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RE: ZANHUA YI, M.D.; SOAH NO. 503-14-4119.MD

Attached please find the Second Amended Complaint

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HEARING CONDUCTED BY THE
 TEXAS STATE OFFICE OF ADMINISTRATIVE HEARINGS
 SOAH DOCKET NO. 503-14-4119.MD
 TEXAS MEDICAL LICENSE NO. N-9666

IN THE MATTER OF THE
 COMPLAINT AGAINST
 ZANHUA YI, M.D.

BEFORE THE
 TEXAS MEDICAL BOARD

SECOND AMENDED COMPLAINT

TO THE HONORABLE TEXAS MEDICAL BOARD AND THE HONORABLE
 ADMINISTRATIVE LAW JUDGE TO BE ASSIGNED:

COMES NOW, the staff of the Texas Medical Board (Board), and files this Second Amended Complaint against Zanhua Yi, M.D. (Respondent), based on Respondent's alleged violations of the Medical Practice Act (Act), Title 3, Subtitle B, Texas Occupations Code, and would show the following:

I. INTRODUCTION

The filing of this Complaint and the relief requested are necessary to protect the health and public interest of the citizens of the State of Texas, as provided in Section 151.003 of the Act.

II. PROCEDURAL BACKGROUND

1. Respondent is a Texas Physician and holds Texas Medical License No. N-9666, originally issued by the Board on May 2, 2011. Respondent's license was in full force and effect at all times material and relevant to this Complaint.

2. Respondent received appropriate notice of an Informal Settlement Conference. The Board complied with all procedural rules, including but not limited to, Board Rules 182 and 187, as applicable.

3. No agreement to settle this matter has been reached by the parties.
4. All jurisdictional requirements have been satisfied.

III. FACTUAL ALLEGATIONS

Board Staff has received information and relying on that information believes that Respondent has violated the Act. Based on such information and belief, Board Staff alleges:

A. General Allegations regarding Respondent's conduct at the Burzynski Clinic.

1. Respondent was one of the treating physicians for Patient¹ E, throughout their treatment directed by Respondent and other physicians working at the Burzynski Clinic.

2. Treatment of the patient in this case was initiated at the Burzynski Clinic pursuant to Respondent's recommendations and supervision and Dr. Stanislaw Burzynski's direction and overall control.

3. The Burzynski Clinic had a medical practice model that was created and directed by Stanislaw Burzynski, M.D. based on marketing his proprietary anti-cancer drugs, antineoplastons², to patients without adequate measures for patient safety and therapeutic value.

4. Respondent and other persons under Respondent's direction and supervision knowingly misled patients by promoting his proprietary drugs as an attraction to bring patients to his medical practice when Respondent was aware that he could not legally include most of those patients in FDA-approved Phase 2³ clinical trials of his proprietary anti-cancer drugs.

5. Board Staff presents the above-described points through a review of the medical care provided to four patients who sought medical care by the Burzynski Clinic and Respondent's employees and through review of promotional statements made by Respondent,

¹ Identification of the patient in this case will be provided to Respondent and the Honorable ALJs as confidential and under seal.

² Respondent's proprietary anti-cancer medication

³ Phase 1, Phase 2, and Phase 3 clinical trials are descriptions of different stages of clinical studies that are regulated by the FDA. Per 21 CFR 312.21, Phase 1 trials are designed to determine the metabolism and pharmacologic actions of drugs in humans, side effects and, to a limited degree, early indications of efficacy. Phase 1 studies involve small patient populations, very closely monitored. Phase 2 trials are designed to study side effects and risks of the drug in humans. Phase 2 trials involve several hundred patients/subjects. Phase 3 trials are designed to study the efficacy and to make an evaluation of overall safety of the drug in humans based on the scientific evidence. Phase 2 trials routinely involve several thousand patients/subjects.

communications from the United States Food and Drug Administration (“FDA”) and medical records related to those communications.

6. Respondent was one of the treating physicians for the patient in this case, Patient⁴ E, throughout their treatment directed by Respondent and other physicians working at the Burzynski Clinic. Treatment of the patient in this case was initiated at the Burzynski Clinic pursuant to Respondent’s control, direction and supervision.

7. Dr. Stanislaw Burzynski’s practice model dictated and directed an approach to evaluation, diagnosis, treatment and billing of patients at the Burzynski Clinic, including his own evaluation, diagnosis and treatment of the patient in this case. This medical practice model included Respondent’s conduct and conduct of employees under Respondent’s direction and supervision that:

- violated the standard of care;
- failed to demonstrate an adequate medical rationale for evaluation, diagnosis and treatment;
- violated standards of adequate documentation;
- constituted inadequate discussion of treatment alternatives;
- constituted improper charges for care, drugs, medical supplies and other services;
- constituted inadequate informed consent;
- aided and abetted the unlicensed practice of medicine;
- constituted inadequate direction and supervision of medical care personnel;
- constituted improper delegation of medical tasks; and
- constituted inadequate disclosure of ownership interest in a facility to which a patient is referred; and
- violated the ethical and professional responsibilities of clinical investigators.

8. Respondent participated in the medical practice model which offered the public anti-cancer therapy at the Burzynski Clinic in Houston, Texas. Respondent’s conduct at the Burzynski Clinic involving the patient in this case violated the Act and Board Rules as described in the allegations below. Many of these violations are due to Respondent’s systematic approach to patient evaluation, diagnosis and treatment that was part of the medical practice model at the Burzynski Clinic. Therefore, those violations are substantially the same or similar for each and

⁴ Identification of the patient in this case will be provided to Respondent and the Honorable ALJs as confidential and under seal.

every patient in this case. Respondent's conduct also constituted distinctive violations of the Act and Board Rules for each individual patient, as described below.

B. Applicable Standard of Care

1. All of the anti-cancer drugs described below that Respondent directed to be prescribed or otherwise ordered for Patient E exhibit some significant toxicity and adverse side effects when taken by patients: (a) Decadron, (b) Xgeva, (c) Phenylbutyrate, (d) Afinitor, and (e) Sutent.

2. The frequency of incidence and the severity of adverse effects of the anti-cancer drugs listed above are increased when those drugs are taken nearly simultaneously. Respondent directed the ordering of many of these drugs to be taken nearly simultaneously by each of the patient in this case.

3. The "standard of care" is defined as what a reasonable physician would do in the same or similar circumstances requires an adequate medical rationale for the use of these anti-cancer treatments. The standard of care when providing anti-cancer treatment includes:

a. An adequate medical rationale for anti-cancer treatments, including classic chemotherapy, medications used for purposes not approved by the federal Food and Drug Administration (FDA) and investigational new drugs, requires performing and documenting:

- 1) adequate histological and pathological examination confirming cancer;
- 2) adequate physical examinations;
- 3) adequate mental status examinations;
- 4) an adequate treatment plan, including description of the therapy (including amounts and dosages), periodic review, measurable objectives and monitoring of progress toward objectives.
- 5) informed consent, including a discussion with a patient about the risks and benefits of the proposed treatment; and
- 6) discussion of alternatives to the treatment.

b. The following elements of a treatment plan:

- 1) objectives to measure treatment effectiveness, including a method for determining effectiveness of polypharmacy, when more than one substance is used to treat a patient during the same time period;
- 2) objectives for alleviation of symptoms;
- 3) monitoring of objectives of treatment effectiveness;
- 4) monitoring of alleviation of symptoms;
- 5) monitoring of side effects of treatment; and

6) dosages and instructions for treatment medications.

c. The following elements of an adequate mental status examination:

- 1) the patient's ability to identify themselves;
- 2) the patient's awareness of their surroundings;
- 3) whether the patient is aware of what they are being seen for;
- 4) the patient's ability to make decisions for themselves;
- 5) the patient's ability to understand the directions for taking the medications;
- 6) the patient's awareness of the risks of the medications; and
- 7) patient's frame of mind and general psychiatric condition, such as anxiety or depression, if any.

4. Violation of the standard of care when recommending and/or directing anti-cancer treatment is non-therapeutic treatment.

C. Violation of the Standard of Care

1. The evaluation, diagnosis and treatment of the patient in this case by Respondent and his subordinates subject to his direction and supervision as set out in this section violated the standard of care by the following:

failure to practice medicine in an acceptable professional manner consistent with public health and welfare. generally, by:

- a. failure to treat a patient according to the generally accepted standard of care - a violation of Section 164.051(a)(6) of the Act, as further defined by Board Rule 190.8(1)(A);
- b. negligence in performing medical services - a violation of Section 164.051(a)(6) of the Act, as further defined by Board Rule 190.8(1)(B);
- c. failure to use proper diligence in one's professional practice - a violation of Section 164.051(a)(6) of the Act, as further defined by Board Rule 190.8(1)(C); and
- d. failure to safeguard against potential complications; a violation of Section 164.051(a)(6) of the Act, as further defined by Board Rule 190.8(1)(D);
- e. prescribing or administering a drug or treatment that is nontherapeutic in nature or nontherapeutic in a manner the drug or treatment is administered or prescribed - a violation of Section 164.053(a)(5) of the Act;
- f. failure to adequately supervise medical personnel - a violation of Section 164.053(a)(8) of the Act.

2. Patient E either suffered considerable toxicity effects or were put at significant risk of considerable toxicity effects due to the medications recommended, ordered or prescribed by Respondent and his subordinates pursuant to Respondent's direction and supervision in treating these patients for cancer. Respondent and other health care providers under

Respondent's direction and supervision violated the standard of care by treating the patient in this case without sufficient regard to the potential combined toxicities of drugs used pursuant to Respondent's recommendations and directions.

3. Respondent and other health care providers under Respondent's direction and supervision improperly referenced the case reports of other physicians not associated with the Burzynski Clinic as support for combined use of the drugs recommended and administered to the patient in this case. In those referenced case reports of cited by the Burzynski Clinic, however, those drugs were only used individually or in other combinations, and were not the combinations of drugs used by Respondent and other health care providers at the Burzynski Clinic. In this regard, Respondent and other health care providers under Respondent's direction and supervision violated the standard of care by having an inadequate medical rationale for the combined use (simultaneous and near-simultaneous) of these drugs.

4. Respondent and other health care providers under Respondent's direction and supervision referenced case reports and literature as the basis of their medical rationale for the use of phenylbutyrate recommended and administered to the patient in this case. Those case reports and literature did not provide an adequate medical rationale to support the use of phenylbutyrate as recommended and administered to the patient in this case. In this regard, Respondent and other health care providers under Respondent's direction and supervision violated the standard of care by having an inadequate medical rationale for the use of phenylbutyrate.

