D-9377

IN THE MATTER OF THE COMPLAINT AGAINST	)(	BEFORE THE
	)(	
	)(	TEXAS STATE BOARD
STANISLAW R. BURZYNSKI, M.D., RESPONDENT	)(	
	)(	OF MEDICAL EXAMINERS

FIRST AMENDED COMPLAINT

TO THE HONORABLE TEXAS STATE BOARD OF MEDICAL EXAMINERS:

COMES NOW, the Texas State Board of Medical Examiners (the "Board"), by and through its Hearings Division, making this Complaint against Stanislaw R. Burzynski, M.D. (the "Respondent"), concerning his violation of the Medical Practice Act (the "Act"), Article 4495b of the Revised Civil Statutes of the State of Texas. This relief is necessary to protect the health of the citizens of the State of Texas as mandated by Section 1.02 of the Act, and in support thereof would show the following:

I

The Respondent was previously issued a Texas medical license, number D-9377, by the Texas State Board of Medical Examiners, which was in full force and effect at all times relevant to this proceeding. All jurisdictional events required prior to the filing of this Complaint have been satisfied.

II

The Texas State Board of Medical Examiners is informed and believes, and upon such information and belief, charges and alleges that:

Count I

A

From September 1, 1989 to the filing of this Complaint, the Respondent administered antineoplastons, including those designated A, A-2, A-3, A-5, A-10, AS2-1, AS2-5 and AS-5, to his patients without having the approval of the Federal Food and Drug Administration (the "FDA") pursuant to Title 21 USC Section 505 and without having a letter of approval or approvability on file with the Commissioner of Health, Texas Department of Health in violation of the Texas Food, Drug and Cosmetic Act (the "TFDCA"), Chapter 431, Subtitle

A, Title 6, Health and Safety Code, V.T.C.A., Section 431.021, Subchapter B, Section 431.114, Subchapter E, which is a violation of Section 3.08(4)(A) of the Act by committing an act that is in violation of the laws of the State of Texas if the Act is connected with the physician's practice of medicine.

B

From September 1, 1985 to September 1, 1989, the Respondent administered antineoplastons, including those designated A, A-2, A-3, A-5, A-10, AS2-1, AS2-5 and AS-5, to his patients without having the approval of the FDA pursuant to Title 21 USC Section 505 and without having a letter of approval or approvability on file with the Commissioner of Health, Texas Department of Health in violation of Section 18(a) of the TFDCA, article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of Section 3.08(4)(A) of the Act by committing an act that is in violation of the laws of the State of Texas if the Act is connected with the physician's practice of medicine.

C

Prior to and until September 1, 1985, the Respondent administered antineoplastons, designated A, A-2, A-3, A-5, A-10, AS2-1, AS2-5, and AS-5, to his patients without having the approval of the Texas Department of Health in violation of Section 16(a)(1) of the TFDCA, which is a violation of Section 3.08(4)(A) of the Act by committing an act that is in violation of the laws of the State of Texas, if the act is connected with the physician's practice of medicine.

D

Prior to June, 1983, the Respondent filed a "Notice of claimed investigational exemption for a new drug" for the antineoplaston designated A-10, identified as IND22,029, with the FDA. On February 13, 1984, the FDA, by letter, notified the Respondent that "(u)ntil the above additional required information is received and you are told that we conclude that it is reasonably safe for you to initiate the trial, the study you propose may not be legally conducted under this IND."; thereby, placing the Respondent's IND on "clinical hold". On

March 16, 1989, the FDA removed the "clinical hold" limiting the Respondents authority to those "...patients may only be treated under the submitted study titled "Treatment of Advanced Breast Cancer with Antineoplaston A-10." The Board alleges that the Respondent from February 13, 1984 until March 16, 1989 administered antinioplaston A-10 in violation of Section 18(b) of the TDFCA which violates Section 3.08(4)(A) of the Act, committing any act that is in violation of the laws of the State of Texas if the act is connected with the physician's practice of medicine.

