

# **TALCUM POWDER LITIGATION**

**NAVAN WARD, PRINCIPAL – BEASLEY ALLEN ET. AL.**

**NAVAN.WARD@BEASLEYALLEN.COM**



# OVERVIEW

- **LITIGATION**

- **VENUES**
- **VERDICTS**
- **TRIAL SETTINGS**

- **PRODUCTS AND PLAYERS**

- **THE LIABILITY STORY**

- **WHAT DID THEY KNOW?**
- **WHEN DID THEY KNOW IT?**

- **DAMAGES**

- **CRITERIA**
- **PREPARING YOUR PLAINTIFF**

# LITIGATION



**WHERE ARE WE NOW?**

# VERDICTS

## ***BERG V. J&J AND IMERYS***

- **SOUTH DAKOTA - OCTOBER 2013**
- **LIABILITY FOR NEGLIGENCE – IN FAVOR OF PLAINTIFF – ZERO DAMAGES**
- **IMERYS DISMISSED ON SUMMARY JUDGMENT**

## ***FOX V. J&J AND IMERYS***

- **ST. LOUIS - FEBRUARY 2016**
  - **COMPENSATORY \$10,000,000**
  - **PUNITIVE DAMAGES FOR WRONGFUL DEATH:**
    - **\$22,000,000 (J&J)**
    - **\$40,000,000 (JJCC)**
- IMERYS – DEFENSE VERDICT**

## ***RISTESUND V. J&J AND IMERYS***

- **ST. LOUIS - APRIL 2016**
  - **COMPENSATORY \$5,000,000**
  - **PUNITIVE DAMAGES:**
    - **\$35,000,000 (J&J)**
    - **\$15,000,000 (JJCC)**
- IMERYS – DEFENSE VERDICT**



# **CURRENT FILINGS**

- **St. Louis (State) – 1000 cases**
- **New Jersey (State) – 140 cases**
- **New Jersey (Federal) – 1 case**
- **Washington D.C. (State) – 1 case**
- **Maryland (Federal) – 1 case**
- **Louisiana (Federal) – 1 case**
- **Los Angeles (State) – 2 cases**

# UPCOMING TRIALS

Case Name	Trial Date
<i>Hogans, et al. v. J&amp;J, et al. (St. Louis State Court)</i>	September 26, 2016
<i>Carl, et al. v. J&amp;J, et al. (New Jersey State Court)</i>	October 11, 2016
<i>Balderrama, et al. v. J&amp;J, et al. (New Jersey State Court)</i>	January 4, 2017
<i>Swann, et al. v. J&amp;J, et al. (St. Louis State Court)</i>	January 9, 2017
<i>Ingham, et al., v. J&amp;J, et al. (St. Louis State Court)</i>	February 21, 2017
<i>Oules v. J&amp;J, et al. (DC)</i>	April 2017

# THE PLAYERS

**JOHNSON & JOHNSON**

**PARENT COMPANY**



**J&J CONSUMER  
COMPANIES, INC.**

**WHOLLY OWNED SUBSIDIARY OF J&J**

**MANUFACTURER OF J&J BABY  
POWDER**

**IMERY'S TALC  
AMERICA, INC.**

**MINING COMPANY AND EXCLUSIVE  
SUPPLIER OF TALC TO J&J**

**F/K/A LUZENAC**

**F/K/A RIO TINTO MINERALS**

**\*We are NOT currently litigating against other talc manufacturers!**

# THE PRODUCT

- **WHAT IS TALC?**
  - **MAGNESIUM SILICATE**
- **WHAT IS IT USED FOR?**
  - **PRETTY MUCH EVERYTHING!**
- **WHERE DOES IT COME FROM?**
  - **MINED FROM THE EARTH**
- **WHY IS IT HARMFUL?**
  - **CREATES FOREIGN BODY REACTION**
  - **CHRONIC INFLAMMATION**