5. Respondent misled patients knowingly by promoting antineoplastons and combinations of other drugs as safe and efficacious when the safety and efficaciousness of antineoplastons and combinations of other drugs had not been determined by sufficient scientific study to adequately support such a conclusion. Respondent and other health care providers under Respondent's direction and supervision treated the patient in this case without an adequate medical rationale for the drugs and drug combinations that he prescribed. This misleading conduct constituted a violation of Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C), and Section 164.052(a)(5) of the Act.

6. Respondent also violated the Act and Board Rules due to his subordinates' violation of the standard of care in the medical tasks that those subordinates performed, as delegated by Respondent, related to the evaluation, diagnosis and treatment of the patient in this case as set out in this section. These violations of the standard of care constituted Respondent's failure to supervise adequately the activities of those acting under his direction and supervision. This conduct constituted a violation of Sections 164.053(a)(8) and 164.053(a)(9) of the Act.

7. Respondent and other health care providers under Respondent's direction and supervision failed to meet the requirements of the standard of care for adequate medical rationale for the evaluation, diagnosis and treatment of the patient in this case. These failures constituted a violation of Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(B); 190.8(1)(C); and 190.8(1)(D); Section 164.053(a)(8) and Section 164.053(a)(9) of the Act. These failures to meet the requirements of the standard of care for adequate medical rationale for the evaluation, diagnosis and treatment of the patient in this case are as follows:

- a. At the time that the patient in this case first presented to Respondent and other doctors at the Burzynski Clinic, each patient was not in a medical condition requiring emergency or intensive medical care.
- b. Prior to initiation of anti-cancer drug treatment for each of the patient in this case, Respondent and other health care providers under Respondent's direction and supervision failed to perform or to receive results of an adequate histological examination and an adequate pathologic documentation of malignancy that confirmed cancer. Respondent and other health care providers under Respondent's direction and supervision initiated treatment of the patient in this case without appropriate, adequate analysis of genomic screening and discussion with the patient about Respondent's genotypic and phenotypic diagnosis. The failures of Respondent and other health care providers' under Respondent's direction and supervision in these regards constituted a violation of the standard of care and/or constituted inadequate direction and supervision on or about each of the service dates listed on Appendix A.
- c. Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision violated the standard of care by failure to perform adequate physical

and mental status examinations of the patient in this contested case at the time that Respondent recommended and/or directed anti-cancer treatment for each patient after the initial physical examination. The failures of Respondent and other health care providers' under Respondent's direction and supervision in these regards violated the standard of care and/or constituted inadequate direction and supervision on each of the service dates listed on Appendix A.

d. Respondent and Burzynski Clinic employees acting under Respondent's direction and supervision failed to satisfy the elements (as stated in Section B.6. herein above) of a treatment plan that are required by the standard of care. The failures of Respondent and other health care providers' under Respondent's direction and supervision in these regards violated the standard of care and/or constituted inadequate direction and supervision on each of the service dates listed on Appendix A.

e. Providing anti-cancer treatments for which the benefits have not been proven by Phase 3 studies to outweigh the known risks of such treatments when recommending and/or directing anti-cancer treatment violates the standard of care. Such conduct is non-therapeutic treatment, unless such treatment is provided pursuant to an appropriate, approved and properly conducted clinical study in compliance with federal law and regulations. Several of Respondent's recommendations and/or direction for the treatment of the patient in this case were not proven by Phase 3 studies to outweigh the known risks of such treatments and not provided pursuant to an appropriate, approved and properly conducted clinical study in compliance with federal law and regulations. The failures of Respondent and other health care providers' under Respondent's direction and supervision in these regards violated the standard of care and/or constituted inadequate direction and supervision on each of the service dates listed on Appendix A.

8. Inadequate medical documentation

Respondent and other health care providers under Respondent's direction and supervision failed to meet the following requirements of the standards of adequate documentation, pursuant

to Section 164.051(a)(3) of the Act, as further defined by Board Rules 165.1, by failure to adequately document:

- a. an adequate medical rationale for the evaluation, diagnosis and treatment of the patient in this case;
 - b. an adequate treatment plan at the time that Respondent recommended and/or directed anti-cancer treatment for each of the patient in this case;
 - c. performance of an adequate physical examination of each patient at the time that Respondent recommended and/or directed anti-cancer treatment for each patient after the initial physical examination;
 - d. a mental status examination at the time that Respondent recommended and/or directed anti-cancer treatment for the patient in this case after the initial mental status examination;
 - e. an adequate medical rationale for the simultaneous use of these agents in anti-cancer therapy;
 - f. an adequate medical rationale for the use of phenylbutyrate in anti-cancer therapy for the patient in this case;
 - g. the results of an adequate histological examination that confirmed cancer prior to initiation of anti-cancer drug treatment;
 - h. an adequate pathologic documentation of malignancy in the medical records for each patient prior to making recommendations for treatment for cancer;
 - i. an adequate analysis of genomic screening and discussion with each of the patients about Respondent's genotypic and phenotypic diagnosis.
9. Violations related to the conduct described in Section C.1 through Section C.8 occurred on or about each of the service dates listed on Appendix A.

