CALDWELL & BAGGOTT
Attorneys at Law
330 LNG Tower
2919 Allen Parkway
Houston, TX 77019

June 21, 1977

713/523-9950

Stanislaw R. Burzynski, M.D. Ph.D.
1213 Hermann Drive, Suite 730
Houston, TX 77004

Re: Use of Antineoplastons in Medical Practice

Dear Dr. Burzynski:

We are advised that you have developed, and are now personally administering to your patients in the course of your medical practice, substances extracted from human urine known as antineoplastons which you believe to have demonstrated a considerable value in the treatment of cancer. You have requested us to render our opinion as to whether the personal administration by you of antineoplastons to your own patients in the course of their medical treatment, and the preparation of antineoplastons in your laboratory for such use, are in violation of applicable federal or state law.

We have concluded that the statutes primarily affecting this question are the Texas Food, Drug and Cosmetic Act, Article 4476-5, Revised Civil Statutes of Texas, and the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301 et seq. Regulations have been issued under both Acts by the appropriate regulatory authorities. Antineoplastons are within the definitions of "drug" and "new drug" set forth in both acts.

After examination of the applicable authorities, we are of the opinion that the preparation of antineoplastons for your own use in your own laboratory and the administra-

tion thereof to your patients in the course of your medical practice:

(1) Is not governed by the Texas Food, Drug and Cosmetic Act and is not otherwise unlawful under the laws of the State of Texas; and

(2) Is not to "introduce or deliver for introduction into interstate commerce any new drug" as prohibited by the applicable sections of the Federal Food, Drug and Cosmetic Act, and is not within the regulatory authority of the Federal Drug Administration.

In addition to the aforementioned statutes and regulations, pertinent case authority and Attorney General's opinions, we rely for our opinion on oral advise from Hal Nelson, Esq., an attorney for the Texas Department of Health Resources and Bob Henna, an employee thereof, with respect to the non-applicability of the state act, and the oral opinions of William R. Pendergast, Esq., of McMurray and Pendergast, Washington, D.C., with respect to the scope of the Federal Act and the regulatory authority thereunder.

Both the state and federal acts and regulations contain conditional exemptions of new drugs for investigational use; however, as long as your use of antineoplastons is limited to the scope described in this letter, it is not believed that you would be required to avail yourself of such exemptions.

It is assumed that, in all cases, antineoplastons will be administered with the informed consent of the patient.

Sincerely yours,

CALDWELL & BAGGOTT

G. Ernest Caldwell

GEC/j