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Antineoplastons

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Unproven Methods of Cancer Management

Antineoplastons

After careful study of the literature and other information available to it, the American Cancer Society does not have evidence that treatment with antineoplastons results in objective benefit in the treatment of cancer in human beings. Lacking such evidence, the American Cancer Society would strongly urge individuals afflicted with cancer not to participate in treatment with antineoplastons.

The following is a summary of information on antineoplastons in the American Cancer Society files as of June 1, 1982. No implication of agreement by the Society with the contents of any proponent material is to be construed because of the Society's reference to it.

Introduction

In a packet of information distributed by the Burzynski Research Institute to patients and other interested persons, it is stated that Stanislaw R. Burzynski, M.D., Ph.D., and his associates have been working on antineoplastons as a new treatment for cancer since 1967.¹ It should be noted that the Institute is not a hospital, but a research clinic.

Antineoplastons are described by Dr. Burzynski as "substances produced by the living organism that protect it against development of neoplastic growth by a non-immunological process which does not

significantly inhibit the growth of normal tissues."² The definition has been further refined to refer only to two specific chemical fractions extracted and purified from human urinary peptides. These, according to Dr. Burzynski, showed the most anticancer activity of 119 urinary peptides tested. One, called antineoplaston A, was claimed to inhibit the growth of osteosarcoma, myeloblastic leukemia, and HeLa cells in tissue culture.² Details of these and other experiments are described in a series of papers published from 1973 to 1979 by Dr. Stanislaw Burzynski and his colleagues.¹⁻⁸

Proponent

The chief developer of antineoplastons as an alleged anticancer treatment is Stanislaw Raimund Burzynski, M.D., Ph.D., of Houston, Texas.

He was born in Poland in 1943, and received all of his education in that country. He was licensed to practice medicine in the United States in 1973 by the Texas State Board of Medical Examiners.⁹

From 1970 to 1972, Dr. Burzynski was employed as Research Associate at Baylor College of Medicine in Houston, Texas. In 1972, he was named Assistant Professor of Medicine at Baylor and remained in this position until 1977.⁹

Since 1977, Dr. Burzynski has been head of the Burzynski Research Labora-

EFFECTS OF TREATMENT WITH "ANTINEOPLASTON A" AS REPORTED BY DR. BURZYNSKI		
	Number	Percent
Complete remission	4	19
Partial remission	4	19
Stabilization of disease	6	28
Died	5	24
Discontinued treatment	2	10
Total	21	100

tory and Institute at 6221 Corporate Drive, Houston, Texas 77036.⁹

Proponent Claims

The initial evaluation of antineoplaston A in cancer patients was first described by Dr. Burzynski in 1977.⁶ Twenty-one far-advanced cancer patients (with cancers of the breast, bladder, colon, leukemia, and eight other sites) were treated with antineoplaston A and followed for nine months. Effects of the treatment as reported by Dr. Burzynski are shown in the table.

According to the proponents, some degree of clinical improvement was noted in 18 of the 21 patients (86 percent). At the recommended doses, antineoplaston A was reported by Dr. Burzynski to be well tolerated, with no evidence of significant toxicity, and minimal or no side effects.^{1,6}

The average time for the initial phase of treatment is said to be about two to three weeks.¹ A full course of treatment, first at the institute and later at the patient's home, is estimated to vary from six weeks to a year. Patients are informed that the full-dose treatment with antineoplastons is administered by intravenous injections.¹

Dr. Burzynski and his colleagues recognize that further clinical experience and long-term, follow-up studies are needed, but claim that the result of a limited trial in 1977 "indicates a promising new approach to the alleviation of cancer."⁶ Careful surveillance of the medical literature for the period since 1977 has revealed no additional reports of clinical trial to date.

Patients and others who call or write Dr. Burzynski's laboratory for information receive a summary of the antineoplaston story, a description of admission and treatment procedures followed at the Burzynski Research Institute, and the fee schedule used. The charge for antineoplaston treatment is \$180 per day for the length of time prescribed by the Institute. In addition, related laboratory and other costs amount to approximately \$655. A deposit of \$5,000 is required when treatment begins.¹

Regulatory Status

There never has been an FDA-approved New Drug Application for antineoplastons, and Dr. Burzynski has not filed a Notice of Investigational Exemption (IND)

providing for investigational use of this drug in humans.¹⁰ Therefore, evidence has not been submitted to the FDA that antineoplastons are safe and effective in the treatment of cancer. Interstate shipment or transportation thereof is illegal.

The FDA advises persons who inquire about Dr. Burzynski's alleged cure that they do not believe antineoplaston is fit for administration to humans, and that there is no reason to believe Dr. Burzynski has discovered an effective cure for cancer.¹⁰



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