

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.

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 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.

A Travesty, at Women's Expense

L.A. Times, June 22, 1992

Thousands are to be given a chemotherapy drug as a breast cancer preventive, despite evidence of deadly side effects

The government's National Cancer Institute this spring launched a large-scale breast-cancer prevention trial, recruiting thousands of healthy women at increased risk of breast cancer -- including those with close relatives with the disease and also anyone over 60. Half are to be treated with tamoxifen, a potent chemotherapy drug; the remainder will get a placebo. The NCI believes tamoxifen can reduce breast cancers by 30%, while also reducing heart attacks and preventing osteoporosis.

With one in nine women expected to develop breast cancer over a lifetime, the trial would seem worthy of unqualified support. However, the evidence that tamoxifen can prevent breast cancer is largely wishful thinking. To make matters worse, the risks to healthy women of a wide range of serious complications, including uterine cancer, fatal liver cancer, liver failure, life-threatening blood clots and crippling menopausal symptoms are unacceptable. This trial must be halted in its tracks.

The NCI's rationale is that tamoxifen, which is modestly successful in treating breast cancer, appears to reduce the risk of new cancers of the other breast. This benefit has only been seen in some patients in about half of the studies that have been done. The protection also appears largely restricted to post-menopausal women. However, the NCI ignores this and misleadingly offers healthy younger women the hope of prevention.

In addition, Swedish studies suggest that tamoxifen increases mortality in post-menopausal women who do develop cancer in the other breast during treatment; these cancers were highly aggressive and treatment-resistant. This evidence appears confirmed by studies showing that while tamoxifen reduces breast cancer in rats, cancers that do develop are highly malignant. There are also questions concerning whether heart benefits actually exist, and to what extent.

If tamoxifen's effectiveness were the only question, our alarm would not be so great. But the drug is implicated in a range of serious and sometimes life-threatening complications, although the NCI dismisses these as "infrequently severe."

Tamoxifen triples the risk of uterine cancer, even in patients followed for relatively short periods. Reaching a new low in medical sexism, statistician Richard Peto, a leading British supporter of the trial, dismisses the risk as "no big deal," since uterine cancer is curable by hysterectomy.

Tamoxifen is also a "rip-roaring liver carcinogen," according to Gary Williams, medical director of the American Health Foundation, inducing aggressive cancers in 100% of rats at high doses and 20% at lower doses equivalent to those being used in the prevention trial. This is acknowledged by the drug's manufacturer, ICI Americas, Inc. The prestigious British Medical Research Council warns of the absence of any safety margin at the trial dose. Yet the NCI misleadingly trivializes evidence of liver cancer in rats and ignores reports of two liver cancers in women just double the dose used in the trials.

Tamoxifen also promotes liver cancer in rats previously exposed to low doses of other carcinogens.

Moreover, as the British council emphasized, "Few women have received tamoxifen for longer than five to seven years, whereas the maximum incidence of liver tumors induced by known carcinogens occurs at eight to 10 years." Indeed, it is probable that a significant number of healthy women receiving tamoxifen may die from liver cancer after a decade or so.

Recent Swedish data suggest a more than 50% increase in new cancers, including gastrointestinal, among breast cancer patients treated with tamoxifen.

Shortly before the NCI started its trial, the blue-ribbon British Committee on Safety of Medicines reported five cases of liver failure with four fatalities, five hepatitis with one fatality and 11 other liver complications in breast-cancer patients treated with tamoxifen. Previously undisclosed similar evidence has just been obtained from the U.S. Food and Drug Administration.

The NCI recognizes a six-fold risk of often-fatal blood-clotting problems with tamoxifen, but the trial's coordinator suggests, with no supporting evidence, that this is due not to tamoxifen itself, but to "the interactive effect of [other] chemotherapy." Sometimes-severe menopausal symptoms, including hot flashes and vaginal discharge, are other recognized complications that the NCI seeks to downplay.

Incredibly, the NCI claims that theirs is "one of the most comprehensive informed-consents we've ever seen." The consent form exaggerates tamoxifen's possible and questionable benefits and trivializes probable and high risks. These concerns have stimulated a congressional inquiry led by Rep. Ted Weiss (D-N.Y.). The consent form's waiver of compensation for illness and injury, which participants must sign, is unlikely to protect the NCI or its investigators and hundreds of U.S. and Canadian centers and institutions involved in the trial from a future flood of malpractice and punitive claims for cancer and other complications. The doctrine of informed consent is legally protective only when all facts relevant to benefits and risks are fully and affirmatively disclosed.