10. Specific Allegations: Violation of Standard of Care Patient E

- a. In December 2010, after suffering acute renal failure, Patient E received a biopsy-based diagnosis of malignant chromophobe renal cell carcinoma⁵. This is a relatively

⁵ Malignant chromophobe renal cell carcinoma is a rare condition according to the National Institute of Health. See <http://cancergenome.nih.gov/cancersselected/ChromophobeRenalCellCarcinoma>

rare cancer. Imaging studies in July 2011 revealed residual metastatic disease centered within the left T3 transverse process of the kidney.

b. Because he had previously suffered significant side effects from chemotherapy, including Votrient, Patient E declined a local physician's recommendation of additional chemotherapy.

c. Patient underwent nephrectomy and adjuvant therapy for a chromophobe type renal cancer in 1994. Beginning with the first disease recurrence in 1997 and over the subsequent years, Patient underwent a sequence of therapies. Patient also had pre-existing renal disease.

d. Patient E sought treatment at the Burzynski Clinic and met with Respondent and other health care providers under Respondent's supervision, direction and control on or about September 7, 2011. Respondent and other health care providers under Respondent's supervision, direction and control treated Patient E at the Burzynski Clinic for Patient's metastatic renal carcinoma on or about September 8, 2011 through on or about September 16, 2011.

e. Patient E discontinued treatment by the Burzynski Clinic after one week due to his belief that Respondent and the persons under Respondent's direction and supervision had been dishonest and deceptive with him about the treatment available to him at the Burzynski Clinic. Respondent's evaluation, diagnosis and treatment of Patient E ended on or about September 15, 2011.

f. Respondent recommended, ordered and directed that Patient E start treatment with phenylbutyrate, Afinitor, Sutent, and Xgeva. A Burzynski Clinic physician, pursuant to Respondent's instructions and control, prescribed multiple targeted agents to Patient E with similar, overlapping toxicity profiles with the potential for considerable toxicities. Specifically, a Burzynski Clinic physician, pursuant to Respondent's instructions and control, prescribed both a tyrosine kinase inhibitor (Sutent) and a motor inhibitor (Afinitor), and directed Patient E to take the drugs simultaneously.

- g. Sutent and Afinitor are cancer treating agents that have a high propensity to cause diarrhea and painful inflammation and ulceration of the mucous membranes lining the digestive tract. Further, patients taking Afinitor are at risk of renal failure.
- h. Respondent and persons under Respondent's direction and supervision non-therapeutically prescribed a combination of two targeting agents in toxic doses, leading to an unacceptable risk of complications faced by Patient E, including renal failure, as Patient E had pre-existing renal disease.
- i. Respondent and persons under Respondent's direction and supervision failed to document any medical rationale in Patient E's medical record for prescribing multiple targeted agents for a chromophobe type renal cancer.
- j. Respondent and persons under Respondent's direction and supervision failed to obtain informed consent from Patient E for simultaneous intake of Sutent and Afinitor.
- k. Respondent and persons under Respondent's direction and supervision non-therapeutically prescribed phenylbutyrate to treat Patient E's renal cell cancer, without medical justification and without documenting any medical rationale in Patient's medical record.
- l. Respondent and persons under Respondent's direction and supervision directed the unnecessary measurement of Patient E's oxygen saturation. Patient E had no significant pulmonary disease, and the medial records are without justification for this testing.
- m. Respondent and persons under Respondent's direction and supervision directed the unnecessary and costly laboratory testing for measures that are without demonstrable benefit to Patient E, including, at the initial visit, an echocardiogram, an assay of plasma VEGF, serum EGFR, and her 2, and later a PET scan, requisitions for serum or plasma analysis and testing, and an amino acid profile for evaluation of nutritional status. Respondent and persons under Respondent's direction and supervision failed to document any medical rationale in Patient E's medical record to medically justify these laboratory studies.
- n. Respondent's above-described conduct violated:

- Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records;
- Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C);
- Section 164.053(a)(5) of the Act, non-therapeutic treatment;
- Section 164.053(a)(7) of the Act, violates Section 311.0025, Health and Safety Code; and
- Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct, and as further defined by Board Rule 190.8(2)(J), providing medically unnecessary services to a patient or submitting a billing statement to a patient or a third party payer that the licensee knew or should have known was improper.

II. Unprofessional Conduct

a. Inadequate Delegation and Inadequate Direction and supervision.

1) Respondent delegated medical tasks which constituted the practice of medicine to health care providers and others who had inadequate education or training related to cancer treatment. Respondent's inadequate direction, supervision and control included failure to adequately document his review of documents related to evaluation, diagnosis and treatment of each patient. Respondent and other health care providers under Respondent's direction, supervision and control further misled patients into accepting care from health care providers and others who had inadequate education or training related to cancer treatment while Respondent misrepresented those health care providers and doctors to have significant advanced education and/or training related to cancer treatment. Respondent allowed employees of the Burzynski Clinic to engage in conduct which misled patients and other health care providers to believe that those employees were performing medical tasks that constituted the practice of medicine and that those employees were licensed to practice medicine when they were not licensed. In these regards, Respondent's violations of the Act (Sections 157.001 of the Act, 164.051(a)(6), 164.053(a)(8), and 164.053(a)(9) of the Act) Board Rules occurred as follows:

The evaluation, diagnosis and treatment of Patient E by the Burzynski Clinic at the time of evaluation of Patient E's medical condition on or about September 7, 2011, September 8, 2011, September 9, 2011, September 10, 2011, September 11, 2011, September 12, 2011, September 13, 2011, September 14, 2011, September 15, 2011, and September 16, 2011.

b. Aiding and Abetting the Unlicensed Practice of Medicine.