**IMERY'S TALC MINED IN CHINA**

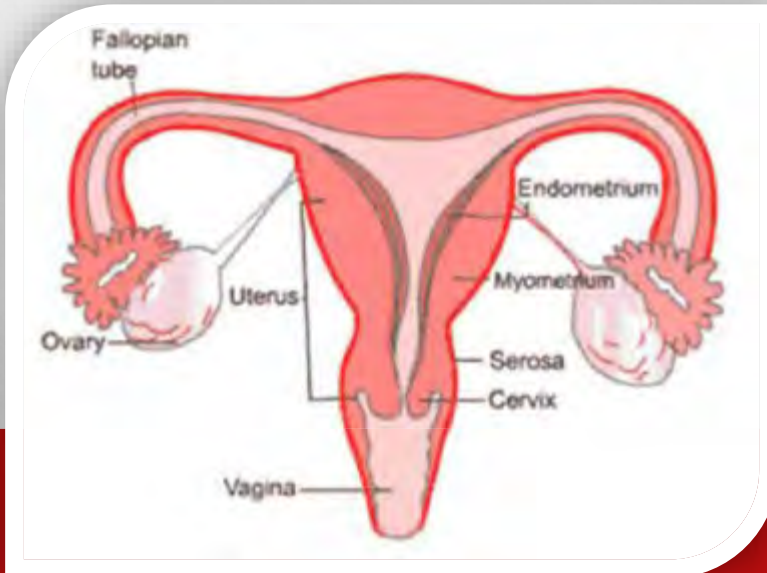




# THE INJURY: OVARIAN CANCER



- **TYPICALLY DIAGNOSED AT STAGE III OR IV**
- **LESS THAN 20% SURVIVAL RATE W/IN 5 YEARS OF DIAGNOSIS**
- **APPROXIMATELY 10% OF ANNUAL DIAGNOSES AND DEATHS RELATED TO TALC USE**



# **THE CASE: IN A NUTSHELL**

- **GENITAL TALC EXPOSURE > 6 YEARS (MINIMUM 2,400 APPLICATIONS)**
- **DIAGNOSIS OF OVARIAN CANCER**
- **DEFENDANTS KNEW OR SHOULD HAVE KNOWN OF INCREASED RISK OF OVCA – NO WARNING!!!**
- **TALC PARTICLES IDENTIFIED IN THE TUMOR TISSUE**
- **PLAINTIFF DAMAGES**

# Consumers receive NO cancer warning



**WARNING: Keep powder away from child's face to avoid inhalation, which can cause breathing problems. Avoid contact with the eyes. For external use only.**



# THE LIABILITY STORY



**WHAT DID THEY KNOW AND WHEN DID THEY KNOW IT??**





## **§ 740.1 Establishment of warning statements.**

**THE LABEL OF A COSMETIC PRODUCT SHALL BEAR A WARNING STATEMENT WHENEVER NECESSARY OR APPROPRIATE TO PREVENT A HEALTH HAZARD THAT MAY BE ASSOCIATED WITH THE PRODUCT.**

**THE DEFENDANTS HAVE A DUTY TO WARN**

Background

On 22nd October 1997, Face Value will air a programme, which will discuss a potential link between talc and ovarian cancer. This issue has been around for many years and there has been a full FDA review of all of the research available. This review has concluded that there is absolutely no causal link between talc and ovarian cancer. This is an industry matter and is not specific to Johnson's Baby powder. The CPTA has issued a full statement on the matter and Johnson & Johnson supports this statement.

The purpose of this document is to supplement the question and answer sheet already issued by J&J corporate. It covers issues specific to what may be aired during the Face Value programme. Any questions on the link to ovarian cancer or the similarities to asbestos are contained within the corporate Q&A also attached.

# J & J Corporate Rep 1997

is the conclusion of the independent review carried out by the FDA. Trust and safety is the basis of our company reputation and if we believed there was even the slightest risk associated with the normal use of Johnson's Baby Powder, we would not hesitate to take the necessary action.

Talc and Ovarian Cancer. This is the view expressed by the independent FDA working party who have reviewed all of the research and is supported by the CPTA.

Q.39: Are you saying that the research is not valid in its conclusions?

A.39: What is most important here is what the independent working party who have reviewed this research have concluded. They have concluded that there is no link to ovarian cancer either implied or actual. We have also carried out our own review of the data and we support the conclusions drawn by the FDA.

Q.40: Why did Johnson & Johnson decline to be interviewed by Face Value?