The use of women as guinea pigs is familiar. There is revealing consistency between the tamoxifen trial and the 1970s trial by the NCI and American Cancer Society involving high-dose mammography of some 300,000 women. Not only is there little evidence of effectiveness of mammography in premenopausal women, despite NCI's assurances, no warnings were given of the known high risks of breast cancer from the excessive X-ray doses then used. There has been no investigation of the incidence of breast cancer in these high-risk women. Of related concern is the NCI's continuing insistence on pre-menopausal mammography, in spite of contrary warnings by the American College of Physicians and the Canadian Breast Cancer Task force, and in spite of persisting questions about hazards even at current low-dose exposures. These problems are compounded by the NCI's failure to explore safe alternatives, especially transillumination with infrared light scanning.

Meanwhile, the NCI ignores other preventable causes of breast cancer, particularly fat contamination with pesticides and other carcinogens. It recently canceled a proposed \$100-million study on dietary fat in favor of the tamoxifen trial.

The tamoxifen project is a travesty of science and a parody of cancer prevention. It also strikingly illustrates fundamental problems with federal cancer policies. The NCI suffers from a mindset myopically fixated on diagnosis, treatment and basic research, with relative indifference to cancer prevention.

Drastic reforms of NCI priorities and policies are essential to curbing the cancer epidemic, including escalating breast cancer rates. Only congressional action and strong support by women's and other concerned citizen groups can make this come about.

Chemical Companies Profiting from Tamoxifen

How are Chemical Companies Profiting from Tamoxifen drug? A Conflict of Interest Story

Q. Why doesn't Breast Cancer Awareness Month (NBCAM) include warnings about chemical carcinogens you could avoid?

A. National Breast Cancer Awareness Month was conceived and funded in 1984 by **Imperial Chemical Industries**, one of the world's largest petrochemical manufacturers.

As the multimillion-dollar funder of Breast Cancer Awareness Month, pharmaceutical giant AstraZeneca influences every leaflet, poster, and commercial product produced by the campaign. It's no wonder these publications focus almost exclusively on mammography while ignoring carcinogenic industrial chemicals and their relation to breast cancer. When it founded Breast Cancer Awareness Month in 1985, AstraZeneca (formerly known as Zeneca before it merged with the Swedish pharmaceutical company Astra) was owned by Imperial Chemical Industries, a leading international manufacturer of industrial chemicals and carcinogenic pesticides. National Breast Cancer Awareness Month is a masterful public relations coup for AstraZeneca, providing the company with valuable, albeit undeserved, goodwill from millions of American women.

AstraZeneca profits from treating breast cancer, and hopes to profit still more from the prospects of large-scale national use of Tamoxifen for breast cancer "prevention." The NCI and the ACS both embraced AstraZeneca's new drug,

aggressively launching a "chemoprevention" program in 1992 aimed at recruiting 16,000 healthy women at "high risk" of breast cancer. The five-year clinical trial claimed that Tamoxifen reduced breast cancer risks by 30 percent. The risks of this toxic drug, including potentially fatal uterine cancer and blood clots, were noted but trivialized. As the trials progressed, it became clear that the risk of serious complications outweighed professed benefits. Women have still not been informed about delayed risks of liver cancer. Equally troubling, neither the ACS nor the NCI has pursued evidence that regular use of a cheap, non-patented, over-the-counter drug— aspirin—has been shown to reduce risks of breast cancer. (A 1996 study found that women who took aspirin three times a week for five years reduced their risk by up to 30 percent, a finding worth pursuing.)

For years the American Cancer Society (ACS) demonstrated its allegiance to the multibillion-dollar cancer drug industry by aggressively attacking potential competitors through its "Committee on Unproven Methods of Cancer Management," created to "review" unorthodox or alternative therapies. This committee, staffed by "volunteer health care professionals," invariably promoted mainstream, expensive, and arguably toxic drugs patented by major pharmaceutical companies, and opposed alternative or "unproven" therapies, which are generally cheap, non-patentable, and minimally toxic. As with Senator Joseph McCarthy's blacklist of suspected communists, once a clinician or oncologist was associated with "unproven methods," harassment and blackballing often followed, and funding would dry up. This witch hunt against alternative practitioners was in striking contrast to the Society's uncritical endorsement of conventional toxic chemotherapy, despite increasing concern that chemotherapy may not significantly improve survival rates for most cancers. After an extensive review of clinical oncology studies, for example, Dr. Ulrich Abel of the Institute of Epidemiology and Biometry at the University of Heidelberg, Germany, concluded that for most patients chemotherapy functions as little more than a placebo, with an attendant decline in quality of life from the toxic treatment.

