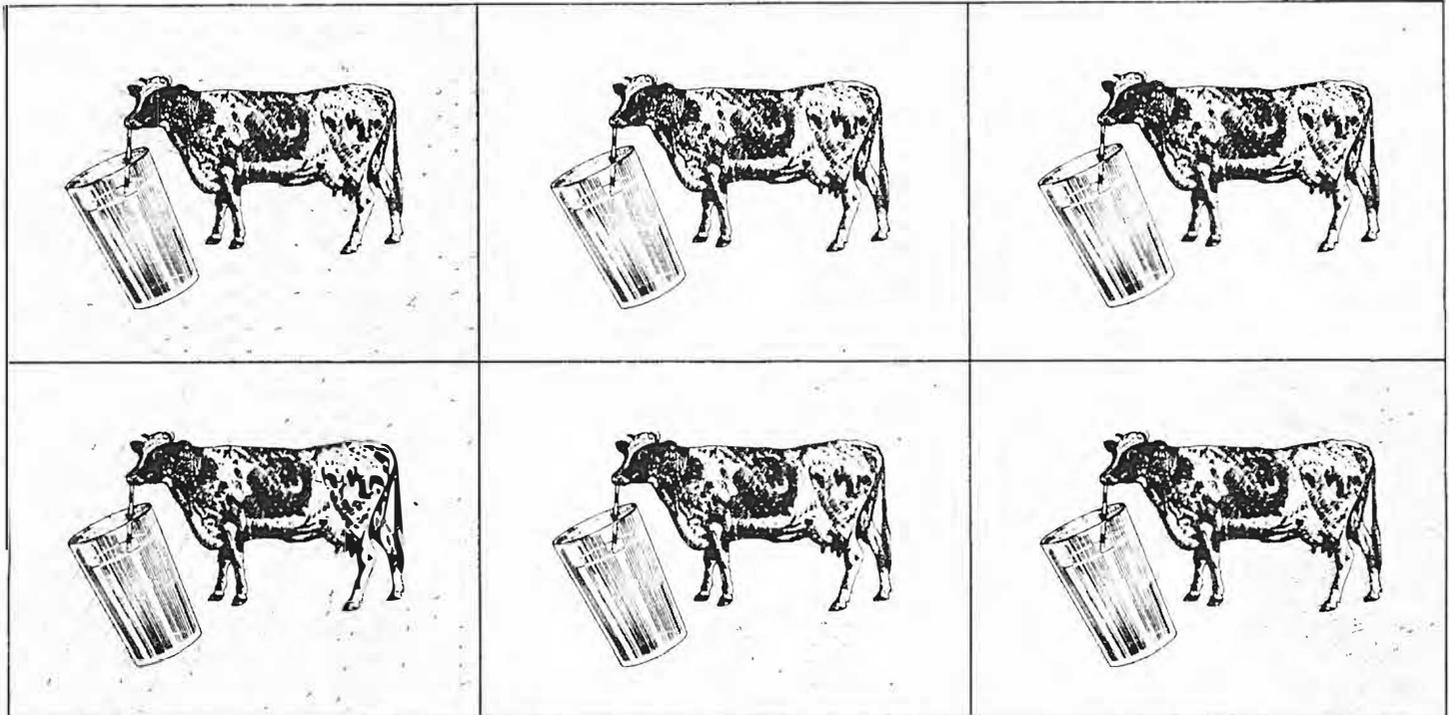




Lab Warns Cow: Don't Drink Your Milk



by Annabel Hecht

"Disaster Linked To The Food You Eat!" screamed the headline on advertisements in a number of upstate New York newspapers last August. Headaches, stomachaches, sinus problems, and skin problems are all linked to the food we eat, according to the ads. The Cytotoxic III testing program provides "detailed examination of food and chemical sensitivities," the ads explained. Interested persons were invited to attend clinics in hotels in Buffalo, Albany and Rochester to learn about this revolutionary new blood test, offered by a California firm called Bio Health Centers.

So enticing were the ads that investigators from both FDA and the New York health department independently decided to investigate. The FDA investigator's interest was not personal food allergies but, rather, possible fraud. The New York officials also were concerned about fraud and about violations of the state's public health laws governing laboratories. When the two agencies learned of one another's investigations, they worked together to put Bio

Health Centers out of business in New York. All of this with the help of some cow's blood from a local slaughterhouse.