A.40: The talc issue is a general industry issue and is not specific to Johnson's Baby Powder. The CPTA issued an industry response to Face Value, which we support. We are more than happy to talk to our consumers directly (as



# J&J ADMITS AWARENESS OF THE STUDIES...



Talc use and ovarian cancer: Influence of histologic type and menopausal status on strength and dose-response of the association

Allison F. Vitonis<sup>1</sup>, Linda Titus-Ernstoff<sup>1</sup>, Daniel W. Cramer<sup>1</sup>

<sup>1</sup> Department of Obstetrics and Gynecology, Brigham and Women's Hospital, Boston, MA



More than 20 epidemiologic studies support an association between talc powder use in the genital area and ovarian cancer;

Data come from three phases of a case-control study of ovarian cancer in New England. We identified ovarian cancer cases diagnosed in Eastern Massachusetts and all of New Hampshire

from May 11, 2003, and C. We enrolled 2,000 controls for identified in supplemental controls. All phases were in Massachusetts. New Hampshire identified the 1,485 were in and 1,600 were enrolled demographic history, and interview. Q. a reference diagnosis del controls. The and Women's Center Institute

We used association b use of genital (estimated in adjusted for oral contraceptives, smoking, alcohol use, dietary fat intake, and family history of breast or ovarian cancer. Separate analyses were done for all cases, non-mucinous invasive cases, serous invasive cases, and serous invasive cases unlikely to have been familial.

history of ovarian cancer or early onset breast cancer

Talc use	Controls N=2000	Cases N=1000	OR (95% CI)	P	Controls N=2000	Cases N=1000	OR (95% CI)	P	Controls N=2000	Cases N=1000	OR (95% CI)	P
Never	75.3%	86.3%	1.00	0.001	77.9%	88.8%	1.00	0.001	79.5%	89.4%	1.00	0.001
Ever	24.7%	13.7%	1.58 (1.14, 2.18)	0.001	22.1%	11.2%	1.38 (0.94, 2.00)	0.001	20.5%	10.6%	1.30 (0.92, 1.85)	0.001

women, the interaction between menopausal status and dose-response was significant for non-mucinous invasive, serous cases, and invasive serous cases unlikely to have been familial. In the latter group the dose response

more unlikely women had for about 5 for women to women was present or whether

needs to a and ovarian effect on the with frequent for invasive ing data sets

is to DWG;