Count II

A

G.T., a 58 year old female, had been previously diagnosed as having extensive intraductal comedocarcinoma in May, 1986. G.T. underwent a left modified radical mastectomy on May 5, 1986. Respondent saw this patient initially on July 10, 1986; antineoplaston treatment with A-10 was initiated on July 11, 1986 and continued until February 2, 1988. During that time, specifically on December 12, 1987, the patient complained of a cough and chest tightness; the patient was treated with Vibramycin 100 mg. daily for two weeks. On December 23, 1987, the patient was examined and continued to complain of unresolved cough and chest tightness. G.T. sought a second opinion in January, 1988; a chest x-ray was performed which revealed pulmonary metastasis.

The Board alleges that the Respondent's treatment of this patient was deficient in the following particulars:

1. From July 11, 1986, until February 2, 1988, the Respondent treated this patient with antineoplaston A-10, an experimental substance not approved for use in humans by the Federal Food and Drug Administration which violates section 431.114 of the Health and Safety Code in violation of section 3.08(4)(A) of the Act.

2. Respondent's failure to order a chest x-ray for a patient, known to have had a mastectomy for extensive intraductal comedocarcinoma, when the patient presented with a persistent cough unresolved by antibiotic therapy is a violation of section 3.08(18) of the Act;

3. Pulmonary metastasis occurred despite alleged therapeutic

treatment for twenty (20) months with antineoplaston A-10 in violation of section 3.08(4)(E) of the Act; and

4. Respondent's treatment of this patient with antineoplaston A-10 for 20 months, i.e. from July 11, 1986 to February 2, 1988 violates section 3.08(4)(G) of the Act.

B

H.B., a 64 year old male, who in March, 1986 was diagnosed as having clear cell renal carcinoma of the left kidney with metastasis to the lungs, and to retroperitoneal and mediastinal lymph nodes. Respondent saw this patient initially on March 31, 1986. The patients' antineoplaston treatment with A-10 intravenously was started through a Hickman catheter on April 1, 1986. On April 9, 1986, a chest x-ray revealed an increase in left lung field haziness; A-5 was added to the treatment regimen as was Augmentin 500 mg. and Levo-Dromoran 2 mg. A repeat chest x-ray on April 17, 1986, revealed no change in the lung condition, however, the Hickman catheter was noted to be withdrawing out of the superior vena cava back into the subclavian vein near the junction with the internal jugular. The antineoplaston treatment continued. The patient was hospitalized in Seattle, Washington, on April 23, 1986. A chest x-ray performed at that time revealed a large pleural effusion. Two thoracentesis were performed and over 2 liters of fluid was removed from the patient's lungs. A CT scan of the patient's abdomen revealed extensive periaortic masses throughout the abdomen with extension into the pelvic area. On May 1, 1986, a repeat CT scan of the abdomen was performed; more extensive abdominal metastasis was noted across the midline, around the cava as well as inferiorly and superiorly to the aortic bifurcation where a large right retrocurled node was noted. The patient died on May 4, 1986 as a result of respiratory failure secondary to clear cell renal carcinoma with metastasis.

The Board alleges that the Respondent's treatment of this patient was deficient in the following particulars:

1. From April 1, 1986 until on or about May 1, 1986, the Respondent treated this patient with antineoplastons A-10 and A-5 both of which are experimental substances not approved for use in humans by

the Federal Food and Drug Administration which violates section 431.114 of the Health and Safety Code is a violation of section 3.08(4)(A) of the Act;

2. The patient was treated with substances not proven to be therapeutic nor indicated for use in the treatment of clear cell renal carcinoma with metastasis in violation of section 3.08(4)(E) of the Act;

3. Respondent's treatment of a terminally ill patient, H.B., with unproven and experimental substances, i.e. antineoplastons A-10 and A-5, violates section 3.08(4) of the Act;

