

# FDA TALK PAPER

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## IMMUNO-AUGMENTATIVE THERAPY

Oklahoma Gov. George Nigh today signed legislation approved unanimously by both chambers of the Oklahoma legislature to permit the prescribing and administration of "immuno-augmentative therapy" in the treatment of any malignancy, disease, illness or physical condition. The following may be used to answer questions:

In December 1974, Rabbi Widom, president of the Immunology Research Foundation, Great Neck, Long Island, submitted to the Bureau of Biologics a Form 1571 seeking to initiate human investigational trials with "immuno-augmentative therapy." Lawrence Burton, an experimental zoologist with a 1955 doctoral degree from New York University, was to be the principal investigator. The bureau responded with questions about the research which, despite several exchanges of correspondence, were not fully answered. The Bureau of Biologics never approved clinical studies. In March 1976 the IND application was placed in the bureau's inactive files, with the understanding from Rabbi Widom that any human trials would be intra-state only, confined to the state of New York. The foundation never has attempted to reactivate the file nor submitted any data to the bureau. The composition and components of the product remain unclear.

According to news media accounts, in 1976 Burton opened the Immunology Researching Centre in Freeport on Grand Bahama Island, where he has been treating cancer patients with injections of a secret "blood serum" alleged to increase the body's immunity against the formation of cancer cells. Fees reportedly range up to \$7,500 per patient, excluding transportation and local housing costs.

The American Cancer Society's Unproven Methods of Cancer Management Committee, the National Cancer Institute and the American Medical Association are aware of Dr. Burton's practice. They and FDA counsel patients to remain in the care of qualified physicians.

In January of 1978, at the request of the Bahamian government, a physician-representative of NCI visited the Freeport clinic. He asked for a sample of the serum for independent testing. Burton refused. Accordingly, it is NCI's position that there is no basis for evaluation of "immuno-augmentative therapy" and no evidence that it is effective against cancer.

In 1981 the Governor of Florida vetoed similar legislation.

FDA advises the public to avoid this unproven nostrum.

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