control approach

control approach

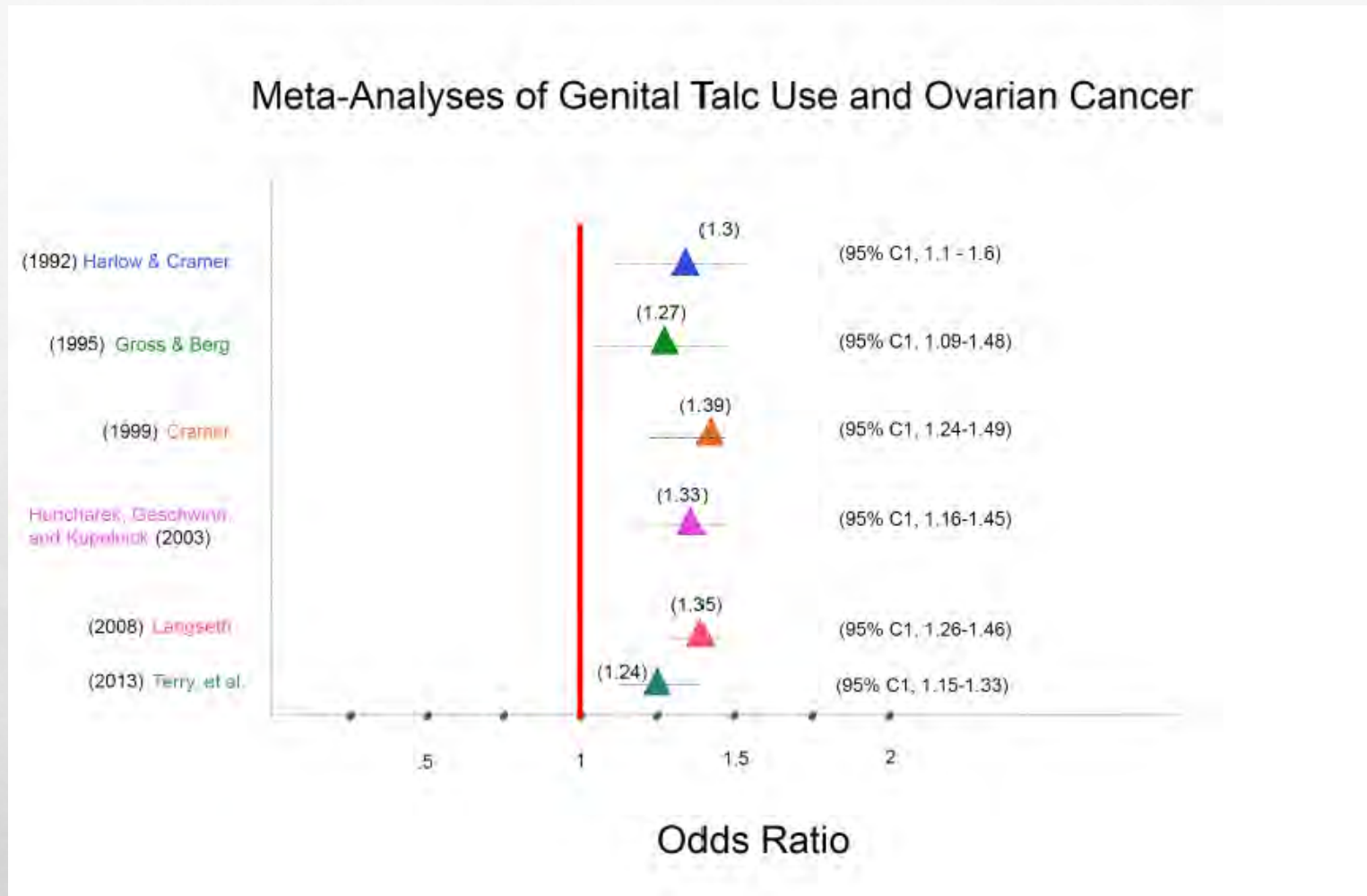
control approach

For invasive serous cancer unlikely to have had a familial origin, premenopausal women had odds ratios (and 95% limits) of 2.12 (1.16, 3.89) for about 2000 to 8400 applications and 3.53 (1.63, 7.65 for women with greater than 8400 applications, compared to women with no use.

# BUT DENIES A CAUSAL LINK!



# WHAT DO THE STUDIES SHOW?



**GENITAL USE OF TALC INCREASES RISK OF OVCA 30 – 60%!**



# 1971

*The Journal of Obstetrics and Gynaecology  
of the British Commonwealth*  
March 1971. Vol. 78. pp. 266-272.

## 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

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, unstained tissue prepared for electron microscopy.

#### Replication Technique

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

immersing 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

deeply embedded within the tumour tissue.

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

*The Journal of Obstetrics and Gynaecology  
of the British Commonwealth*  
March 1971. Vol. 78. pp. 266-272.

W. J. HENDERSON.

ovarian tumours.

talc particles were found

# 1975

Johnson & Johnson

New Brunswick, N.J.  
December 3, 1975

Subject: Talc in the Ovaries

Attached is a letter received from Dr. Keith Griffiths, who is Director of the Tenovus Institute for Cancer Research in Cardiff. The letter arrived in response to a small donation I had sent the Cardiff Scientific Society with the main objective of trying to determine what research is in actual fact being conducted at the Tenovus Institute.

It might be of value to identify the precise scientific data to Tenovus concerning talc and ovarian cells. We are

GHS/cd  
Att.

*you know we were planning to  
donate to the C.S.S. ? It has  
certainly given Griffiths the  
opening to put us on notice  
re the talc/ovary problem.*

*Don*

1 of 1

*he was  
donating  
C.S.S.  
Griffiths the  
us on notice  
ovary problem.*

*Don*

JNJ 000026241

Pltf\_JNJ\_00003336

"It has certainly given support to the opening to put us on notice re the talc/ovary problem"



# 1986

*Rev 3* *Joan 1986 P. 2/9*

TECHNOLOGICAL FORECAST  
- POWDERS -

Powders refers to various inorganic and organic compounds that are applied to baby and adult skin, that are generally considered inert, and that provide skin benefits mainly from their physical characteristics, rather than their chemical compositions. This forecast does not cover medicated powders, where the powder is a vehicle for an active ingredient such as an anti-diaper rash agent.

2. PRODUCT BACKGROUND

1. Attribute Factors

User and benefit attributes and product attributes have been defined for both baby and adult needs.