4. The patient received 33 antineoplaston treatments from April 1, 1986 to May 3, 1986 at a total cost of $6,940 or at an average of $210 for each treatment and the charge for 9 office visits from April 1 until April 18, 1986 totaled $540 which is an average of $60 per visit in violation of section 3.08(4)(G) of the Act;

5. Respondent (1) failed to perform baseline chest and abdominal x-rays prior to initiating antineoplaston treatment, (2) prescribed Augmentin for the patient without documenting the treatment indication for such, and (3) initiated treatment with Levo-Dromoran when the use of the medication was not indicated in violation of section 3.08(18) of the Act; and

6. Respondent led the patient's surviving spouse to believe that Respondent had concluded that, based on x-ray findings and changes in the patient's lab studies, the patient's cancer was arrested when in reality the chest x-ray was unreadable because of pleural effusion and when in reality no change had been documented in two previous x-rays, in violation of section 3.08(4) of the Act.

C

M.F., a 54 year old female, underwent a left modified radical mastectomy in Poland in July, 1981. The patient received 4500 rads of radiation post-operatively. The patient underwent lymph node dissection in July, 1984 with ten (10) nodes testing positive for cancer. Treatment with Methotrexate, 5FU, Cytoxan and Tamoxifen was initiated. In March, 1985 new tumors in the supraclavicular area and the right breast were noted; treatment with 5FU, Epidoxorubicin,

Mitomycin C and Bleomycin was initiated. The patient began treatment with Respondent on October 1, 1985 at which time Respondent documented the presence of a 1.5 cm left supraclavicular lymph node enlargement, a 3 cm left subclavicular nodule, a 1.5 cm enlargement in the right and left axillary lymph area and extensive skin involvement, i.e. elevated plaques and subcutaneous nodules of the anterior and posterior chest wall. The patient was started on antineoplaston A-10 at that time. On October 7, 1985, Respondent noted marked reduction of the skin involvement. The antineoplaston treatment was continued and Methotrexate 2.5 mg 2 x daily for 5 days was added to the treatment regimen. On January 23, 1986 Respondent documented a 70% decrease in the size of the lymph nodes size; Respondent also noted that the right breast tumor was no longer palpable and that the skin involvement previously noted had completely cleared. On February 12, 1986, two upper anterior chest wall tumors were noted and on April 30, 1986 increased recurrent skin involvement was noted. The patient last saw Respondent on August 4, 1986. M.F. expired on September 27, 1986.

The Board alleges that the Respondent's treatment of this patient was deficient in the following particulars:

1. Respondent's treatment of this patient from October 1, 1985 until approximately August 4, 1986 with antineoplaston A-10, an experimental substance not approved for use in humans by the Federal Food and Drug Administration which violates section 431.114 of the Health and Safety Code is a violation of section 3.08(4)(A) of the Act;

2. Respondent's treatment of this patient with lymphadenoma with antineoplaston A-10, a substance which has not been proven to be therapeutic nor indicated in the treatment of lymphadenoma, is a violation of section 3.08(4)(E) of the Act;

3. Respondent (1) failed to perform baseline x-rays on the patient prior to initiating treatment; (2) failed to perform follow-up x-rays 2-3 months after treatment was initiated in order to determine treatment effectiveness, if any; (3) failed to change the patient's treatment when it was apparent that Respondent's antineoplaston treatment was not working, (4) prescribed a subtherapeutic dose of Methotrexate to the patient, and (5) Respondent failed to document the

indication for prescribing Gentamycin 80 mg. for the patient violates section 3.08(18) of the Act.

