

# Public Citizen

## NEWS RELEASE

SILICONE BREAST IMPLANTS

DO NOT USE UNTIL:  
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**Statement of Sidney M. Wolfe, M.D.  
Director, Public Citizen's Health Research Group  
Concerning the June 22, 1995 *New England Journal of Medicine*  
Article on Silicone Breast Implants**

There are several serious problems with the design and/or the interpretation of this study:

1/ It is misleading to repeatedly call the study a "large cohort study" since only 1183 women out of the total 87,501 had breast implants. This number is so small that for all of the traditional connective tissue diseases other than rheumatoid arthritis--even if they were occurring at the same rate as in the general population--less than one case would have been expected among these 1183 women. Even if there had been a five-fold increase in scleroderma, polymyositis, Sjogren's syndrome or mixed connective-tissue disease, fewer than one case of any of these would have shown up. Although slightly larger than the Mayo Clinic study, both studies had fewer than one-tenth of the 12,000 women with breast implants in an ongoing NIH-conducted study, designed to be that large to get much more definitive answers to questions such as the relationship of breast implants to connective-tissue disease.

2/ Because of the very small size, the two studies cannot rule out as much as a tripling (Mayo Clinic) or a doubling (current study) of the risk of connective-tissue disease in women with implants. The authors' description of this two-fold possible increased risk as a "minor association" in women with breast implants trivializes the potential public health impact. If there were a doubling (consistent with the upper bound of the 95% confidence interval of 2.0) of connective-tissue diseases in women with implants, this would mean that there would be an excess of between 5000 and 11,000 women afflicted with these disorders (depending on whether there are 1 million or 2.2 million women with implants).

3/ In stating they did not find an association between breast implants and connective-tissue diseases or signs and symptoms of

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these diseases, the authors misled in that they did find an association, increased risk of 50% (relative risk of 1.5 with 95% confidence intervals of 0.9 to 2.4) of self-reported signs or symptoms of connective-tissue disease which was barely short (0.9 instead of 1.0) of being statistically significant. Given the atypical nature of the problems women with implants are having, this finding, similar to one in the Mayo Clinic study, means that there could be such problems affecting tens of thousands of women with implants.

4/ The design of the study excluded what would have been an important quantification of well-documented, non-disputed risks of silicone gel breast implants such as ruptures, serious local and regional scar-tissue formation and disabling pain (some of which could have an immune basis), and interference with mammography.

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