Users	Baby	Adult
Attributes:		
End Benefits:	- <u>DRY SLIP</u> : softness, smoothness, lubricity	
	- <u>Net slip</u> : ability to convey the same tactile feel of softness, smoothness, slipperiness as found with powder on dry skin	
	After bath, during diaper change	After bath, shower
	- <u>Absorbency</u> : take up water/moisture	
	- <u>Adhesion</u> (Not considered important)	Vertical surface retention, esp. when applying after showering.
	- <u>Lowest Friction</u> : prevent chafing & rubbing	
Product	- <u>Flow</u> : ease of dispensing	
	- <u>Spreadability</u> : ease of application to the skin	

## Safety Factors

Safety of cosmetic powders has been a concern, especially among health professionals. They have decided that powders provide no health benefit.

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2ND 000000523

1986

## TECHNOLOGICAL FORECAST

- POWDERS -

Safety is of concern – Powders have "no health benefit"

# 1992

- JOHNSON'S

## - JOHNSON'S BABY POWDER -

8/5/92

s in Drug and Mass; Mass

ded on 9 oz and 14 oz sizes of the  
Drug and making these skus part

### Major Opportunities

1. Continue to fully leverage the diaper rash claim against JBP cornstarch.  
- Current household usage on Johnson's Baby Powder Pure Cornstarch has declined from 13% in 1989 to 8% in 1991. Continue to support diaper rash claim in order to rebuild product usage.
2. Investigate ethnic (African American, Hispanic) opportunities to grow the franchise.  
- Johnson's Baby Powder has a high usage rate among African Americans

2. Negative publicity from the health community on talc (inhalation, dust, negative doctor endorsement, cancer linkage) continues.

### Major Obstacles

1. The franchise faces weakness on several key skus in factory sales and in consumption.

	<u>YTD % +/- YAG</u>	
	<u>JBP</u>	<u>JBP/CS</u>
9 OZ	-35.6%	-26.4%
14 OZ	-9.7%	+6.3%
24 OZ	-14.8%	-31.2%

- JBP 4 OZ is down -6% in all outlets; Drug distribution down 5 points versus YAG.

2. Negative publicity from the health community on talc (inhalation, dust, negative doctor endorsement, cancer linkage) continues.



# 1992

- JOHNSON'S

## - JOHNSON'S BABY POWDER -

8/5/92

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ded on 9 oz and 14 oz sizes of the  
Drug and making these sizes part

### Major Opportunities

2. Negative publicity from the health community on talc (inhalation, dust,  
negative doctor endorsement, cancer linkage) continues.

2. Investigate ethnic (African American, Hispanic) opportunities to grow the franchise.

- Johnson's Baby Powder has a high usage rate among African Americans (52.0%) and among Hispanics (37.6%). Additionally usage indices are high for African American and Hispanic females for JBP talc (139 and 101 respectively). Hispanic females also have a high index (151) against JBP cornstarch. The brand can increase volume in 1993 by targeting these groups.

*The brand will institute an adult hispanic media program and potentially launch an adult Black print effort.*

2. Negative publicity from the health community on talc (inhalation, dust, negative doctor endorsement, cancer linkage) continues.

# 1992

## Perineal Exposure to Talc and Ovarian Cancer Risk

BERNARD L. HARLOW, PhD, DANIEL W. CRAMER, MD, ScD, DEBRA A. BELL, MD,  
AND WILLIAM R. WELCH, MD

J. 80, NO. 1, JULY 1992

applying these ORs to the exposure rate among cases,<sup>24</sup> the proportion of ovarian cancer incidence attributable to this level of talc exposure is about 10%. Nevertheless, given the poor prognosis for ovarian cancer, any potentially harmful exposures should be avoided, particularly those with limited benefits. For this reason, we discourage the use of talc in genital hygiene, particularly as a daily habit.



# 1994

NOV 16 '94 12:18 PM J-T CORP FS  
NOV 15 '94 04:10 PM J-T CORP FS  
908 TO 00741206 P.01/02  
NOV 14 1994 7:57 PM  
CANCER PREVENTION COALITION  
420 NORTH MICHIGAN AVENUE - SUITE 410 CHICAGO, IL 60611 • 312-467-1000 • FAX 312-467-0888

BOARD OF DIRECTORS  
to Attend  
Advisory  
John Doe, M.D.  
Susan Smith, M.D.  
James Wilson, M.D.  
John Doe, M.D.  
Giles Graham  
William L. Smith, M.D.  
Thomas Wilson, M.D.  
Peter G. Smith, M.D.  
Lester H. Wilson, M.D.