D

G.A., a 53 year old male, who was diagnosed as having a 25 x 28 mm nodule in the left lower lobe of his lung. A lung biopsy revealed poorly differentiated carcinoma for which he underwent a left lower lobectomy on April 14, 1987. The patient also received radiation to the left hilar area, the mediastinum and bilateral supraclavicular area. Follow-up CT scans revealed suspicious areas in the left parietal lobe; subsequently, a 1.3 cm. left parietal tumor and a 5 mm nodule in the posterior right lower lung lobe were noted. The patient began treatment with Respondent on February 29, 1988 with antineoplaston A-10 intravenously. On April 8, 1988, a head and chest CT scan identified an increase in the size of the left parietal lesion to 2.1 cm. A CT scan of the head performed on May 11, 1988 revealed no change in the parietal lesion but the report mentioned an area of increased hypodensity which may have indicated some tumor resolution. The chest CT revealed bilateral pleural effusion and three suspicious areas, i.e, a pleural tag in the left posterior costophrenic sinus region, a nodular density in the right lower lobe measuring 1 cm. in diameter and a 1 cm. size nodule in the medial aspect of the right costophrenic sinus toward the mediastinum. On May 12, 1988, the patient was started on antineoplaston AS2-1 which was continued concurrently with A-10 until August 31, 1988 when the AS2-1 was discontinued. On August 8, 1988, repeat CT scans of the head and chest revealed peripheral ring shaped enhancement of the left parietal lesion and an increase in the right mid and lower lung field lesions by about 40%. Platinol and VP-16 was added to the treatment regimen on August 12, 1988. G.A. was referred to another physician for evaluation and treatment of brain metastasis after he suffered a grand mal seizure on August 16, 1988. Radiation therapy consisting of 4100 rads in 15 days to the whole brain and an additional 1500 rads in 6 days to the left parietal area was given. From September 8 until September 20, 1988 the patient had a second course of chemotherapy. The patient was last seen on September 17, 1988.

The Board alleges that the Respondent's treatment of this patient was deficient in the following particulars:

1. From February 29, 1988 until September 27, 1988 Respondent's treatment of this patient with antineoplastons A-10 and AS2-1, both of which are experimental substances not approved for use in humans by the Federal Food and Drug Administration is a violation of Section 431.114 of the Health and Safety Code which is a violation of section 3.08(4)(A) of the Act;

2. Respondent's treatment of this patient with antineoplastons A-10 and AS2-1 from February 29, 1988 until September 27, 1988 with substances not proven to be therapeutic nor indicated in the treatment of lung cancer with brain metastasis is a violation of section 3.08(4)(E) of the Act; and

3. Respondent's failure to offer to treat G.A. with irradiation either initially or when metastasis was documented is a violation of section 3.08(18) of the Act.

Count III

Respondent's treatment of the below listed patients with the antineoplaston treatment for the cancer listed during the time indicated:

a. R.A., a 48 year old male, had been diagnosed as having transitional cell carcinoma of the bladder. He was treated by Respondent from October 26, 1982 until August 30, 1983, with antineoplaston A-5, an experimental substance that is not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

b. J.P., a 26 year old female, had been diagnosed on March 1, 1985, as having Hodgkin's Disease, mixed cellularity with Diffuse Fibrosis. Respondent treated this patient from January 21, 1986, until March 11, 1987, with antineoplastons AS2-1, A-10 and A-5, which are experimental substances that are not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

c. M.K., a 52 year old male, had been diagnosed as having transitional cell carcinoma of the bladder on May 6, 1982. Respondent treated this patient from April 15, until July 29, 1982, with antineoplaston A-2, an experimental substance that is not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

d. E.D., a 49 year old female, had been diagnosed as having adenocarcinoma suggesting carcinoma of the breast. Respondent treated this patient from April 15 until June 5, 1980, with antineoplaston A-3, an experimental substance that is not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

e. J.K., a 56 year old male, had been diagnosed as having malignant lymphoma, nodular and diffuse, small cleaved cell (Nodular and Diffuse Poorly Differentiated Lymphocytic Lymphoma). Respondent treated this patient from February 25, until September 11, 1985, with antineoplaston AS2-1 and A-10, which are experimental substances that are not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

f. J.K., a 59 year old female, had been diagnosed as having metastatic undifferentiated carcinoma of the liver. Respondent treated this patient from September 15, 1982 until November 6, 1984, with antineoplastons A-10, AS2-1, A-2 and A-5, which are experimental substances that are not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

