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PRESS RELEASE

Embargoed for Release
November 17, 1994

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DUSTING WITH CANCER

COALITION URGES CHICAGO DRUG STORES TO LABEL TALC

Chicago - According to the Cancer Prevention Coalition the regular use of talc increases the risk of ovarian cancer. The Cancer Prevention Coalition (CPC) will announce its plans for a talcum powder labeling initiative here in Chicago at a Thursday, November 17, 1994 press briefing.

Speakers at the press briefing will include CPC Chair Dr. Samuel Epstein, CPC board members Dr. Quentin Young and Dr. Peter Orris, and an ovarian cancer survivor. The speakers will explain why a labeling initiative is important to residents of Chicago, and will also answer questions from the press.

Recently, CPC sent letters to the Chicago corporate offices of Osco and Walgreen drug stores urging that they provide customers with information on the dangers associated with the use of talc. Additionally, CPC is filing a petition with the FDA requesting that talc products be explicitly labeled.*

The use of talc poses a serious risk of ovarian cancer. Estimates are that up to 17 % of American women regularly use talc in the genital area. Women have been compelled, through advertisements of the cosmetic industry, to dust themselves to mask odors. Talcum powder has historically been a symbol of freshness, cleanliness and purity. Talc is even more commonly used on infants.

Ovarian cancer is a silent killer. It causes 38 deaths daily among American women – totalling 14,000 deaths annually. It is the fourth highest women's cancer death rate in the U.S. Over 60% of ovarian cancer victims die within five years of diagnosis.

(more)

"Studies seem to indicate that talc poses an increased risk factor for Ovarian Cancer, thus I would support a warning label to alert women to this possible risk," stated Diane Farrell, a Chicago resident who has been fighting ovarian cancer for the last two years.

According to Dr. Samuel Epstein, of the Cancer Prevention Coalition, "A wide range of scientific studies over the last three decades have clearly linked regular talc use by women and ovarian cancer."

The talc labeling project is the first phase of a "Consumer Labeling Initiative" that will inform citizens of the presence of undisclosed carcinogenic ingredients and contaminants in cosmetics, other consumer products, and food and how to avoid them.

WHEN: Thursday, November 17, 1994 at 10:30 a.m.

WHAT: Press briefing to announce the talc labeling initiative

WHERE: Cancer Prevention Coalition, 520 North Michigan, Suite 410

PHOTO OPPORTUNITY: CPC Board members, ovarian cancer survivor, products that contain talc, and a poster size version of a proposed label.

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The Cancer Prevention Coalition is a Chicago-based, national organization of leading independent experts on cancer prevention and public health, together with citizen activists, organized labor, public interest and women's cancer groups.

**The New York-based Center for Constitutional Rights, one of the nation's leading public interest legal organizations in the country, will be acting as CPC's legal counsel.*

**Citizen Petition Seeking Carcinogenic Labeling on all
Cosmetic Talc Products.**

17 November 1994

David A. Kessler, M.D.
Commissioner
Food and Drug Administration, Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

The undersigned submits on behalf of the Cancer Prevention Coalition, Inc. (CPC), Samuel S. Epstein, M.D., Chair and National Advisor of the Ovarian Cancer Early Detection and Prevention Foundation (OCEDPF), Nancy Nehls Nelson, member of the Ovarian Cancer Early Detection and Prevention Foundation, Peter Orris, M.D. and Quentin Young, M.D. This citizen petition, is based on scientific papers dating back to the 1960s which warn of increased cancer rates resulting from frequent exposure to cosmetic grade talc.

The undersigned submits this petition under 21 U.S.C. 321 (n), 361, 362, and 371 (a); and 21 CFR 740.1, 740.2 of 21 CFR 10.30 of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to require that all cosmetic talc products bear labels with a warning such as "Talcum powder causes cancer in laboratory animals. Frequent talc application in the female genital area increases the risk of ovarian cancer."

A. AGENCY ACTION REQUESTED

This petition requests that FDA take the following action:

- (1) Immediately require cosmetic talcum powder products to bear labels with a warning such as "Talcum powder causes cancer in laboratory animals. Frequent talc application in the female genital area increases the risk of ovarian cancer."
- (2) Pursuant to 21 CFR 10.30 (h)(2), a hearing at which time we can present our scientific evidence.

B. Statement of Grounds

Ovarian cancer is the fourth deadliest women's cancer in the U.S., striking approximately 23,000 and killing approximately 14,000 women this year. Ovarian cancer is very difficult to detect at the early stages of the disease, making the survival rate very low. Only three percent of ovarian cancer cases can be attributed to family history.¹ One of the avoidable risk factors for ovarian cancer is the daily use of talcum powder in the genital area.²

Research done as early as 1961 has shown that particles, similar to talc and asbestos particles, can translocate from the exterior genital area to the ovaries in women.^{3,4,5} These findings provide support to the unexpected high rate of mortality from ovarian cancer in female asbestos workers.^{6,7,8} Minute particles such as talc are able to translocate through the female reproductive tract and cause foreign body reactions in the ovary.

