FDA
TALK PAPER

FOOD AND DRUG ADMINISTRATION
U.S. Department of Health and Human Services
Public Health Service 5600 Fishers Lane Rockville, Maryland 20857

T86-60
Aug. 7, 1986

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FDA ISSUES ALERT AGAINST DANGEROUS CANCER REMEDY

FDA has issued an Import Alert to halt the importation of the so-called Immuno-Augmentative Therapy agents used by Lawrence Burton, a zoologist, at his Bahamas-based Immunology Researching Center Ltd. The substances not only lack evidence of effectiveness as cancer therapies, but have been contaminated with hazardous substances, including AIDS and hepatitis viruses.

The following information may be used to answer questions:

As noted in an earlier FDA Talk Paper (T82-14), Immuno-Augmentative Therapy purportedly boosts the body's immune system through injections of an undisclosed "blood serum" often derived from apparently non-sterile conditions. A recent article on the "therapy" and Dr. Burton's clinic in the Journal of the American Medical Association (Jan. 24/31, 1986 -- Vol 255, No. 4) points out that repeated studies and investigations by the National Cancer Institute and the Pan-American Health Organization have uncovered no evidence that this therapy is in any way effective in the treatment of any disease.

Sponsors of this treatment in 1974 submitted a request to FDA for investigational new drug exemption for clinical testing of the therapy, but never adequately responded to FDA requests for supporting information. Soon thereafter, Dr. Burton chose to withdraw his investigational exemption request and established his Immunology Researching Center in Freeport, Grand Bahama Island, Bahamas, where he began administering his treatment to paying patients.

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In recent years, however, U.S. health authorities have had opportunities to examine patients who have been treated at the Burton clinic, as well as vials of the blood serum that had been surreptitiously brought into the United States.

In 1984, the Centers for Disease Control reported 16 cases of injection site abscess formation experienced by patients of the Burton clinic. Centers for Disease Control analysis of four vials of the Burton clinic's blood serum revealed that all four were non-sterile and, in fact, were contaminated with a wide variety of disease producing organisms.

In 1985, tests of 18 vials of serum conducted by Washington State laboratories and confirmed by the Centers for Disease Control found six to be contaminated with HTLV-III antibody (strongly suggestive of the presence of the AIDS virus). Subsequent examination of 72 additional vials by the National Cancer Institute demonstrated that more than half were possibly contaminated with the HTLV-III virus. Moreover, the Centers for Disease Control was actually able to isolate viable HTLV-III virus from one of the serum samples examined in the study it conducted with Washington State laboratories.

All 18 vials of serum tested by Washington State and the Centers for Disease Control were also found to contain the hepatitis B surface antigen (strongly suggestive of the presence of that virus). The Centers for Disease Control has also reported at least two cases of hepatitis B in immuno-augmentative therapy patients who lacked any other risk factor associated with that disease.

During the summer of 1985, Bahamian Ministry of Health officials along with consultants from the Centers for Disease Control and the Pan-American Health Organization visited the Burton Clinic and concluded it posed a public health hazard. On July 17, 1985, the Ministry closed the clinic down, but later the clinic was permitted to reopen -- and currently remains in operation.

In order to protect U.S. citizens from continued exposure to this dangerously contaminated blood serum, FDA is issuing an Import Alert directing U.S. Customs and Postal Service authorities to detain all quantities of these biological agents that are being brought into United States.

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