Bio Health Centers (BHC) is a division of Tannare International Inc., a corporation with its principal place of business in Costa Mesa, Calif. Director of operations is David Diem, and Dr. Roger J. Palmieri, Newport Beach, Calif., is directing physician. BHC conducts the Cytotoxic III food sensitivity testing program through a mail-order operation as well as in clinics in hotels and other establishments.

Cytotoxic testing is being touted by some allergy clinics, health centers, and testing laboratories as a means of detecting food allergies that supposedly are the cause of a variety of bodily ills. The theory behind the procedure is that the white cells in a sample of blood taken from a patient will react in some way (such as disintegrating, collapsing or changing shape) when exposed to a food to which the patient is allergic. The testing is supposedly done with specially prepared extracts of foods. (See "The Flaw In Cytotoxic Testing: There's No Proof It Works" in the October 1984 *FDA Consumer*.)

One problem with this theory is that there are no products on the market that have been demonstrated to be effective in cytotoxic testing, according to FDA, and no manufacturer has submitted evidence to support the marketing of any product for this use. As far as the agency is concerned, the cytotoxic test is an unproven diagnostic procedure.

BHC's method of operating in New York was to set up blood collection clinics in local hotels and solicit clients through newspaper advertisements. Those who responded were offered the Cytotoxic III testing program. All they had to do was part with some blood and \$350. The blood sample was to be sent to California for analysis. In due course, the clients were to receive a diagnosis of their food and chemical sensitivities, which would enable them to determine what foods to avoid in order to cure or alleviate obesity, fatigue, high blood pressure, and a wide variety of other ailments.

Investigator Frank Golden of FDA's Buffalo office made an appointment to attend one of BHC's clinics, but before he got there, the testing program was

abruptly canceled. The New York investigators were similarly thwarted.

The firm was not about to lose these potential customers, however. Golden and the state investigators were told that the Cytotoxic III test was available through the mail and were subsequently sent a packet of information. Both federal and state investigators ordered BHC's blood collection kit—at a cost of \$50—and received an empty tube for the blood sample, a styrofoam shipping container, and a cold pack (which was to be frozen and packed in the container to preserve the blood sample when it was shipped).

Also included were two pages of directions, a four-page questionnaire, a "client agreement," and an "authorization for venipuncture" over Palmieri's stamped signature. Peter Eiss, an investigator employed by the New York attorney general, filled out the questionnaire with his own health history, but he submitted blood provided by a doctor employed by the state health department. The cytotoxic analysis that came back, duly signed by

Palmieri, indicated that the patient was sensitive to a variety of foods, such as halibut, watermelon, string beans, cheese, pork, turkey and goat's milk. In fact, the woman who gave the blood sample enjoys excellent health and has never had an allergic reaction to any of the foods listed.

FDA's Golden went one better. He obtained cow's blood from a local slaughterhouse and submitted it as his own, along with the questionnaire, completed with partially factual and partially fictitious data, and \$300, the balance due.

In just over a week, the laboratory sent back the blood analysis, an insurance claim form, a suggested diet, and various pieces of promotional literature for

Cytotoxic III. Apparently, whoever did the testing didn't recognize that Golden had sent something other than human blood, for the analysis showed that the cow was allergic to 22 of 187 substances tested, including cow's milk, cottage cheese and yogurt.

In February, the New York attorney general obtained a temporary restraining

order against BHC, based in part on evidence provided by FDA's Golden. The order prevents BHC from soliciting or accepting blood specimens for laboratory examinations and from collecting, processing or storing human blood or blood derivatives within the state of New York without a permit pursuant to the state's public health laws. Cooperating with the Buffalo district office and New York officials, FDA's Santa Ana, Calif., resident post served the restraining order.

The story hasn't ended for Bio Health Centers. Even before New York's action was initiated, California's Board of Medical Quality Assurance had already become interested in the firm's activities. Investigator Golden was asked for an affidavit as evidence in support of California's case. In addition, FDA's Los Angeles district office is also investigating BHC and two possible suppliers of the blood-testing kits.

Annabel Hecht is a member of FDA's public affairs staff.