1) Respondent and other health care providers under Respondent's direction and supervision further misled patients into accepting care from unlicensed persons. Respondent misrepresented those unlicensed persons to be licensed medical doctors in Texas and the United States of America. At the time each of the patients first met with Respondent and the other employees of the Burzynski Clinic under his direction and supervision and continuing throughout the Burzynski Clinic's care of each patient, those unlicensed persons performed medical tasks that constituted the practice of medicine in the state of Texas. Respondent and other health care providers under Respondent's direction and supervision represented to the patient in this case and their family members that those unlicensed individuals were licensed to practice medicine in Texas. The unlicensed persons who were identified by Respondent and at the Burzynski Clinic as "doctor", "Dr." or otherwise licensed to practice medicine were as follows:

Tolib Rakhmanov, Lourdes DeLeon and Muhamed Khan, who were involved in the evaluation, diagnosis and anticipated treatment of Patient E by the Burzynski Clinic at the time of evaluation of Patient E's medical condition on or about the following dates: September 7, 2011, September 8, 2011, September 9, 2011, September 10, 2011, September 11, 2011, September 12, 2011, September 13, 2011, September 14, 2011, September 15, 2011, and September 16, 2011.

2) Respondent's actions and failures to inform the patients, patients' family members and other health care professionals who treated the patient in this case accurately in regard to the licensure status of persons identified as "doctor" and "Dr." constituted aiding and abetting the unlicensed practice of medicine and inadequate direction and supervision. Respondent's violations of the Act (Sections 157.001 of the Act, 164.051(a)(6) and 164.053(a)(17) of the Act).

c. Failure to Disclose Reasonably Foreseeable Side Effects and Failure to Obtain Adequate Informed Consent.

1) Respondent and other persons under Respondent's direction and supervision participated in knowingly misleading the patient in this case by promoting combinations of anti-cancer drugs as safe and efficacious when the safety and

efficaciousness of those combinations of drugs had not been determined by sufficient scientific study to adequately support such a representation.

2) The combinations of drugs that Respondent and other health care providers under Respondent's direction and supervision prescribed to the patient in this case posed a significantly greater risk to the patient than any of the drugs alone. Respondent and Respondent's subordinates at the Burzynski Clinic provided the patients with information about each of the drugs singularly, but they did not provide the patients with a discussion of the combinations of drugs that were prescribed to the patient in this case. Respondent and other health care providers under Respondent's direction and supervision failed to adequately discuss and document any discussion of the side effects of those combinations of drugs.

3) Respondent and other health care providers under Respondent's direction and supervision also failed to adequately inform the patient in this case of the increased risks of simultaneous or near-simultaneous combinations of the drugs that Respondent directed to be used in treating the patient in this case for cancer.

4. The failure of Respondent and other health care providers under Respondent's direction and supervision to disclose reasonably foreseeable side effects in this regard constituted a violation of Sections 164.051(a)(6), 164.052(a)(5) and 164.053(a)(8) of the Act and Board Rules 190.8(1)(A), (C), (G) and (I) on each of the service dates listed on Appendix A.

d. Inadequate Disclosure

1) Respondent had an ownership interest in the pharmacy that dispensed the drugs that were prescribed to the patient in this case.

2) Respondent had an ownership interest in the laboratory that performed the tests ordered by Respondent and other health care providers under Respondent's direction and supervision.

3) The failure by Respondent and other health care providers under Respondent's direction and supervision to disclose these ownership interests constituted unprofessional conduct that violated Section 164.051(a)(6), 164.052(a)(5) and

164.053(a)(8) of the Act and Board Rule 190.8(1)(C) and 190.8(2)(H) on each of the service dates listed on Appendix A.

e. Improper Charges

1) Respondent and other persons under Respondent's direction and supervision participated in (1) misleading patients into paying funds as a retainer prior to receiving any evaluation, diagnosis or treatment and (2) exorbitant charges for drugs, medical supplies and medical services.

2) Respondent and other persons under Respondent's direction and supervision charged patients and third-party payors for diagnostic testing, drugs, treatments other than drugs, medical supplies and medical services that were not medically necessary. These improper charges for evaluation, diagnosis and treatment of each of the patients in the case by the Burzynski Clinic under the direction and supervision of Respondent were not adequately supported by documentation in the medical record. These improper charges, as listed on Appendix B attached hereto, constituted violations of Section 164.053(a)(1) of the Act authorizes the Board to take disciplinary action against Respondent based upon Respondent's commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, specifically, Health and Safety Code, Section 311.0025 of the Texas Health and Safety Code, prohibiting a hospital, treatment facility, mental health facility, or health care professional, from submitting to a patient or a third party payor, a bill for a treatment that the hospital, facility, or professional knows was not provided or knows was improper, unreasonable, or medically or clinically unnecessary and Section 164.052(a)(5) of the Act and Board Rules 190.8(2)(J), providing medically unnecessary services to a patient.

f. False, Misleading and or Deceptive Advertising and Marketing Conduct

1) Respondent participated in marketing Dr. Stanislaw Burzynski's proprietary anti-cancer drugs, antineoplastons, and combinations of anti-cancer drug therapies to patients without adequate measures for patient safety and without sufficient scientific support to establish therapeutic value and claims of efficaciousness. The patient in

this case sought treatment by the Burzynski Clinic with antineoplastons in part due to reading or viewing statements referenced on the websites of the Burzynski Clinic and the Burzynski Research Institute.

