

CancerNet from the National Cancer Institute

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National Cancer Institute-Sponsored Clinical Trials of Antineoplastons

Antineoplastons are a group of compounds originally isolated from urine by Dr. Stanislaw Burzynski, who claims that they inhibit cancer cell growth. Dr. Burzynski has used these compounds to treat patients with various cancers.

In 1991, a "best-case series" review was conducted by the National Cancer Institute (NCI) to evaluate clinical responses in a group of patients treated at Dr. Burzynski's Houston facility. For this review, Dr. Burzynski selected from his entire clinical experience seven brain tumor patients whom he felt had a beneficial effect from antineoplastons. This series did not constitute a formal clinical trial, since it was a retrospective review of medical records, did not include all available patient information, and included only cases selected by Dr. Burzynski. The reviewers of this series determined that there was presumptive evidence of antitumor activity and NCI then proposed that Phase II clinical trials be conducted to evaluate more definitively the response rate and toxicity of antineoplastons in adult patients with refractory brain tumors. The decision by NCI to sponsor a study of an agent in a clinical trial does not indicate that the agent is or will be useful in the treatment of cancer patients, only that it merits further evaluation in a research setting.

Efforts to study antineoplastons in a scientifically rigorous manner have required complex interactions among NCI, clinical investigators, the National Institutes of Health's (NIH) Office of Alternative Medicine, the Food and Drug Administration, advocates from the alternative medicine community, and Dr. Burzynski. Two protocols were developed by the participating Cancer Center investigators with extensive review and input from NCI and Dr. Burzynski. These studies began in 1993 at Memorial Sloan-Kettering Cancer Center, Mayo Clinic, and the NIH Clinical Center. However, accrual to these studies was very slow and only nine patients were enrolled.

On August 18, 1995, the studies were closed because a consensus could not be reached with Dr. Burzynski on the proposed changes in the protocol to increase accrual, and there was no hope of completing the studies in a timely manner.

Because these studies were closed prior to completion, no conclusions can be made about the effectiveness or toxicity of antineoplastons. It is rare that this kind of NCI-sponsored clinical study cannot be successfully completed. The NCI is disappointed by this outcome but is continuing to evaluate related compounds in clinical trials in order to determine if they may be of benefit in the treatment of patients with cancer.

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The Cancer Information Service (CIS), a program of the National Cancer Institute, provides a nationwide telephone service for cancer patients and their families, the public, and health care professionals. CIS information specialists have extensive training in providing up-to-date and understandable information about cancer and cancer research. They can answer questions in English and Spanish and can send free printed material. In addition, CIS offices serve specific geographic areas and have information about cancer-related services and resources in their region. The toll-free number of the

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