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> Cover: This aerial view of the Continuous Electron Beam Accelerator Facility (CEBAF) in Newport News, Va., shows work proceeding on the three round, experimental halls (foreground) where high-energy electrons will interact with protons and other nuclei to provide information on the structure of matter. Meanwhile, researchers at Rensselaer Polytechnic Institute in Troy, N.Y., find themselves enmeshed in the surprisingly complicated task of designing and building one of the detectors for the smallest of the three halls. (Photo: CEBAF)

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Science Service, a nonprofit corporation founded in 1921, gratefully accepts tax-deductible contributions and bequests to assist its efforts to increase the public understanding of science, with special emphasis on young people. More recently, it has included in its mission increasing scientific literacy among members of disadvantaged groups. Through its Youth Program it administers the International Science and Engineering Fair, the Science Talent Search for the Westinghouse Science Scholarships, and publishes and distributes the Directory of Student Science Training Programs for Precollege Students.

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Letters

Tamoxifen concerns

My family history and age apparently fit the entry criteria for the tamoxifen trial in healthy women ("Tamoxifen Quandary," SN: 4/25/92, p.266). Before your article came out, my background knowledge on the trial came primarily from an account in a local newspaper, which stated that the therapy's "only known side effects are occasional hot flashes and vaginal discharge." Encouraged by my newspaper's glowing report, I called a participating medical center to express interest in volunteering. (I had not yet seen your story.)

My mother, who took tamoxifen after her surgery for very early-stage breast cancer, died suddenly from a very aggressive new tumor that had spread to the liver and small bowel. Indeed, only a month before her death, she wrote me that she had just been checked by her oncologist and told there were no signs

of the original tumor's recurrence nor of a contralateral breast tumor. I now realize her cancer is consistent with the laboratory findings of Stephen Zimniski, which you described in your article.

I called the National Cancer Institute's tollfree information line to inquire about any other reports relating tamoxifen to liver cancer. I was told there were two liver cancers in women, but that these may have been metastases from the breast. NCI also said the drug caused liver cancer in animals, but only at excessively high doses. In light of the research described in your article, both of these statements appear false.

I no longer wish to participate in NCI's trial. In fact, I am deeply concerned that its design may compromise public health. In addition to exposing healthy women to the risks your article described, it will expose premenopausal women to the risk of unintended pregnancy,

because volunteers must agree not to use estrogenic or IUD birth-control methods. Tamoxifen not only stimulates ovulation and has been used to enhance fertility in some countries, but it also (as you pointed out) has a chemical structure similar to DES. So children of tamoxifen users may face a risk of birth defects and conceivably other DES-like outcomes.

Since I have failed to interest NCI in launching an investigation to see whether there have been changes in rates of diagnoses of second primary breast cancers in tamoxifen patients and/or in length of their survival following such diagnoses, I have petitioned the Department of Health and Human Services to suspend the new NCI tamoxifen trial "in light of scientific evidence of its unacceptable risk in

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- Charles Tart Professor of Psychology U.C.-Davis

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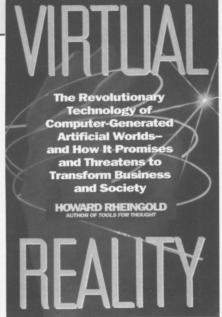
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the absence of disease."

Hazel Cunningham Sacramento, Calif.

"Tamoxifen trial begins amid new concerns" (SN: 5/9/92, p.309) is right on the mark.

Not only are there the cited valid worries over the testing of 16,000 healthy women, half of whom are supposed to be given tamoxifen, but there are concerns about the possibility of permanent eye damage.

'Ocular toxicity of tamoxifen," in the ANNALS OF OPHTHALMOLOGY, 1989 21:420-423, by Edward W. Gerner, reports in detail on toxicity to the cornea, retina and optic nerve - damage that did not increase once the drug was stopped and another substituted, but which could not be repaired. "Tamoxifen retinopathy: A rare but serious complication" was reported in the British Medical Journal, 1992 304:495-6, with a detailed report of a 72-yearold woman whose eye problems were first blamed on diabetes (which she developed after starting tamoxifen); three years later, physicians learned (from results of fluorescein angiography) that the destructive changes were similar to those described in previous reports of tamoxifen retinal toxicity. By then she could barely make out her fingers before her face.

Even if the occurrence is as rare as 0.3 percent, 24 women should not have to go blind unnecessarily. At the very least, women taking part in the study should be advised to have their eyes examined regularly.

Doris Patterson Ardmore, Pa. Researchers at the University of Ioannina, Greece, have reached much the same conclusion. In the June 15 Cancer, they describe "the first prospective study... indicating that even conventional low-dose tamoxifen treatment can induce ocular toxicity." Four of the study's 63 women (6.3 percent), all receiving the now conventional 20 milligrams of tamoxifen daily, developed a battery of visual problems and some swelling. These symptoms largely disappeared when the drug was discontinued.

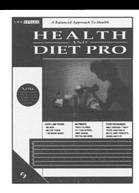
According to Leslie G. Ford, who is overseeing the National Cancer Institute's tamoxifen trial, "an eye exam is required before you can go on the study," and NCI is considering involving some of its tamoxifen volunteers in ancillary "substudies" to better delineate the magnitude of potential long-term side effects of tamoxifen treatment, such as endometrial and ocular changes.

In addition, although the informed-consent forms that volunteers in the NCI study must sign before entering this study vary among participating institutions, several of the forms do mention eye effects. One version states: "An increased risk of cataracts has been noted in rats ... [and] other eye problems, such as corneal scarring or retinal changes, have been reported in a few patients."

— J. Raloff

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