Excerpted from [The High Stakes of Cancer Prevention](#) by Samuel Epstein and Liza Gross. *Tikkun* Nov/Dec 2000 <http://www.tikkun.org>

Drug Manufacturers Avoid Scrutiny of Chemical Causes of Cancer by Promoting Mammography and Tamoxifen

BREAST CANCER UNAWARENESS MONTH

Press Release, October 14, 1996-- Commenting on the anniversary of National Breast Cancer Awareness month (NBCAM), Dr. Samuel Epstein, Chairman of the Cancer Prevention Coalition (CPC) stated, "A decade-old multi-million dollar deal between National Breast Cancer Awareness Month sponsors and Imperial Chemical Industries (ICI) has produced reckless misinformation on breast cancer." Dr. Epstein, a leading international authority on cancer causing effects of environmental pollutants, will be speaking on breast cancer prevention at a conference, "Women, Health, & the Environment" in Albuquerque, New Mexico on October 14-15. It is sponsored by CPC, in conjunction with Greenpeace and Women's Environmental and Development Organization (WEDO).

Zeneca Pharmaceutical, a U.S. subsidiary and recent spinoff of Imperial Chemical Industries (ICI), has been the sole funder of National Breast Cancer Awareness Month since 1984. ICI is one of the largest manufacturers of petrochemical and chlorinated organic products, such as acetochlor and vinyl chloride, and the sole manufacturer of Tamoxifen, the world's top-selling cancer drug used for breast

cancer. Financial sponsorship by Zeneca/ICI gives them editorial control over every leaflet, poster, publication, and commercial produced by NBCAM. NBCAM is promoted by the cancer establishment, the National Cancer Institute (NCI) and the American Cancer Society (ACS) with their corporate sponsors.

ICI has supported the NCI/ACS blame-the-victim theory of the causes of breast and other cancers. This theory attributes escalating cancer rates to heredity and faulty lifestyle, rather than avoidable exposures to industrial carcinogens contaminating air, water, food, consumer products, and the workplace.

Dr. Epstein will summarize the evidence on avoidable environmental and other causes of breast cancer ignored in NBCAM promotional materials:

- **Since the 1950's scientific evidence has incriminated chlorinated organic pesticides as breast cancer risk factors** because of their carcinogenicity, estrogenic effects, and accumulation in body fat, particularly the breast.
- **The unregulated use of growth promoting hormonal cattle feed additives has resulted in near universal contamination of meat products.** This results in life-long exposure to carcinogenic estrogens, and poses a major avoidable risk of breast cancer.
- **Where you work increases your breast cancer risks.** Excess breast cancers were found in the 1970's in women working with vinyl chloride. There is similar evidence among petrochemical and electrical workers. In spite of more women working in such industries, NCI recently admitted that it has still not investigated these risks among working women.
- **Where you live increases risks of breast cancer.** Based on a review of 21 New Jersey counties, and more recently 339 nationwide counties, statistically significant associations were found between excess breast cancer mortality and residence in counties where hazardous waste sites are located.
- **Living near a nuclear facility increases your chances of dying from breast cancer.** Based on a nationwide survey of 268 counties within 50 miles of 51 military and civilian nuclear reactors, CPC member Dr. Jay Gould, showed that breast cancer mortality in these "nuclear counties" has increased at 10 times the national rate from 1950 to 1989. Counties near military reactors, such as Hanford, Oak Ridge and Savannah River, have registered the greatest increases, ranging from 27 to 200%. Dr. Gould charged NCI with "misrepresentation of such findings."
- **Premenopausal mammography increases your risk of breast cancer.** Increases in breast cancer mortality have been consistently reported following repeated mammograms in younger women in six randomized controlled clinical trials over the last decade. Based on this evidence, NCI has recently withdrawn recommendations for pre-menopausal mammography. ACS, with financial support from Dupont and General Electric (both heavily invested in mammography equipment), and self-interested radiologists are still promoting this dangerous practice.
- **Participation in the 1972 NCI/ACS reckless, high dose mammography experiments** has increased breast cancer risks for the 400,000 women involved.

- **Breast implants, particularly polyurethane foam, pose serious risks of breast cancer.** Evidence on the carcinogenicity of polyurethane foam dates back to the early 1960's. One breakdown product of polyurethane is 2,4-toluenediamine which was removed from hair dyes in 1971 following discovery of its carcinogenicity. Frank admission of these risks are found in internal NCI, FDA and industry documents.
- **The Tamoxifen "chemoprevention" trial is a travesty!** Since 1992, the cancer establishment recruited 16,000 healthy women in a Tamoxifen "chemoprevention" trial. NCI and ACS claimed in their patient consent forms that Tamoxifen could substantially reduce breast cancer risks, while trivializing risks of drug complications. There is strong evidence of Tamoxifen's toxicity, including high risks of uterine, gastrointestinal and fatal liver cancer. "This trial is scientifically and ethically reckless, and participating institutions and clinicians are at serious risk of future malpractice claims," warned Dr. Epstein.

" The ICI/NBCAM public relations campaign has prevented women from knowing of avoidable causes of breast cancer," concluded Dr. Epstein.

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Taken from <http://www.preventcancer.com/>