DATE  
Ralph Larson  
C.E.O.  
Johnson & Johnson, Inc.  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933

November 10, 1994

Dear Mr. Larson,

Ralph Larson  
C.E.O.  
Johnson & Johnson, Inc.  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933

Dear Mr. Larson,

A wide range of scientific studies dating back to the 1960s shows conclusively that the frequent use of talcum powder in the genital area poses a serious risk of ovarian cancer.

1104

Cancer prevention through reduction of carcinogens in air, water, food, consumer products, and the workplace.

NOV 15 '94 16:02  
201 874 1123 PAGE 02  
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JND 000018645

November 10, 1994

**LETTER TO J&J CEO - "TALCUM POWDER IN THE GENITAL AREA POSES A SERIOUS RISK OF OVARIAN CANCER"**



# 1996

JERSEY JOURNAL (CITY  
EDITION)  
JERSEY CITY, N.J.  
DAILY 65,000  
WEDNESDAY  
APR 17 1996

212  
BURELLE'S PI

## Women's health concerns prompt condom makers to stop using talc

By Marie McCullough  
Knight-Ridder Newspapers  
Candace Sue Kasper believes

Concern about talc as an ovarian carcinogen goes back 50  
years in the medical literature. By the 1970s, evidence

Concern about talc as an ovarian carcinogen goes back 50 years in the medical literature. By the 1970s, evidence was mounting that talc particles might migrate into a woman's fallopian tubes where they could cause scarring and irritation of the ovaries. Scientists believed in some cases that the scarring led to infertility or cancer.

Carter-Wallace, which makes Trojans and claims 60 percent of the American condom market, said in a statement that "to allay any possible concern," it has "discontinued the use of talc in its condom manufacturing process."

**TALC CAN MIGRATE/CAUSE CANCER – CONDOM MAKERS REMOVE TALC**

# 1997

9/17/97

97-02-10 00:34 R.P.

P.1

ALFRED P. WERNER, D.M.D., S.D., C.D., M.D.  
FEDERAL AGENCY OF TOBACCO REGULATION  
312 SAINT STREET  
RICHLAND, WASHINGTON 99352

9/17/97

Mr. Michael R. Chudkowsky  
Manager, Preclinical Toxicology  
J&J Consumer Products, Inc.  
Skillman, NJ 08558-9416

Dear Mike:

There is a German saying which translates as follows:

"A true friend is not he who bequeils you with flattery  
but he who discloses to you your mistakes  
before your enemies discover them."

In this spirit I would like to volunteer a critique of the  
three CTFA response statements which you faxed me on September

At that time there had been about 9 studies (more by now) published in the open literature that did show a statistically significant association between hygienic talc use and ovarian cancer. Anybody who denies this risks that the talc industry will be perceived by the public like it perceives the cigarette industry: denying the obvious in the face of all evidence to the contrary.

Of one of these studies knowable in public test, would have to do at a hearing (or any occasion, at that) to demolish the credibility of the talc industry is to refer to the studies by Kleinfeld et al, Thomas, and Thomas and Stewart!

Referring in a 1992 statement to a 1977 editorial in defense of one's position is not a very persuasive argument. Much can happen in 15 years.

509/375-0875 Fax 509/375-5693




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JN3 000024462

**MORE THAN 9 STUDIES SHOW LINK – RISK LOOKING LIKE THE CIGARETTE INDUSTRY**

# 2000

**CONFIDENTIAL**  **LUZENT AMERICA**  
DENVER TECHNICAL CENTER  
8800 E. NICHOLOSAVE, • ENGLEWOOD, CO 80112 • USA

INTEROFFICE MEMORANDUM

DATE: January 30, 2000

TO: R. Moli; R.S. Bernstein; E. Turner

FROM: R. J. Zazenski

SUBJECT: ACTION PLAN *RECOMMENDATIONS*  
for FINAL PHASE of NTP TALC REVIEW PROCESS

Executive Summary

The National Toxicological Program's (NTP) carcinogenic review of talc has entered the final phase of a four-step review process that will conclude with a listing recommendation by the NTP Executive

## Significant Issues

- Non-asbestiform talc was recommended for NTP listing by the first two review groups (RG1 & 2) by votes of 6-1 and 7-1. This overwhelming margin of 13-2 suggests that the reviewers found the epidemiology studies associating talc and ovarian cancer provided convincing evidence of talc carcinogenicity in humans.

