ms. Kessler simultaneously moved to consolidate all of the then-pending cases for pretrial discovery and management in Atlantic County, which was granted on the same day by Judge Mendez. The cases were originally assigned to the Hon. Carol E. Higbee, P.J.Cv., then to Judge Johnson when Judge Higbee was elevated to the Appellate Division.

Despite having moved for consolidation in 2014, last month Ms. Kessler filed suit on behalf of a New York state resident in Hudson County. Defendants have asked Ms. Kessler to agree to transfer of this case to Atlantic County. She has refused to do so. Defendants have filed a motion to change venue in that case, Langdon v. Daiichi Sankyo, Inc, Docket No. HUD-L-1240-15.

A federal Multi-District Litigation was created on April 3, 2015, and assigned to the Hon. Robert B. Kugler, U.S.D.J. and the Hon. Joel Schneider, U.S.M.J., of the United States District Court for the District of New Jersey, Camden vicinage.

Since being assigned the consolidated Olmesartan cases, Judge Johnson has conducted two Case Management Conferences, has adjudicated various discovery motions, and on May 8, 2015 conducted a "Science Day" presentation. Both Judge Kugler and Magistrate Judge Schneider attended the May 8, 2015 Science Day Presentation. Judge Johnson has ruled that discovery in the cases before him will be coordinated with discovery in the newly-created MDL. In addition, Judge Johnson

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drafted and entered a Protective Order after the sides were unable to reach agreement on the terms of that Order.

Defendants have provided extensive discovery responses in the consolidated litigation before Judge Johnson. The Daiichi defendants and the Forest defendants have each responded to 173 document requests and 78 interrogatories, including subparts, and anticipate serving responses to 156 requests for admissions within the next 45 days. The Daiichi defendants have also responded to case-specific interrogatories in 19 additional cases. After Defendants served written discovery responses, the Mazie Slater firm served in one state court case extensive and overlapping discovery requests on all Defendants. Defendants moved to quash, arguing among other things that in a consolidated proceeding there should be one set of discovery requests. Judge Johnson granted Defendants' motion by Order dated December 18, 2014. Before the motion was decided, Defendants agreed to respond to certain case-specific interrogatories, and have since served answers in 19 cases where individual discovery was served.

To date, Defendants have made 28 productions of documents totaling over 3 million pages, including TIFF productions for electronic mail and data and scanned paper documents, and native productions for certain limited categories of documents. Rolling productions continue on a weekly basis, as they have since September 2014. Defendants' productions include such documents as the Benicar®, Benicar HCT®, Azor® and Tribenzor® Investigational New Drug Applications and New Drug Applications, regulatory submissions and FDA correspondence, marketing and detail training materials,

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adverse event reports, insurance policies, document retention policies, and custodial electronic mail.

Judge Johnson is ably managing these cases as if they were centralized. However, given the volume of cases and the fact that plaintiffs' counsel is now filing cases in other counties, the time has come for centralized case management to be formalized. Centralized management of these cases before Judge Johnson will help conserve judicial resources, avoid the risks of duplicative discovery and avoid the risk of inconsistent rulings.

THE MEDICATION

At issue in this litigation are four oral prescription medicines – Benicar®, Benicar HCT®, Azor®, and Tribenzor® – indicated for the treatment of hypertension, alone or with other antihypertensive agents, to lower blood pressure. They belong to the class of drugs known as angiotensin II receptor blockers (ARB). ARBs, which have been on the market for over 20 years, block the action of angiotensin II by binding to AT₁ receptors, which mediate the physiological actions of angiotensin II. All of these medications remain on the market today as safe and effective methods for controlling high blood pressure.

Over 40 million patients worldwide have been treated with olmesartan medoxomil products. The litigation was started after the publication of a case series report on 22 patients with a new and rare gastrointestinal ailment called “sprue-like enteropathy.” The condition is characterized by severe, chronic diarrhea, substantial weight loss and villous

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atrophy, which is erosion of the villi in the lining of the small intestine. See, Rubio-Tapia A. et al., Severe Sprue-like Enteropathy Associated with Olmesartan, 87 MAYO CLIN. PROC. 732 (2012).

Defendant Forest Laboratories, Inc., now known as Forest Laboratories, LLC, co-promoted the medicines between 2002 and 2008. Defendants Forest Laboratories, LLC, Forest Pharmaceuticals, Inc., Forest Research Institute, Inc., and Daiichi Sankyo U.S. Holdings, Inc. have never had responsibility for labeling, designing, or manufacturing the medicines. Daiichi Sankyo Company, Limited is a Japanese parent company.

LEGAL ARGUMENT

This litigation meets the criteria required under Directive #8-12 for Centralized Case Management. Defendants respectfully request that these cases be consolidated for case management in the Atlantic County Superior Court before Judge Johnson.