g. J.R., a 54 year old male, had been diagnosed as having a poorly differentiated adenocarcinoma of the lung. Respondent treated this patient from January 8, 1980 until June 17, 1982, with A-2, a

non-FDA approved experimental substance, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

h. J.S., a 33 year old female, had been diagnosed as having FIGO Stage II (a squamous cell carcinoma of the Cervix). Respondent treated this patient from September 25, 1980, until August 4, 1982, with antineoplastons A-3 and AS2-1, which are experimental substances that are not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

i. B.B., a 45 year old male, had been diagnosed as having Grade III transitional cell carcinoma of the bladder. Respondent treated this patient from October 9, 1975, until October 11, 1982, with antineoplastons A, A-2 and A-10, which are experimental substances that are not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

j. S.H., a 17 year old male, had been diagnosed as having myeloproliferative disease and Glioma consistent with chronic myelocytic Leukemia. Respondent treated this patient from January 8, 1980, until August 9, 1984, with antineoplastons A-2, A-10, AS2-1, AS2-5, which are experimental substances that are not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

k. D.B., a 47 year old female, had been diagnosed as having adenocarcinoma of the Bartholin gland. Respondent treated this patient from June 16, 1986, until February 10, 1987, with antineoplaston A-10, an experimental substance that is not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

l. B.S., a 52 year old female, had been diagnosed as having large cell lymphoma with sclerosis. Respondent treated this patient from February 3, 1986, until February 10, 1987, with antineoplastons AS2-1, A-5 and A-10, which are experimental substances that are not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

m. S.J., a 21 year old male, had been diagnosed as having Hodgkin's disease, nodular sclerosing type, in lymph nodes from left neck. Respondent treated this patient from July 21, 1986, until March 25, 1987, with antineoplastons AS2-1, A-5 and A-10, which are experimental substances that are not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

n. A.D., a 53 year old female, had been diagnosed as having malignant lymphoma, follicular, large cell. Respondent treated this patient from April 22, 1985, until February 24, 1987, with antineoplastons AS2-1 and A-10, which are experimental substances that are not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

o. L.S., a 59 year old female, had been diagnosed as having malignant lymphoma, large non-cleared, follicular center cell. Respondent treated this patient from February 5, 1985, until April 7, 1987, with antineoplastons AS2-1 and A-10, which are experimental substances that are not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

p. C.M., a 46 year old male, had been diagnosed as having malignant lymphoma, non-Hodgkin's type, lymphoblastic lymphoma. Respondent treated this patient from April 4, 1985, until February 26,

1986, with antineoplastons AS2-1 and A-10, which are experimental substances that are not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

q. J.H., a 50 year old female, had been diagnosed as having malignant lymphoma, diffuse, poorly differentiated lymphocytic type. Respondent treated this patient from November 18, 1985, until January 21, 1986, with antineoplastons AS2-1 and A-10, which are experimental substances that are not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

r. C.B., a 56 year old male, had been diagnosed as having carcinoma of the sigmoid colon with liver metastasis. Respondent treated this patient from December 5, 1979, until April 27, 1981, with antineoplastons A, A-2, A-3, A-5, and AS2-1, which are experimental substances that are not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

s. S.Z., a 36 year old male, had been diagnosed as having a poorly differentiated carcinoma consistent with squamous cell carcinoma of the nasopharynx. Respondent treated this patient from August 5, 1985, until January 15, 1986, with antineoplaston AS2-1 and A-10, which are experimental substances that are not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

t. M.T., a 60 year old female, had been diagnosed as having metastatic breast cancer to bone and brain. Respondent treated this patient from December 2, 1986, until March 12, 1987, with antineoplastons AS2-1, A-10 and A-2, which are experimental substances that are not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code

(Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

u. J.S., a 52 year old female, had been diagnosed as having infiltrating duct cell carcinoma with demonstrable metastosis to two axcillary lymph nodes. Respondent treated this patient from June 9, 1980, until October 5, 1980, with antineoplastons AS2-1 and AS2-5, which are experimental substances that are not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

v. C.H., a 30 year old female, had been diagnosed as having a frontal brain tumor, questionably a glioblastoma. Respondent treated this patient from January 8, 1986, until March 27, 1987, with antineoplastons A-10 and AS2-1, which are experimental substances that are not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

w. W.M., a 60 year old male, who had been diagnosed as having adenocarcinoma, moderately differentiated (Dukes Stage D) of the sigmoid colon and metastatic adenocarcinoma of the liver. Respondent treated this patient from January 26, 1982, until September 1, 1982, with antineoplastons A-10 and AS2-1, which are experimental substances that are not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

x. N.M., a 6 year old male, had been diagnosed as having an astrocytoma, Grade II. Respondent treated this patient from July 29, 1985, until January 30, 1987, with antineoplaston AS2-1, an experimental substance that is not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

y. S.K., a 19 year old female, had been diagnosed as having a well-differentiated chondrosarcoma of the right nose. Respondent treated this patient from May 6, 1982, until Mav 13, 1986, with antineoplastons A-10, AS2-1, A-2, A-3, and A-5, which are experimental substances that are not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

z. G.M., a 72 year old male, had been diagnosed as having poorly differentiated adenocarcinoma of the prostate. Respondent treated this patient from October 18, 1979, until April 26, 1982, with antineoplaston A and A-3, which are experimental substances that are not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

aa. S.M., a 25 year old female, had been diagnosed as having a right frontal lobe tumor, astrocytoma, grade III/IV. Respondent treated this patient from July 24, 1984, until February 1, 1985, with antineoplastons AS2-1 and A-3, which are experimental substances that are not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

bb. E.F., a 47 year old female, had been diagnosed as having poorly differentiated adenocarcinoma of the ovaries with metastasis. Respondent treated this patient from September 12, 1986, until February 2, 1987, with antineoplaston A-10, an experimental substance that is not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

cc. J.M., a 64 year old male, had been diagnosed as having adenocarcinoma of the prostate. Respondent treated this patient from October 12, 1979, until May 13, 1981, with antineoplaston A, A-2 and A-3, which are experimental substances that are not FDA approved,

which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

dd. C.B., a 65 year old male, had been diagnosed as having squamous metaplasia, moderate atypia with early dysplasia of the right upper lobe. Respondent treated this patient from March 19, 1980, until July 12, 1981, with antineoplastons A-3, AS2-1, A-2 and A-5, which are experimental substances that are not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

ee. S.C., a 54 year old male, had been diagnosed as having squamous cell carcinoma with faci of karatinization. Respondent treated this patient from February 12, 1980, until July 2, 1980, with antineoplastons A-2 and AS2-1, which are experimental substances that are not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

ff. A.S., a 39 year old male, had been diagnosed as having transitional cell carcinoma of the bladder. Respondent treated this patient from May 13, 1980, until May 15, 1983, with antineoplastons A-2, A-10, A-5 and A-3, which are experimental substances that are not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

gg. W.D., a 61 year old male, had been diagnosed as having epidermoid carcinoma of right vocal cord with microinvasion. Respondent treated this patient from June 10, 1980, until January 23, 1982, with antineoplaston AS2-5, which is an experimental substance that is not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

hh. B.G., a 61 year old female, had been diagnosed as having adenocarcinoma of the right breast. Respondent treated this patient from April 1, 1980, until November 18, 1981, with antineoplastons A-2, AS2-5, AS2-1, A-5, and A-4, which are experimental substances that are not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

ii. D.D., a 54 year old female, had been diagnosed as having invasive papillary transitional cell carcinoma, Grade II, of the urinary bladder. Respondent treated this patient from June 13, 1979, until July 20, 1982, with antineoplastons A, A-2, A-5 and AS2-1, which are experimental substances that are not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

