

Breast Implant Study Results Reflect Funding
Wednesday April 19, 2006 12:41 pm ET
Independent Studies Raise Serious Safety Concerns for Implant
Recipients

WASHINGTON, April 19 /PRNewswire/ -- As the FDA considers whether to approve silicone gel breast implants for the first time, three newly published peer-reviewed studies provide information that makes the decision more difficult for the FDA.

"The FDA needs more independent research to find out what is causing the higher rates of suicide, and to examine other potentially serious health risks for women with implants," says Dr. Diana Zuckerman, President of the National Research Center for Women and Families and an associate at the Center for Bioethics at the University of Pennsylvania.

A study published today in the Journal of the National Cancer Institute (Dow Study), was funded by Dow Corning, a major manufacturer of silicone. At one time, Dow was the major manufacturer of breast implants. The company has funded almost four dozen research articles in the last decade, all of which conclude that breast implants are safe. However, studies funded by scientists who do not have ties to implant manufacturers have consistently found implant problems that the Dow-funded studies have not.

The new Dow-funded study, conducted in Sweden, found that Swedish women with breast implants were more than twice as likely to have lung cancer as women in the general Swedish population, but concluded that this was "expected due to the high prevalence of smoking." However, the researchers did not statistically control for smoking to determine if smoking was in fact the likely cause of lung cancer among these women, and the researchers did not mention that almost one-third of women with lung cancer never smoked. The Dow-funded study also found a 30% increase in brain cancer among women with implants, but since that risk was not statistically significant the authors conclude there is no problem.

"The conclusions of the Dow-funded study need to be viewed in the context of independent research that is not funded by any implant

companies," explains Dr. Zuckerman. "They accurately report the results, but their conclusions go beyond the data."

A new study by scientists at the National Cancer Institute (NCI Study) is larger, longer, and better-designed than the Dow-funded study, with findings that are strikingly similar, but different conclusions. Published in the peer-reviewed journal *Epidemiology*, the NCI study found a 60% increase in deaths from respiratory cancers among women with breast implants compared to other plastic surgery patients. NCI scientists did not attribute this to smoking, since implant patients have similar smoking habits to other plastic surgery patients. The NCI study also found a doubling of deaths from brain cancer among women with implants, as well as an increase in non-cancerous brain neoplasms. "The NCI authors are appropriately cautious about the meaning of these findings, clearly indicating that they are not sure if implants are causing cancer deaths," says Judy Norsigian, Executive Director of the nonprofit organization *Our Bodies, Ourselves* and editor of internationally-respected book by that title. "In contrast, the Dow-funded researchers are concluding that the implants are safe."

The most worrisome finding in the NCI study was the significant increase – – more than double –– in suicides among women with breast implants compared to other plastic surgery patients. Three Dow-funded studies have also found significant increases in suicides among women with implants, all of them comparing implant patients to the general population. The controversy is whether women who want breast implants are more prone to suicide (which would suggest that women are getting plastic surgery when what they need is mental health treatment) or whether breast implants are causing pain, complications, or financial stresses (from repeated surgeries and implant replacements) that are increasing the risk of suicide.

"The goal of breast implants is to help women feel better about themselves. So, the NCI findings of almost a tripling of suicides should be shocking to plastic surgeons and the public," points out Cynthia Pearson, Executive Director of the National Women's Health Network, a nonprofit health advocacy organization.

A new study in a peer-reviewed chemistry journal, *Analytical Chemistry*, adds to the FDA's problems and to patients' worries. The

study, to be published in May but already available online, found very high and potentially toxic levels of platinum in the breast milk, urine, hair, and nails of women with silicone gel breast implants. Platinum is used in the manufacture of silicone elastomer, the rubber balloon-like material that the implant shell is made of. Urine samples of women who had silicone gel breast implants for an average of 14 years had between 60 and 1700 times the amount of platinum when compared to women with no platinum exposure. Even more disturbing, women who had breast implants had 100 times the levels of platinum in their breast milk.

"Our hotline hears from women every day, desperately trying to get their leaking silicone implants removed, and finding it difficult to afford (\$5,000- \$10,000) or to find a plastic surgeon who wants to remove leaking silicone implants without replacing them with new implants. They feel trapped with a leaking implant in their body that they don't have the resources to remove," Dr. Zuckerman concluded.

The National Research Center for Women & Families (NRC) is a nonpartisan, nonprofit research and education organization that works to improve policies and programs that affect the health and safety of women, children, and families.
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