HEARING CONDUCTED BY THE
TEXAS STATE OFFICE OF ADMINISTRATIVE HEARINGS
SOAH DOCKET NO. 503-14-1342
LICENSE NO. D-9377

STATE OFFICE OF ADMINISTRATIVE HEARINGS
2014 NOV 14 PM 3:25

IN THE MATTER OF THE	BEFORE THE
COMPLAINT AGAINST:	
STANISLAW R. BURZYNSKI, M.D.	TEXAS MEDICAL BOARD

SECOND AMENDED COMPLAINT

TO THE HONORABLE ADMINISTRATIVE LAW JUDGES ROY SCUDDAY AND CATHERINE C. EGAN:

COMES NOW, the Staff of the Texas Medical Board (Board staff), and files this Second Amended Complaint against Stanislaw R. Burzynski, 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. LEGAL AUTHORITY AND JURISDICTION

A. Respondent is a Texas Physician and holds Texas Medical License No. D-9377, issued by the Board on January 13, 1973.

B. Respondent's license was in full force and effect at all times material and relevant to this Complaint.

C. Respondent received notice of Informal Settlement Conferences (ISC) regarding these matters. The Board complied with all procedural rules, including but not limited to, Board Rules 182 and 187, as applicable.

D. No agreement to settle this matter has been reached by the parties.

E. 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. Board Staff alleges that Respondent created a medical practice model based on marketing his proprietary anti-cancer drugs, antineoplastons[1], to patients without adequate measures for patient safety and therapeutic value.

2. Respondent and other persons under Respondent's direction, supervision and control 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 2[2] clinical trials of his proprietary anti-cancer drugs.

3. Board Staff presents the above-described points through a review of the medical care provided to seven patients who sought medical care by Respondent and Respondent's employees and through review of promotional statements made by Respondent, communications from the United States Food and Drug Administration ("FDA") and medical records related to those communications.

4. Respondent was one of the treating physicians for each of the seven principal patients in this case, Patients[3] A through G, throughout their treatment directed by Respondent and other physicians working at the Burzynski Clinic. Treatment of each patient in this case was initiated at the Burzynski Clinic pursuant to Respondent's control, direction, supervision and control.

5. 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 patients in this case. This medical practice model included Respondent's conduct and conduct of employees under Respondent's direction, supervision and control 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;

---

[1] Respondent's proprietary anti-cancer medication

[2] 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.

[3] Identification of the patients in this case will be provided to Respondent and the Honorable ALJs as confidential and under seal.

- constituted inadequate direction, supervision and control 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.

6. 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 each 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 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 each of the patients in this case exhibit some significant toxicity and adverse side effects when taken by patients: (a) Votrient, (b) Oxaliplatin, (c) Avastin, (d) Xeloda, (e) Decadron, (f) Xgeva, (g) Phenylbutyrate, (h) Tarceva, (i) Afinitor, (j) Sprycel, (k) Nexavar, (l) Zolinza, (m) Antineoplastons, (n) Dexamethasone, (o) Vectibix, (p) Carboplatin, (q) Cisplatin, (q) Pemetrexed, (r) Rapamune, (s) Gencitabine. (t) Sutent and (u) