Tamoxifen Prescribed to Healthy Women is a Highly Potent Cause of Liver Cancer

The U. S. Food and Drug Administration (FDA) encourages healthy women to become " guinea pigs" for this highly profitable drug.

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FDA Advisory Committee Urged To Reject Zeneca's Application of Tamoxifen For Preventing Breast Cancer in Healthy Women; Tamoxifen is Ineffective and Toxic

Press Release 9/1/98 PRNewswire -- The following was released today by Samuel S. Epstein, M.D., Professor Environmental Medicine, University of Illinois School of Public Health and Chairman of Cancer Prevention Coalition; Barbara Seaman, co-founder National Women's Health Network, Washington, D.C.; and Ann Fonfa, the Annie Appleseed Project, New York:

On September 2, FDA's Advisory Committee on Oncologic Drugs will review Zeneca Pharmaceutical's New Drug Application (NDA) for approval of tamoxifen "for the prevention of breast cancer in (healthy) women at high risk." Claims that tamoxifen can prevent breast cancer are based on an April 6, 1998 National Cancer Institute (NCI) preliminary report, unsupported by a scientific publication, of a short term trial on some 13,000 healthy women at "high risk" of breast cancer, including women over the age of 60, who were randomly given tamoxifen or a placebo; further details of the report are still not available to the scientific community and the public. The trial was terminated prematurely in view of the reduction in the incidence of breast cancer in all tamoxifen treated age groups. However, serious and sometimes fatal complications, including uterine cancer and pulmonary embolism, were seen in postmenopausal women among whom the incidence of breast cancer was reduced by 1.7%, while the incidence of serious complications was increased by 2.2% in non-hysterectomized women.The brevity of the trial prevented recognition of other delayed serious health risks. Of particular concern is the fact that tamoxifen is a highly potent carcinogen, inducing liver cancer in rats at low doses equivalent, based on blood levels, to those used in the trial. Disturbingly, women in the trial were not informed of the clear evidence of these risks. The absence of reported liver cancer in women treated with tamoxifen for breast cancer is hardly reassuring as relatively few women have been treated for over 5 years and followed up for a further 20 years before which the development of liver cancer would be most unlikely. Additionally, there are serious questions as to whether tamoxifen actually reduced the incidence of breast cancer or merely delayed its onset by treating small undetected tumors. In fact, two articles published on July 11, 1998 in the highly prestigious journal, The Lancet, reported no evidence of breast cancer prevention by tamoxifen in two major European trials.

In an August 17 written statement, which will be read into the record at

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the September 2 Advisory Committee Hearing, Dr. Epstein concluded:"NCI's preliminary April 6 report on the prevention of breast cancer by tamoxifen has still not yet been finalized and published in a scientific journal. The Advisory Committee should also consider the propriety of Zeneca's NDA as it is based, in part, on data which have not been made fully available to the public although the underlying (NCI) research was funded by the public. Furthermore, the claimed evidence for chemoprevention has been discredited by two subsequent scientific publications. Of as great concern is the well documented evidence of short term life-threatening complications, and also risks of delayed fatal complications, evidence for which has been trivialized and suppressed by NCI. Based on these scientific and ethical considerations, the Advisory Committee is urged to deny approval of Zeneca's NDA."

Finally, the NDA poses further serious questions in view of Zeneca's control and funding of the heavily promoted annual October National Breast Cancer Awareness Month. This campaign urges women to have mammography, in spite of its highly questionable effectiveness and risks in premenopausal women, while avoiding any reference to a wide range of scientifically documented safe and effective methods for reducing risks of breast cancer. These include avoidance of prolonged and early onset use of oral contraceptives; obesity and inactivity;and high fat and dairy food products contaminated with carcinogenic and estrogenic industrial chemicals. Such critical omissions are favorable to Zeneca's efforts to influence public policy in favor of approval of large scale tamoxifen chemoprevention, targeted for up to 30 million U.S. women at "high risk" of breast cancer.

More…

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Chemical Companies Profiting from Tamoxifen

Drug Companies Push Tamoxifen, NBCAM

Carcinogenicity of Tamoxifen: *New York Times* letter

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Web site: http://www.preventcancer.com/