2). Respondent and/or employees of the Burzynski Clinic under his direction and supervision informed each patient that the patient would be considered for treatment with antineoplastons in one of Dr. Stanislaw Burzynski's sponsored clinical studies. At the time Respondent and/or employees under his direction and supervision made this representation, Respondent and/or employees under his direction and supervision failed to inform the patient that Respondent was not going to assist the patient in obtaining access to being treated in an FDA-approved clinical study. Respondent and/or employees under his direction and supervision made additional representations to each patient that the Burzynski Clinic would soon be initiating a Phase 3 FDA-approved clinical study of antineoplastons. These representations were false.

3) The patient in this case initially informed Respondent and/or employees of the Burzynski Clinic under his direction and supervision that the patient wanted "antineoplaston" therapy rather than classic or other chemotherapy treatments. After assuring each patient that they would soon obtain the treatment they desired, Respondent and the employees of the Burzynski Clinic under his direction and supervision directed each patient to pay a large sum of money on retainer for anti-cancer therapy by the Burzynski Clinic. After assuring each patient that they would soon obtain the treatment they desired, and after the patient paid a large sum of money on retainer for anti-cancer therapy by the Burzynski Clinic, Respondent and/or employees of the Burzynski Clinic under his direction and supervision recommended, ordered and directed treatments for each patient that did not include "antineoplaston" therapy.

For Patient E After the initial office visit physical examination in October 2010 during the time period of office visits in October 2010. At the time that Patient E returned to the Burzynski clinic in August 2011. During the nine month period between October 2010 and when Patient E returned to the Burzynski clinic in August 2011.

4) Respondent recommended, ordered and directed treatments with these other substances without adequately explaining to each patient the difference in safety and efficacy between classic chemotherapy, the therapy requested by the patient and the therapy provided by Respondent and the employees of the Burzynski Clinic under his direction and supervision.

5) The above-described conduct of Respondent and other persons under Respondent's direction and supervision constituted a violation of Sections 164.051(a)(3), 164.051(a)(6), 164.052(a)(5), 164.052(a)(6) and 164.053(a)(8) of the Act and Board Rules on each of the service dates listed above.

12. Violation of Ethical and Professional Responsibilities Regarding Clinical Investigations - Clinical Investigations not approved by the FDA

a. Dr. Stanislaw Burzynski was the only source of his proprietary drugs, antineoplastons, for any patient. Respondent was a clinical investigator conducting clinical studies of investigational new drugs for the Burzynski Clinic, Burzynski Research Institute, and Burzynski Research Institute-Institutional Research Board ("BRI-IRB"). As clinical investigator Respondent assumed (1) the legal obligation to comply with all applicable laws and rules related to clinical studies and (2) the obligations of the ethical and professional responsibilities as expressed by all applicable laws and rules related to clinical studies. These laws and rules include: 21 CFR 312.3(b); 21 CFR 312.50; 21 CFR 312.60; and Tex. Occ. Code 164.051(a)(3), violation of a Board rule; to wit Board Rule 200.3(7), regarding the ethical and professional responsibilities of clinical investigators. The CFR's cited set out the federal regulatory requirements related to the ethical and professional responsibilities of clinical investigator. Board Rule 200.3(7) states:

"Clinical Investigations. Physicians using conventional medical practices or providing complementary and alternative medicine treatment while engaged in the clinical investigation of new drugs and procedures (a.k.a. medical research, research studies) are obligated to maintain their ethical and professional responsibilities. Physicians shall be expected to conform to the following ethical standards:

- (A) Clinical investigations, medical research, or clinical studies should be part of a systematic program competently designed, under accepted standards of scientific research, to produce data that are scientifically valid and significant;
- (B) A clinical investigator should demonstrate the same concern and caution for the welfare, safety and comfort of the patient involved as is required of a physician who is furnishing medical care to a patient independent of any clinical investigation; and
- (C) A clinical investigator must have patients sign informed consent forms that are compliant with federal regulations, if applicable, and that indicate that the patients understand that they are participating in a clinical trial or investigational research.”

b. Respondent failed to maintain his ethical and professional responsibilities as set out in Board rule 200.3(7), in the following manner during the clinical studies not approved by the FDA:

1) Respondent also failed to adequately protect the patients who were subjects in the clinical investigations of drug combinations that were not approved by the FDA (Patients E).

