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## FDA's Approval of Tamoxifen to Reduce Incidence of Breast Cancer in Healthy Women Puts Women at Risk

WASHINGTON, D.C. -- Public Citizen's Health Research Group finds it incredible that the Food and Drug Administration (FDA) has approved tamoxifen, a drug that is a known human carcinogen, to reduce the risk of breast cancer in women who are at a so-called high risk of the disease. Tamoxifen can induce tumors by altering a woman's DNA and may cause other types of cancers years later.

"I have great concern that otherwise healthy women may be injured or killed from tamoxifen, thinking that it was going to prevent them from dying from breast cancer," said Larry D. Sasich, a pharmacist with Public Citizen's Health Research Group

The FDA based it decision on the results of the Breast Cancer Prevention Study published in the Sept. 16, 1998, issue of the *Journal of the National Cancer Institute*. This study showed that tamoxifen has only a meager effect in reducing the risk of breast cancer. In contrast, the study demonstrated no survival benefit for women taking tamoxifen, but did show that the drug increased the risk of uterine cancer by 2.5-fold and can cause other serious adverse effects such as stroke, blood clots in the lungs and legs, and cataracts.

The results of the study are as follows:

- <u>Survival Benefit</u>. The Breast Cancer Prevention Study showed no survival benefit for women taking tamoxifen.
- Invasive Breast Cancer. Tamoxifen may be advertised to women and physicians as reducing the risk of this type of breast cancer by as much as 49 percent relative to a placebo. This is very misleading as the actual difference in the risk of developing invasive breast cancer between those women who took tamoxifen compared to a placebo was only 1.3 percent (2.7% vs 1.4%) after a median of 4.2 years of treatment with the drug. This means that 77 women would have to take tamoxifen for 4.2 years to prevent a single case of invasive breast cancer. And no woman can tell if she will be that one case. The other 76

of invasive breast cancer. And no woman can tell if she will be that one case. The other 76 women will derive no benefit but will be exposed to the demonstrated harms caused by this drug.

- Endometrial Cancer. There was an increased risk of endometrial cancer in those women who took tamoxifen. There were 36 cases (1.4 percent) of endometrial cancer in the tamoxifen group and 15 (0.2 percent) in the women receiving placebo. Thus, for every 83 women who take tamoxifen for 4.2 years one women will develop endometrial cancer.
- <u>Stroke.</u> The incidence of stroke increased from 24 (0.4 percent) cases in the placebo group to 38 cases (0.6 percent) in the women taking tamoxifen. This difference approached statistical significance. Seven cases of stroke were fatal, three in the placebo group and four in the tamoxifen group. For every 500 women who take tamoxifen one will experience a stroke.
- Pulmonary Embolism. This type of blood clot in the lungs that is potentially fatal occurred in 6 (0.09 percent) women taking the placebo and in 18 (0.28 percent) women receiving tamoxifen. Three cases of pulmonary embolism in the tamoxifen group were fatal, compared to none in the placebo group. For every 526 women who take tamoxifen one will develop a blood clot in the lungs.
- <u>Cataracts</u>. Cataracts developed in 507 (7.8 percent) of the women taking the placebo and 574 (8.8 percent) in the women receiving tamoxifen. This difference was statistically significant as was the difference in the probability of cataract surgery between women in the placebo and tamoxifen groups.
- Quality of Life. The percentage of women who reported hot flashes as being either "quite a bit or extremely bothersome" was 45.7 percent in the tamoxifen group, compared with 28.7 percent in the placebo group. The percentage of women reporting vaginal discharge that was "moderately bothersome or worse" was 29 percent in the tamoxifen group, compared with 13 percent in the placebo group.

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