I. THESE CASES SATISFY THE CRITERIA FOR CENTRALIZED CASE MANAGEMENT

A. The litigation involves a large number of parties.

There are 59 cases pending in New Jersey. The wide majority of plaintiffs are not New Jersey residents. The plaintiffs' firms which have filed the actions so far have stated their intention to file additional claims. The litigation meets the "large number" of parties requirement.

B. The litigation involves many claims with common, recurrent issues of law and fact, all associated with a similar product.

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Each of the pending cases alleges that treatment with Olmesartan caused gastrointestinal maladies, most notably a newly-discovered and rare condition called sprue-like enteropathy. While each plaintiff will have an individualized medical history, alleged exposure history and unique facts, each of the Complaints contains similar allegations and demands for damages against the Defendants. As such, the recurrent issue of law requirement is met, with the note that the plaintiffs at this time are from 24 different states. The defendants are the same in all the cases.

C. Geographical dispersement and Remoteness of Counsel require Centralized Management.

Defendants have offices in New Jersey and Japan. As outlined in the attached case listing at Exhibit A, only five of the 59 plaintiffs are New Jersey residents. This geographical diversity meets the geographic disbursement and remoteness requirement.

D. Centralized Management will promote fairness and provide convenience to all parties and their Counsel.

Centralized Management of cases such as those in this litigation that involve a significant number of parties, court filings, court hearings and motion practice is appropriate. It makes no sense in the context of this litigation to have the cases proceed before different Judges in different counties. Centralized Management in a Multi-County litigation venue, with an experienced Judge, will help 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 Atlantic and Hudson Counties.

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Centralized management is particularly appropriate here, as all but one of the cases already were consolidated for discovery in Atlantic County, and Judge Johnson has been managing the consolidated litigation for nearly a year. That all but one of the cases is consolidated before Judge Johnson is solely the result of plaintiffs' motion to consolidate in June 2014. Plaintiffs chose Atlantic County. They cannot argue now that centralization in the venue they chose for consolidation is either unfair or inconvenient.

Centralization of this litigation before Judge Johnson will result in the efficient utilization of judicial resources. Allowing plaintiffs to file lawsuits in counties other than Atlantic County, such as Ms. Kessler's recent filing in Hudson County, will lead to a risk of inconsistent or duplicative rulings, inconsistent orders and inconsistent judgments.

E. Related Matters Pending

An MDL has been established, and as noted above Judge Johnson, Judge Kugler and Magistrate Judge Schneider have attended a Science Day scheduled by Judge Johnson. Judge Johnson at the May 8, 2014 Case Management Conference made clear his intent to coordinate discovery with the MDL proceedings. Centralized Management before Judge Johnson, one of New Jersey's experienced Multi-County litigation Judges, together with his 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

This point bears repeating: Plaintiffs chose Atlantic County when seeking consolidation of these cases. These matters have been pending in Atlantic County for over a year. Judge Johnson has been actively overseeing this docket of cases as it has

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grown. 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.

Further, based upon review of the current Civil Division caseloads, Atlantic County is the proper venue for this litigation. The Hudson County Superior Court, Civil Division added 34,536 new cases to the docket between July 2014 and March 2015, compared to the Atlantic County Superior Court, Civil Division which added just 16,859 new civil cases in the same time period. See New Jersey Judiciary, Court Management Statistics, July 2014 – March 2015, <http://www.judiciary.state.nj.us/quant/cman1503.pdf>.

CONCLUSION

All parties are hereby notified that this application will be sent by the Administrative Director to all Assignment Judges and Civil Presiding Judges, will be published by the Administrative Director in the legal newspapers, and will be posted on the Judiciary's Internet website both in the Notices section and in the Mass Tort Information Center. Once the comment period has closed, the Administrative Director will present this application, along with a compilation of any comments and objections received to the Supreme Court for its review and determination.

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For all of the foregoing reasons, Defendants Daiichi Sankyo, Inc., Daiichi Sankyo U.S. Holdings, Inc., Forest Laboratories, Inc., Forest Pharmaceuticals, Inc., and Forest Research Institute, Inc. respectfully request each of the matters identified in Exhibit A, and any additional cases filed in New Jersey alleging sprue-like enteropathy as a result of taking prescription medicine containing Olmesartan be consolidated for Centralized Management in Atlantic County.

Respectfully submitted,

DRINKER BIDDLE & REATH LLP
Attorneys for Defendants

By: 
Susan M. Sharko

-and-

By: 
Daniel B. Carroll

Date: May 18, 2015

cc: Honorable Nelson C. Johnson, J.S.C.
Honorable Peter F. Bariso, Jr., J.S.C.
All Plaintiffs' Counsel