

D-9377

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

SECOND 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, amending its 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 Second Amended 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 Respondent's 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 antineoplaston 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

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 (Vernons 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 (Vernons 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, 1982, 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 (Vernons 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, 1980, 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 (Vernons 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, 1985, until September 11, 1985, 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 (Vernons 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 (Vernons 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 antineoplaston 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 (Vernons 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 (Vernons 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 (Vernons 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

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 (Vernons 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 (Vernons 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 (Vernons 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 (Vernons 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 (Vernons 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-cleaved, 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 (Vernons 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 (Vernons 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 (Vernons 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 (Vernons 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 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 (Vernons 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 (Vernons 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 metastasis to two axillary 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 (Vernons 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 (Vernons 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 (Vernons 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 (Vernons 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 May 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 (Vernons 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 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 (Vernons 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 (Vernons 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 (Vernons 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 antineoplastons 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 (Vernons 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 18, 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 (Vernons 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 foci of keratinization. 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 (Vernons 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 (Vernons 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 (Vernons 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 (Vernons 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 (Vernons 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 (Vernons 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 (Vernons 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 (Vernons 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 (Vernons 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 (Vernons 1989), formerly article 4476-5, TEX. REV. CIV. STAT. ANN., which is a violation of section 3.08(4)(A) of the Act.

Count III

From September 1, 1985, to the filing of this Second Amended Complaint, the Respondent, through his promotional literature, writings and publications represents to the public that antineoplastons, including those designated A, A-2, A-3, A-5, A-10, AS2-1, AS2-5 and AS-5 affect human neoplasms (cancers). Such representations violate the Texas Health and Safety Code, V.T.C.A. § 431.183(a)(2) which is a violation of Section 3.08(4)(A) of the Act, and Section 3.08(6) 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.

Count IV

From September 1, 1985, to the date of the filing of this Second Amended Complaint, Respondent has charged a fee for antineoplastons, including those designated A, A-2, A-3, A-5, A-10, AS2-1, AS2-5 and AS-5. Such conduct of charging a fee constitutes a violation

of Section 312.7(a) and (d), Promotion and Charging for Investigational Drugs, 21 C.F.R., Chapter 1 which is a violation of Section 3.08(4)(G) 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)(G), and 3.08(6) of the Medical Practice Act of Texas.

The Respondent's violations of Sections 3.08(4), 3.08(4)(A), 3.08(4)(G) and 3.08(6) 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.

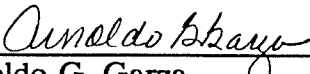
The Respondent's violations of Sections 3.08(4), 3.08(4)(A), 3.08(4)(G), and 3.08(6) of the Act are grounds for the Board to enter an order imposing other means of discipline upon the Respondent pursuant to section 4.12 of the Act.

The Respondent's violations of Sections 3.08(4), 3.08(4)(A), 3.08(4)(G), and 3.08(6) 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

VERIFICATION

THE STATE OF TEXAS §

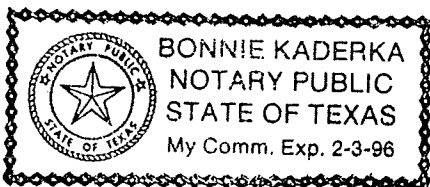
COUNTY OF TRAVIS §

BEFORE ME, the undersigned authority, personally appeared ARNOLDO G. GARZA, and being by me duly sworn on his oath states:

1. that he is Director of Hearings for the Texas State Board of Medical Examiners;
2. that he is over 21 years of age and fully competent to make this statement;
3. that he is duly authorized to make this verification;
4. that the matters contained in the foregoing Second Amended Complaint are based on knowledge and belief and are true and correct.

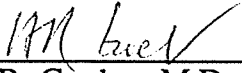
Arnoldo Garza
ARNOLDO G. GARZA

SUBSCRIBED AND SWORN to before me on this the 14th day of August, 1992.



Bonnie Kaderka
Notary Public in and for the
State of Texas

Filed with the Texas State Board of Medical Examiners on this the 14th day of
August, 1992.



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