There is a large body of scientific evidence, dating back thirty years, on the toxicity and mineralogy of cosmetic talc products. As early as 1968, Cralley et al. concluded:

All of the 22 talcum products analyzed have a...fiber content...averaging 19%. The fibrous material was predominantly talc but probably contained minor amounts of tremolite, anthophyllite, and chrysotile [asbestos-like fibers] as these are often present in fibrous talc mineral deposits...Unknown significant amounts of such materials in products that may be used without precautions may create an

¹SEER Cancer Statistics, 1973-1990

²Harlow BL, Cramer DW, Bell DA, Welch WR. "Perineal exposure to talc and ovarian cancer risk." Obstet Gynecol, 80: 19-26, 1992.

³Egeli GE, Newton M. "The transport of carbon particles in the human female reproductive tract." Fertility Sterility, 12: 151-155, 1961.

⁴Venter PF, Iturralde M. "Migration of particulate radioactive tracer from the vagina to the peritoneal cavity and ovaries." S African Med J, 55: 917-919, 1979.

⁵Henderson WJ, Hamilton TC, Baylis MS, Pierrepoint CG, Griffiths K. "The demonstration of migration of talc from the vagina and posterior uterus to the ovary in the rat." Environ Research, 40: 247-250, 1986.

⁶Newhouse ML, Berry G, Wagner JC, Turok ME. "A study of the mortality of female asbestos workers." Brit J Indust Med, 29: 134-141, 1972.

⁷Wignall BK, Fox AJ. "Mortality of female gas mask assemblers." Brit J Industrial Med, 39: 34-38, 1982.

⁸Acheson ED, Gardner MJ, Pippard E, Grime LP. "Mortality of two groups of women who manufactured gas masks from chrysotile and crocidolite asbestos: a 40-year follow-up." Brit J Ind Med, 39: 344-348, 1982.

unsuspected problem.⁹

As a follow-up to previous findings, Rohl, et al., examined 21 samples of consumer talcums and powders, including baby powders, body powders, facial powders and pharmaceutical powders between 1971-1975. (See Appendix I) The study concluded:

"...cosmetic grade talc was not used exclusively. The presence in these products of asbestiform anthophyllite and tremolite, chrysotile, and quartz indicates the need for a regulatory standard for cosmetic talc...We also recommend that evaluation be made to determine the possible health hazards associated with the use of these products."¹⁰

Talc is a carcinogen, with or without the presence of asbestos-like fibers. In 1993, the National Toxicology Program published a study on the toxicity of non-asbestiform talc and found clear evidence of carcinogenic activity.¹¹

Recent cancer research in the United States has found conclusively that frequent talcum powder application in the genital area increases a woman's risk of developing ovarian cancer.^{12,13,14,15} Cramer, et al., suggested that talc application directly to the genital area around the time of ovulation might lead to talc particles becoming deeply imbedded in the substance of the ovary and perhaps causing foreign body reaction (granulomas) capable of causing growth of epithelial ovarian tissue.^{16,17}

Harlow, et al., found that frequent talc use directly on the

⁹ Crallley LJ, Key MM, Groch DH, Lainhart WS, Ligo RM. "Fibrous and mineral content of cosmetic talcum products." Am Industrial Hygiene Assoc J, 29: 350-354, 1968.

¹⁰ Rohl AN, Langer AM, Sellifoff EJ, Tordini A, Klimentidis R, Boves CA, Skinner DL. "Consumer talcums and powders: mineral and chemical characterization." J Toxicol Environ Health, 2: 255-284, 1976.

¹¹ National Toxicology Program. "Toxicology and carcinogenesis studies of talc (CAS No 14807-96-6) in F344/N rats and B6C3F₁ mice (Inhalation studies)." Technical Report Series No 421, September 1993.

¹² Hartzge J, Hoover R, Lasher LG, McGowan L. "Talc and ovarian cancer." Lectures, JAMA, 250: 1844, 1983.

¹³ Rosenblatt KA, Saklo M, Rosenheim NB. "Mineral fiber exposure and the development of ovarian cancer." Gynecol Oncol, 45: 23-25, 1992.

¹⁴ Whittemore AS, Wu ML, Paffenberger RS, Sarles DL, Kampert JB, Grosser S, Jung DT, Ballon S, Hendrickson M. "Personal and environmental characteristics related to epithelial ovarian cancer. II. Exposures to talcum powder, tobacco, alcohol, and coffee." Am J Epidemiol, 1118 1218-1240, 1988.