• Non-asbestiform talc was recommended for NTP listing by the first two review groups (RG1 & 2) by votes of 6-1 and 7-1. This overwhelming margin of 13-2 suggests that the reviewers found the epidemiology studies associating talc and ovarian cancer provided convincing evidence of talc carcinogenicity in humans.

• The primary reason non-asbestiform talc was able to survive the third NTP meeting in December and not be recommended for listing was the introduction of doubt concerning the characterization of talc utilized in dusting powders cited in the epidemiology studies. All but one of the sixteen ovarian cancer

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LUZB13053

1 of 3

Pltf\_LUZ\_00005591

**NTP VOTE SUGGESTS THERE IS CONVINCING EVIDENCE OF CARCINOGENICITY**



# 2006

Page 2: [1] Deleted Judy Brown 7/18/2006 10:54:00 AM  
July 12, 2006

Mark Ellis  
President  
Industrial Minerals Association - North America  
Suite 301  
2011 Pennsylvania Ave. N.W.  
Washington, D.C. 20006

## July 12, 2006

Page 2: [2] Deleted

Judy Brown

7/18/2006 10:54:00 AM

When IARC concluded their review and classified "perineal use of talc-based powders" as a Group 2b carcinogen, we began to question the value of proceeding any further with the Mossman study. To put it in the vernacular, the "horse has already left the barn."

Mark Ellis  
President

Page 2: [3] Deleted

Judy Brown

7/18/2006 10:54:00 AM

One of their primary arguments is that there are simply too many positive epidemiology studies published to stem the tide of negative sentiment

Page 2: [4] Deleted

Judy Brown

7/18/2006 10:54:00 AM

Sincerely,

Eric Turner

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LUZ001443

LUZ001444

3 of 4

PRF\_LUZ\_00000190

4 of 4

PRF\_LUZ\_00000190

# SAFER ALTERNATIVE?

October 08, 2008

10/8/2014

[www.medicape.com/NewsArticle581781\\_p146](http://www.medicape.com/NewsArticle581781_p146)

[www.medicape.com](http://www.medicape.com)

## Talc Use in Genital Area Linked to Increased Risk for Ovarian Cancer

Zbysza Chruscielka | October 08, 2008

To read this article for CME, click here.

October 8, 2008 — Regular use of talc in the genital area was significantly associated with an increased risk for ovarian cancer in a new analysis reported in the September issue of *Cancer Epidemiology Biomarkers and Prevention*. The researchers say that genital use of talc should be avoided.

"We believe that women should be advised not to use talcum powder in the genital area, based on our results and previous evidence supporting an association between genital talc use and ovarian cancer risk," commented author Margaret Gates, ScD, research fellow at Brigham and Women's Hospital, in Boston, Massachusetts.

Margaret Gates, ScD, research fellow at Brigham and Women's Hospital, in Boston, Massachusetts. "Physicians should ask the patient about talc use history and should advise the patient to discontinue using talc in the genital area if the patient has not already stopped."

"An alternative to talc is cornstarch powder, which has not been shown to increase ovarian cancer risk, or to forgo genital powder use altogether,"

use was defined as the application of powder to the genital/perineal region at least once a week.

Genital talc use was associated with an increased risk for ovarian cancer in both study populations, although the 95% confidence intervals were wide in the NHS because of the limited sample size, the researchers comment. In the pooled analysis, the relative risk for the association with regular talc use was 1.35 for total ovarian cancer and 1.60 for the serous, invasive subtype.

This is broadly similar to the findings from the meta-analysis of 16 previous studies, which reported an approximately 30% increase in the risk for total epithelial ovarian cancer with regular genital exposure to talc (*Anticancer Res* 2003;23:1965-1969).

[http://www.medicape.com/NewsArticle581781\\_p146](http://www.medicape.com/NewsArticle581781_p146)

# CORNSTARCH!

# Annual number of new cases?

5 Q. Doctor, did you do any or run any data to  
6 determine in your opinion, statistical data to determine a  
7 percentage of cancers that could be attributable to talc?

8 A. As part of my 1999 paper I did do that, yes.

21 Q. So according to your statistical numbers, if  
22 22,000 women were diagnosed with ovarian cancer this year,  
23 according to your analysis and opinions, 2,200 of those  
24 could be attributable to talc use?

