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Statement of Sidney M.Wolfe, M.D., Public Citizen's Health Research Group
Institute of Medicine Committee on the Safety of Silicone Breast Implants
July 24, 1998

Breast implants are now in their fourth decade of use, no regulations for pre-market safety testing having been in place when they were first marketed. Studies which should have been done long ago are only now being done, well after most of the approximately two million women had their implants. Of 1135 published studies in the National Library of Medicine database under the search terms "silicone implants" and "adverse effects", 387 or only 34% were published between 1966 and 1989, a 24-year interval. 748, or 66% were published in the past 8+ years (1990 to now). The situation with breast implants is similar to occupational exposures in that only after largely uncontrolled and untested exposures are studies done on previously exposed people. Hexavalent chromium, with cases of lung cancer in exposed workers first described in the 1890's, is only now beginning to be regulated as a carcinogen, adequate epidemiological studies not having been done until recently.

Almost ten years ago, when Public Citizen's Health Research Group asked FDA to ban the use of silicone gel breast implants, we had three major sets of concerns:

We were concerned about the unrefuted (then or now) problems of rupture, capsular contracture, other serious chest wall problems, including many women in whom silicone gel, from a ruptured implant, had migrated to adjacent organs or formed foreign body granulomas or other debilitating local and regional disease, often quite painful because of extensive inflammation and scar tissue formation. Data from the American College of Plastic and Reconstructive Surgeons showed that in 1994 alone, there were more than 28,000 American women who had implants surgically removed because of physical symptoms related to well-documented problems such as rupture and hardening of the fibrous capsule (capsular contracture).

Next, we were and are still concerned about cancer. In 1988, we learned that an unpublished Dow study found that in more than 23% of animals injected with silicone gel, malignant, highly metastatic sarcomas developed. Although "written off" by Dow and others as being just "solid state carcinogenesis" (even though silicone gel is not a solid), there are well-documented cases of fibrosarcoma (desmoid) tumors arising within the fibrous capsule around the breast implant. Although epidemiological studies have not found an increase in breast cancer, and most of these studies did not have a very long follow-up and did not involve adequate numbers of women, the present NCI study was designed to correct these deficiencies. We agree with Drs Brinton and Brown's statement in the Journal of the National Cancer Institute last year that " animal as well as

clinical data suggest possible risks of sarcomas and hematologic cancers, including multiple myeloma."

Finally, we were concerned about the possibility of systemic disease being caused by breast implants. The first two epidemiological studies were too small--less than one-tenth as large as a current NIH study involving well over 13,000 women with implants. Thus, they could not rule out the possibility of as much as a doubling in the risk of classic connective tissue diseases in the second study or a tripling of risk in the Mayo Clinic study. In addition, neither was designed to adequately address the issue of non-classical connective tissue disease syndromes such as muscle or joint pain, fatigue, dry eyes, or dry mouth--found by many rheumatologists to be the main problems in women with implants. The third study, based on self-reported information by health professionals, found that there was a statistically significant 24% excess of any connective disease in the women in the study.

Although previous epidemiologic studies were unable to draw firm conclusions about such risks, several lines of evidence from other human studies increase concerns about a link between breast implants and autoimmune diseases: First, one well-documented cause of autoimmune disease is occupational exposure to silica. Worker exposure to this mineral, also called quartz, has been associated with a large increase in connective tissue diseases in sandblasters and increases in other occupationally-exposed workers.. Approximately one-fourth of the silicone rubber envelope which encloses breast implants is made up of silica, and recent studies have found that women with implants were much more likely than women without implants to have lymphocytes (white blood cells) immunologically sensitized to silica.

Second, there is new evidence, discussed in more detail by Dr. Fred Miller of FDA, that women of certain genetic types appear to be more susceptible to particular autoimmune effects of breast implants than women with other genetic types. The HLA type much more common in women with breast implant-related polymyositis (DQ alpha 102) than in women with polymyositis who did not have implants has a prevalence of about 20% in the general population. It is entirely possible that there are different genetic susceptibilities for other varieties of autoimmune diseases which may also turn out to be linked to the use of breast implants.

Less well-documented evidence suggestive of a link comes from a growing number of published cases in which women with otherwise irreversible autoimmune diseases such as scleroderma had significant improvement following breast implant removal.

Finally, Canadian plastic surgeon Walter Peters summed up these lines of evidence in the Annals of Plastic Surgery. While admitting there is yet no proven cause-and-effect relationship between breast implants and autoimmune connective tissue disease, he said "there is growing concern that immunological sensitization could potentially develop in certain susceptible patients and that this could contribute to the development of autoimmune connective tissue disease."

Although all of these problems were known to breast implant makers in the 1960's or 70's, Dow-Corning's official labeling for implants failed to disclose information about many of these dangers until 1985, by which time most women now with implants had had the operation. Then, only after losing a lawsuit attacking the company's failed duty to warn, was the warning label greatly

strengthened. In a remarkable admission by Dow-Corning of serious problems, eight frequently-reported complications were listed in the 1985 label for the first time including, "... immunological responses or sensitization...can occur.... If sensitization is suspected and the response persists, removal of the prosthesis is recommended ...to minimize the amount of residual silicone that may be left at the implant site." Other additions included "Implant rupture: ..If [the released gel] left in place, complications such as enlarged lymph nodes, scar formation, inflammation, silicone granulomas and nodule formation may result."