¹⁵ Harlow, 1992.

¹⁶ Ibid.

¹⁷ Cramer DW, Welch WR, Scully RE, Wojciechowski CA. "Ovarian cancer and talc: a case control study." Cancer, 50: 372-376, 1982.

genital area during ovulation increased a woman's risk threefold. That study also found:

"The most frequent method of talc exposure was use as a dusting powder directly to the perineum [genitals]...Brand or generic "baby powder" was used most frequently and was the category associated with a statistically significant risk for ovarian cancer."

In Harlow's report, arguably the most comprehensive study of talc use and ovarian cancer to date, 235 ovarian cancer cases were identified and compared to 239 controls, women with no sign of ovarian cancer or related health problems. Through personal interviews, Harlow, et al., found that 16.7% of the control group reported frequent talc application to the perineum.¹⁸ This percentage is useful in estimating the number of women in the general population exposed to cosmetic talc in the genital area on a regular basis. Harlow, et al., concludes:

"...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."

Clearly, large numbers of women - an estimated 17% - are using cosmetic talc in the genital area and may not be adequately warned of the risk of ovarian cancer from daily use.

C. Claim for Categorical Exclusion

A claim for categorical exclusion is asserted pursuant to 21 CFR 25.24 (a)(11).

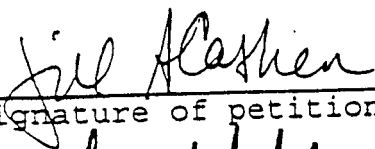
D. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition

¹⁸ Harlow, 1992.

This petition is submitted by:

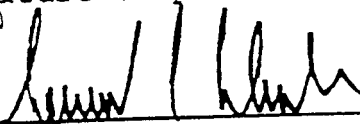
Jill A. Cashen
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Cancer Prevention Coalition
520 North Michigan Avenue, Suite 410
Chicago, Illinois 60611
312.467.0600 - phone
312.467.0599 - fax



Signature of petitioner

11/17/94

Date



Signature of petitioner

11-17-94

Date

Council to the Cancer Prevention Coalition:
Center for Constitutional Rights
Michael E. Deutsch, Legal Director
666 Broadway
New York, NY 10012
212-614-6427

APPENDIX I:
Results from an informal survey of talc products in Chicago
drug stores.

Baby Powders:

Johnson & Johnson Baby Powder (Johnson & Johnson, Skillman, NJ)
Contains: TALC, fragrance

Osco Brand Baby Powder (Osco Drug, Oak Brook, IL)
Contains: TALC, fragrance

Body Powders:

Jean Nate Perfumed Talc (Revlon, New York, NY)
Contains: TALC, kaolin, magnesium carbonate, fragrance.

Shower to Shower (Johnson & Johnson, Skillman, NJ)
Contains: TALC, cornstarch, sodium bicarbonate, fragrance,
polysaccharides.

Osco Brand Body Powder (Osco Drug, Oak Brook, IL)
Contains: TALC, cornstarch, sodium bicarbonate, fragrance,
polysaccharides.

Ammens Medicated Powder (Bristol-Myers Squibb, New York, NY)
Contains: Zinc oxide, cornstarch, fragrance, isostearic
acid, PPG-20, methyl glucose ether, TALC.

Cashmere Bouquet Perfumed Powder (Colgate, New York, NY)
Contains: TALC, magnesium carbonate, zinc stearate,
fragrance.

Gold Bond Medicated Powder (Martin Himmel, Hypoluxo, FL)
Contains: Menthol, Zinc oxide, boric acid, eucalyptol,
methyl salicylate, salicylic acid, TALC, thymol, zinc
stearate.

Feminine products:

Vagisil Feminine Powder (COMBE, Inc., White Plains, NY)
Contains: Cornstarch, aloe, mineral oil, magnesium
stearate, silica, benzethonium chloride, fragrance.

Vaginex Feminine Powder (Schmid Laboratories, Sarasota, FL)

Contains: Zinc oxide, cornstarch, fragrance, 6-hydroxquinoline, 8-hydroxquinoline sulfate, isostearic acid, PPG-20, methyl glucose ether, TALC.

Summer's Eve Feminine Powder (CB Fleet Co., Lynchburg, VA)

Contains: Cornstarch, tricalcium phosphate, oxoxynol-9, benzethonium chloride, fragraence.

FDS Feminine Deodorant Spray (Alberto Culver, Melrose Park, IL)

Contains: isobutane, isopropyl myristate, cornstarch, mineral oil, fragrance, lanolin alcohol, hydrated silica, magnesium stearate, benzyl alcohol.