

Jury Still Out on Trials Of Breast-Cancer Drug

"Ire Over Listing a Cancer Drug as a Carcinogen" (Marketplace, May 11) questions the listing of AstraZeneca's breast-cancer drug tamoxifen (Nolvadex) as a carcinogen in the next federal Report on Carcinogens, scheduled for 2002. AstraZeneca argues that in view of tamoxifen's benefits, besides those of other carcinogenic drugs, it should be categorized and listed separately from pesticides and other industrial carcinogens, especially in view of FDA's 1998 approval of its effectiveness "in reducing high risk women's risk of developing breast cancer."

Claims for tamoxifen's effectiveness in preventing breast cancer in healthy women, including all women over the age of 60, are at best arguable. They are based on a National Cancer Institute (NCI) "Breast Cancer Prevention Trial" (BCPT), aggressively promoted by the American Cancer Society (ACS), in which the incidence of breast cancer was reduced in tamoxifen-treated women compared with a placebo group. However, the trial was prematurely terminated in March 1998, with a median follow-up of only four years, thus precluding determination as to whether the drug prevented cancer or merely delayed its onset by treating small undetected tumors.

Compounding the absence of any evidence for cancer prevention is alarming evidence for tamoxifen's serious short-term and sometimes lethal complications, including uterine cancer, pulmonary embolism and deep vein thrombosis in postmenopausal women. The incidence of these complications was greater than the alleged benefits.

Strong support for both the initial and ongoing BCPT by the National Alliance of Breast Cancer Organizations, claiming to be an umbrella group of cancer survivor organizations and with close financial links to the cancer drug and other industries including Astra-Zeneca, does not extend to the growing and nationwide network of independent breast, women's health and other cancer prevention activists, with strong priorities on cancer prevention besides on just damage control, diagnosis and treatment, and who are strongly opposed to BCPT trials.

In this connection, it is of particular interest to note that NCI and ACS have failed to inform women of a wide range of preventable risk factors, particularly those reflecting avoidable environmental and industrial exposures. Of further interest is failure of NCI and ACS to inform women of several studies since 1995 documenting the effectiveness of aspirin in reducing risks of breast cancer by up to 30%, and also to initiate prevention trials on this relatively harmless and cheap non-prescription drug.

SAMUEL S. EPSTEIN, M.D.
Professor of Environmental
and Occupational Medicine
University of Illinois

Chicago

(The letter was also signed by Barbara Brenner, executive director, Breast Cancer Action, San Francisco.)