2) In regard to the above-described failures, specifically, Respondent:

- (a) failed to take adequate measures to minimize risks to patients; (b) failed to ensure that the risks to patients were reasonable in relation to anticipated benefits and the importance of the knowledge that may be expected to result; (c) failed to demonstrate the same concern and caution for the welfare, safety and comfort of the patient in this case as would be required of a physician furnishing medical care to the patient independent of any clinical investigation; and (d) failed to obtain adequate informed consent from each of the patient in this case.

c. Respondent, as a clinical investigator when using any drug that was not approved by the FDA (“off-label treatment”) for the use of that drug had ethical and professional responsibility:

- to ensure that risks to all patients who received that “off-label” treatment were minimized and reasonable in relation to anticipated benefits;
- to report all adverse events that occurred for all patients who received “off-label treatment”;
- to ensure that persons under his direction and supervision providing care to all patients who received “off-label treatment” in a clinical study are

adequately trained or retrained after adverse events, such as overdose of the investigational new drug;

- to consider and report the effect of corticosteroids on Patient E's responses to the investigational new drug;
- to ensure that patients in the clinical studies were provided informed consent in accordance with Respondent's ethical and professional responsibilities expressed by federal regulations.
- to submit informed consent documents for all patients who received "off-label treatment" that complied with Respondent's ethical and professional responsibilities expressed by federal regulations;
- to provide an adequate clinical protocol for all patients who received "off-label treatment";
- to only report therapeutic responses based on how the all patients who received "off-label treatment" tumors responded to the study drug;

f. Respondent and health care providers under Respondent's direction and supervision evaluated, diagnosed and treated Patient E in the state of Texas in the United States of America. Respondent entirely failed to maintain his ethical and professional responsibility in regard to Patient E, because Respondent failed to treat Patient E under a protocol approved by the FDA.

g. Ensuring that risks to patient/subjects are minimized and reasonable in relation to anticipated benefits requires (1) review of the subject's medical records (history and physical examination) and (2) clarifying any outstanding issues with respect to the suitability of treating the patient/subject prior to granting institutional review board approval.

h. Patient E was receiving corticosteroids under Respondent's recommendations and direction that exceeded those dosages needed to maintain physiologic levels.

i. Ensuring that protocols were followed to isolate the impact of corticosteroids on Patient E's tumor response was crucial to the Respondent's responsibility to ensure that complete and accurate data obtained regarding the safety, efficacy and benefits of the study drug to Patient E.

j. Respondent, as principal clinical investigator, provided inaccurate reports of Patient E's tumor response while Patient E was receiving corticosteroids during the time period for which the tumor response was measured.

- k. Respondent and persons under Respondent's direction and supervision failed to assess Patient E's tumor response in accordance with the protocol requirements. This failure jeopardized Patient E's safety and welfare and raises concerns about the validity and integrity of the data collected in the clinical study.
- l. The consent forms that Respondent directed for use in Patient E's clinical study were inadequate and violated Respondent's ethical and professional responsibilities expressed by federal regulations, particularly due to the lack of a statement informing the patient of any additional costs.
- m. Failure to provide Patient E with information regarding any additional costs prior to obtaining her informed consent denied Patient E the opportunity to make an informed decision regarding their participation in the clinical investigation.
- n. Respondent's failed to maintain adequate and accurate medical records for Patient E in that clinical study
- o. The above-described conduct of Respondent, as a clinical investigator of the clinical study of antineoplaston therapy for Patient E, violated Respondent's ethical and professional responsibilities expressed by federal regulations, the Act and Board Rules as follows:

- Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; and 200.3(7) regarding the ethical and professional responsibilities of clinical investigators;
- Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(C); (3) Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct;
- Section 164.053(a)(1) of the Act, commission of an act that violates any state or federal law if the act is connected with the physician's practice of medicine, including 21 CFR 312.50-59, and 21 CFR 312.60-71;
- Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the direction and supervision of the physician; and
- Section 164.053(a)(9) of the Act, delegation of professional medical responsibility or acts to a person if the delegating physician knows or has reason to know that the person is not qualified by training, experience or licensure to perform the responsibility or acts.

IV. AGGRAVATING FACTORS:

Under Texas Administrative Code, Title 22, Part 9, Board Rule 190.15(a), in any disciplinary action, aggravating factors that warrant more severe or restrictive action by the Board may be considered by the Board. This case includes the following aggravating factors:

1. harm to one or more patients;
2. severity of patient harm;
3. one or more violations that involve more than one patient;
4. increased potential harm to the public;
5. prior similar violations, and

V. APPLICABLE STATUTES, RULES AND AGENCY POLICY

The following Statutes, Rules, and Agency Policy are applicable to the procedures for conduct of the hearing this matter:

1. Section 164.007(a) of the Act requires that the Board adopt procedures governing formal disposition of a contested case before the State Office of Administrative Hearings.
2. 22 Tex. Admin. Code, Chapter 187 sets forth the procedures adopted by the Board under the requirement of Section 164.007(a) of the Act.
3. 22 Tex. Admin. Code, Chapter 190 sets forth aggravating factors that warrant more severe or restrictive action by the board.
4. 1 Tex. Admin. Code, Chapter 155 sets forth the rules of procedure adopted by SOAH for contested case proceedings.
5. 1 Tex. Admin. Code, Chapter 155.507, requires the issuance of a Proposal for Decision (PFD) containing Findings of Fact and Conclusions of Law.
6. Section 164.007(a) of the Act, Board Rule 187.37(d)(2) and, Board Rule 190 et. seq., provide the Board with the sole and exclusive authority to determine the charges on the merits, to impose sanctions for violation of the Act or a Board rule, and to issue a Final Order.

