

PRESS RELEASE

CANCER PREVENTION COALITION

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\$4.25 BILLION IMPLANT SETTLEMENT IGNORES RISK OF BREAST CANCER

Chicago - The recent \$4.25 billion settlement to women with silicone breast implants ignores the risks of developing breast cancer for two million women. Cancer Prevention Coalition (CPC) Chair, Dr. Samuel Epstein said, "The Food and Drug Administration (FDA) and the implant industry have failed to warn women of serious cancer risks, although they have known of this information for decades." CPC urges that women immediately be informed of these risks.

Unpublished Dow Corning studies, from 1976 onwards and discovered in a 1987 FDA inspection, showed that silicone gel injection induced malignant tumors in rats. FDA scientists concluded in 1988 confidential memoranda that: "While there is no direct proof that silicone causes cancer in humans, there is considerable evidence that it can do so," and recommended that, "a medical alert be issued to warn the public of the possibility of malignancy following long term implant(ation)." FDA's only response was to reassign the concerned scientists. A report in the July 1994 Journal of the National Cancer Institute further confirmed gel's carcinogenicity in experiments in mice.

Supporting this experimental evidence, a 1989 confidential FDA report warned: "A survey of the literature indicates numerous case reports of (breast) cancer" long after implantation; that population studies, claimed as proof of safety by industry and plastic surgeons, are too short term and flawed to "negate the potential risk of cancer"; and of the "possibility of worsened diagnosis" and prognosis when implanted women developed breast cancer. These criticisms have been confirmed in a 1993 National Cancer Institute (NCI) internal analysis.

At still higher risk are some 350,000 women with silicone implants wrapped in industrial polyurethane foam to reduce scarring. Polyurethane foam is manufactured from the carcinogenic petrochemical toluene diisocyanate (TDI) which breaks down into another carcinogen, TDA. TDI and TDA have also been identified in fresh implants, and TDA has been identified in milk and urine of women with foam implants. It should be further noted that TDA had been removed from hair dyes by the cosmetic industry in 1971 following discovery of its carcinogenicity.

Large scale use of foam-wrapped implants since the 1980s ignored evidence published two decades before by NCI's leading authority on carcinogenesis, the late Dr. Wilhelm Hueper. His studies showed that foam gradually degrades and induces malignant tumors in rats. He warned: "Since the polyurethane plastics have been used in cosmetic surgery, ... these observations are of practical importance, ...(and) should caution against (their) indiscriminate use." He also noted that carcinogenic effects "might require an induction period of some 30 years or more," as with other carcinogens such as asbestos.

Dr. Epstein emphasized, "There is extensive previously undisclosed documentation of industry's secret knowledge of cancer risks from implants, which were nevertheless marketed with assurances of safety. In fact, Dow Corning's carcinogenicity information on silicone implants is two decades old." Shortly after foam implants were first marketed on a large scale, a Bristol-Myers subsidiary admitted that: "Degradation products of polyurethane are toxic and in some cases carcinogenic. ...The breakdown products of the fuzzy implant material may well be carcinogenic. How would anyone defend himself in a malpractice suit of a patient developed a breast malignancy." At a 1985 industry-sponsored conference, a leading plastic surgeon cautioned that "foam could be a time bomb... (in view of its) carcinogenic potential. Surgeons should not go on implanting." Following identification of TDA in foam, a Bristol-Myers employee warned "... there is pretty solid evidence that (it) is a carcinogen. The question is does PU foam... release TDA in the human breast to an extent that causes an unacceptable risk of cancer." Of still further concern is the identification in 1987 of residues of the carcinogenic, sterilizing agent ethylene oxide in foam implants.

"Polyurethane implants are carcinogen-impregnated sponges. The foam gradually disintegrates and releases carcinogens into sensitive breast cells," concluded Dr. Epstein.

CPC urges that an immediate medical alert be sent to all implanted women, with priority for those with foam implants. This should be followed by offers to remove the implants of concerned women at industry's expense, quite apart from the recent \$4.25 billion dollar settlement. This should be followed by comprehensive surveillance of all implanted women.

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

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