jj. H.F., a 67 year old male, had been diagnosed as having poorly differentiated malignant neoplasia highly suggestive of carcinoma of the liver. Respondent treated this patient from April 2, 1980, until August 25, 1982, with antineoplastons A-2, AS-5, A-5, A-10, A-3 and AS2-1, which are experimental substances that are not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

kk. H.H.F., a 52 year old female, had been diagnosed as having metastatic brain tumor from primary lung neoplasm. Respondent treated this patient from December 3, 1979, until July 28, 1981, with antineoplastons A-3, A-5, A and A-2, which are experimental substances that are not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

ll. E.T., a 36 year old female, had been diagnosed as having mesothelioma in the ileum and mesentary. Respondent treated this

patient from November 8, 1979, until March 3, 1981, with antineoplastons A, A-2, AS2-1, and AS2-5, which are experimental substances that are not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

mm. B.S., a 47 year old male, had been diagnosed as having transitional cell carcinoma, Grade II, of the urinary bladder. Respondent treated this patient from April 18, 1978, until January 21, 1983, with antineoplastons A and A-3, which are experimental substances that are not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

nn. J.H., a 56 year old female, had been diagnosed as having metastatic carcinoma of the right neck, giant cell carcinoma of the lung, insitu and infiltrating lobular carcinoma of the left breast. Respondent treated this patient from June 18, 1980, until June 7, 1983, with antineoplastons AS2-5, A-2, A-3, A-5, and A-10, which are experimental substances that are not FDA approved, which is a violation of the Texas Food, Drug and Cosmetic Act, Section 431.114 of the Health and Safety Code (Vernon's, 1989), formerly article 4476-5, Tex. Rev. Civ. Stat. Ann., which is a violation of section 3.08(4)(A) of the Act.

III

The Respondent by his actions, conduct and behavior has violated Sections 3.08(4), 3.08(4)(A), 3.08(4)(E), 3.08(4)(G), 3.08(5), and 3.08(18) of the Medical Practice Act of Texas.

The Respondent's violations of Sections 3.08(4), 3.08(4)(A), 3.08(4)(E), 3.08(4)(G), 3.08(5), and 3.08(18) of the Act are grounds for cancellation, revocation or suspension of the Respondent's license to practice medicine in the State of Texas pursuant to section 4.01 of the Act.

The Respondent's violations of Sections 3.08(4), 3.08(4)(A), 3.08(4)(E), 3.08(4)(G), 3.08(5), and 3.08(18) of the Act are grounds

for the Board to enter an order imposing other means of discipline upon the Respondent pursuant to section 4.12 of the Act.

The Respondent's violations of Sections 3.08(4), 3.08(4)(A), 3.08(4)(E), 3.08(4)(G), 3.08(5), and 3.08(18) of the Act resulting in the cancellation, revocation or suspension of the Respondent's Texas medical license or the imposition of other means of discipline may be probated pursuant to section 4.11 of the Act.

WHEREFORE, PREMISES CONSIDERED, it is prayed that a hearing on this complaint be held before the Texas State Board of Medical Examiners and that the Board enter its order herein to (1) cancel, revoke or suspend the Respondent's medical license; (2) impose other means of discipline, or (3) probate the cancellation, revocation, suspension or the Respondent's Texas medical license, or the imposition of other means of discipline.

Respectfully submitted,

Arnoldo G. Garza
Director of Hearings

THE STATE OF TEXAS)(
)(
COUNTY OF TRAVIS)(

SUBSCRIBED AND SWORN to before me by the said Arnoldo G. Garza on this the 12th day of July, 1990.

LAURINE H. BALTZ
Notary Public
STATE OF TEXAS
My Comm. Exp. 8-22-93

Notary Public, State of Texas

Filed with the Texas State Board of Medical Examiners on this the 12th day of July, 1990.

Homer R. Goehrs, M.D.
Executive Director
Texas State Board of Medical Examiners

(comp.& not. 8.25)