25 A. That's what my calculation suggested.

53

1 UNITED STATES DISTRICT COURT  
2 DISTRICT OF SOUTH DAKOTA  
3 SOUTHERN DIVISION  
\* \* \* \* \*  
Civ. 09-4179

Plaintiff,

VOLUME 2  
SEPTEMBER 25, 2013

INC.,

Defendants.

U.S. District Courthouse  
Sioux Falls, SD  
September 25, 2013  
9:00 a.m.

\* \* \* \* \*  
JURY TRIAL  
VOLUME 2  
\* \* \* \* \*

Honorable Karen E. Schreier, and a Jury  
District Court Judge  
Falls, SD

iesland  
land  
d Law Offices  
7709-6900

23 Mr. R. Allen Smith, Jr.  
24 The Smith Law Firm  
25 681 Towne Center Boulevard, Suite B  
Ridgeland, MS 39157



## CRAMER 2015

The association between talc use and ovarian cancer: a retrospective case-control study in two US states

Running Title: Ovarian cancer and talc

<sup>2</sup>Department of Epidemiology, Harvard School of Public Health, 677 Huntington Ave., Boston,

Massachusetts 02115, U.S.

<sup>3</sup>Department of Pathology, Br

may suggest a r  
and inflammato

Race	002 (70)	200 (30)	042 (00)	200 (34)	1.20 (1.0)	
White	1500 (74)	531 (26)	1321 (68)	612 (32)	1.35 (1.17, 1.55)	0.002
African American	17 (74)	6 (26)	16 (46)	19 (54)	5.08 (1.32, 19.6)	
Hispanic	27 (82)	6 (18)	25 (81)	6 (19)	1.10 (0.30, 4.12)	
Asian	5 (50)	5 (50)	34 (94)	2 (6)	0.04 (0.01, 0.34)	
Other	2 (67%)	1 (33)	3 (50)	3 (50)	--	

**Represents over 400% increase in ovarian cancer risk!**

- Histologic subtypes of epithelial ovarian cancer more likely to be associated with talc include serous and mucinous borderline tumors and invasive serous and endometrioid tumors.
- For epithelial ovarian cancer categories based on certain effect modifiers or histologic subtypes, stronger overall associations and dose-responses were observed.
- The association may be stronger in African Americans.

# DAMAGES



# RISK FACTORS

## FACTORS THAT INCREASE RISK

- **BRCA1/BRCA 2 GENETIC MUTATION**
- **FAMILY HISTORY OF OVCA/BRCA**
- **NO CHILDREN**
- **NO USE OF ORAL CONTRACEPTIVES**
- **ENDOMETRIOSIS**
- **USE OF FERTILITY DRUGS**
- **GENITAL TALC USE**

## PROTECTIVE FACTORS

- **HAVING CHILDREN**
- **BREASTFEEDING**
- **ORAL CONTRACEPTIVES**
- **NO FAMILY HISTORY/GENETIC MUTATION**
- **AFRICAN-AMERICAN HERITAGE W/NO TALC USE**



# CRITERIA

**Daily use of talc for minimum of 6 years**

**Diagnosis of Epithelial OVCA or  
Serous Invasive Fallopian Tube Cancer**

**Age at diagnosis between 30 years old and 60 years old**

**No immediate family history of Breast and/or OVCA  
(not a factor if BRCA negative)**

**NO INVENTORY factors**

# PREPARING THE PLAINTIFF

- **MUST PROVIDE STRONG PRODUCT IDENTIFICATION**
- **MUST BE ABLE TO DESCRIBE FREQUENCY AND DURATION OF USE**
- **MUST BE ABLE TO DESCRIBE (IN DETAIL) THE METHOD OF POWDER APPLICATION TO GENITALS**
- **CORROBORATION OF USE IS HELPFUL**
- **MUST HAVE READ THE WARNINGS (OR LACK THEREOF) ON BOTTLE, AND TESTIFY THAT HAD THERE BEEN A WARNING, SHE WOULD NOT HAVE USED THE PRODUCT**
- **MUST PRESERVE ANY CONTAINERS OF TALC STILL IN HER POSSESSION**
- **ENCOURAGE PHOTOGRAPHS OF INJURY/TREATMENT**
- **MONITOR HER HEALTH – BE PREPARED TO TAKE A TRIAL PRESERVATION DEPOSITION IF NECESSARY**

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**TALCOM POWDER LITIGATION**