VI. NOTICE TO RESPONDENT

IF YOU DO NOT FILE A WRITTEN ANSWER TO THIS COMPLAINT WITH THE STATE OFFICE OF ADMINISTRATIVE HEARINGS WITHING 20 DAYS AFTER THE DATE OF RECEIPT, A DEFAULT ORDER MAY BE ENTERED AGAINST YOU, WHICH MAY INCLUDE THE DENIAL OF LICENSURE OR ANY OR ALL OF THE REQUESTED SANCTIONS, INCLUDING THE REVOCATION OF YOUR LICENSE. A COPY OF ANY ANSWER YOU FILE WITH THE STATE OFFICE OF ADMINISTRATIVE HEARINGS SHALL ALSO BE PROVIDED TO THE HEARINGS COORDINATOR OF THE TEXAS MEDICAL BOARD.

VII. PRAYER

WHEREFORE, PREMISES CONSIDERED, Board Staff requests that an administrative law judge employed by the State Office of Administrative Hearings conduct a contested case hearing on the merits of the Complaint, and issue a Proposal for Decision ("PFD") containing Findings of Fact and Conclusions of Law necessary to support a determination that Respondent violated the Act as set forth in this Complaint.

Respectfully submitted,

CHRISTOPHER PALAZOLA

Litigation Manager

SUSAN RODRIGUEZ

Lead Staff Attorney



Lee Bukstein, J.D., Attorney-in-Charge

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THE STATE OF TEXAS

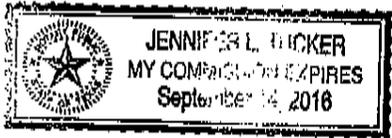
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COUNTY OF TRAVIS

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SUBSCRIBED AND SWORN to before me by the said Lee Bukstein on this 18th
day of December, 2014.



[Signature]
Notary Public, State of Texas

Filed with the Texas Medical Board on this 25 day of NOV, 2014.

[Signature]
Mari Robinson, J.D.
Executive Director
Texas Medical Board

CERTIFICATE OF SERVICE

I certify that on the 19th day of December, 2014, a true and correct copy of the foregoing document has been served as follows:

VIA FAX TO (512) 322-2061

Docket Clerk
State Office of Administrative Hearings
William P. Clements Bldg.
300 W. 15th Street, Suite 504
Austin, Texas 78701-1649

Via CMRRR #7008 2810 0000 1319 6077 and First Class Mail

Zanhua Yi, M.D.
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770 L Street Suite 950
Sacramento, CA 95814

VIA HAND DELIVERY

Sonja Aurelius
Hearings Coordinator
Texas Medical Board
333 Guadalupe, Tower 3, Suite 610
Austin, Texas 78701



Lee Bukstein, J.D.

Appendix A – List of Service Dates:

For Patient E, beginning September 7, 2011, September 8, 2011, September 9, 2011, September 10, 2011, September 11, 2011, September 12, 2011, September 13, 2011, September 14, 2011, September 15, 2011, and September 16, 2011.

Appendix B List of Zanhua Yi Improper Charges

Patient E

a.	<u>September 7, 2011</u>	
	Genetic Examination	\$40.00
	VEGF Vascular Endothelial	\$400.00
	Her-2/Neu	\$350.00
	Prolonged Ser. W/O Contact	\$350.00
	Molecular Diagnostics	\$600.00
	Prolonged Ser. W/O Contact	\$150.00
	Molecular Diagnostics	\$40.00
	Office Consultation	\$1,000.00
	Molecular Mutation Identify	\$200.00
	EGFR Epidermal Growth Factor	\$400.00
b.	<u>September 8, 2011</u>	
	Office/Outpatient Visit	\$100.00
	Measure Blood Oxygen Level	\$35.00
	Dr. Burzynski/Nutritional Medical Therapy	\$300.00
	Sodium Phenylbutyrate 500 mg	\$60.00
c.	<u>September 9, 2011</u>	
	Office/Outpatient Visit	\$100.00
	Measure Blood Oxygen Level	\$35.00
	Sodium Phenylbutyrate 500 mg	\$120.00
d.	<u>September 10, 2011</u>	
	Medical services after hours	\$95.00
	Sodium Phenylbutyrate 500 mg	\$180.00
	Measure Blood Oxygen Level	\$35.00
	Office/Outpatient Visit	\$75.00
e.	<u>September 11, 2011</u>	
	Medical services after hours	\$95.00
	Office/Outpatient Visit	\$75.00
	Sodium Phenylbutyrate 500 mg	\$240.00
	Measure Blood Oxygen Level	\$35.00
f.	<u>September 12, 2011</u>	
	Sodium Phenylbutyrate 500 mg	\$300.00
g.	<u>September 13, 2011</u>	
	Therapeutic or Diagnostic Inj	\$100.00
	Sodium Phenylbutyrate 500 mg	\$360.00
	Xgeva 1 mg	\$3,300.00
h.	<u>September 14, 2011</u>	
	Afinitor	\$473.88
	Sodium Phenylbutyrate 500 mg	\$360.00
	Office/Outpatient Visit	\$100.00
	Measure Blood Oxygen Level	\$35.00
i.	<u>September 15, 2011</u>	
	Lipid Panel	\$50.00
	Measure Blood Oxygen Level	\$35.00

	LD Lactate Dehydrogenase	\$25.00
	Dr. Burzynski/Office/Outpatient Visit	\$125.00
	Monthly Case Management	\$4,500.00
	Sodium Phenylbutyrate 500 mg	\$360.00
	Mg Magnesium	\$50.00
j.	<u>September 16, 2011</u>	
	Dr. Burzynski/Office/Outpatient Visit	\$125.00
	Measure Blood Oxygen Level	\$35.00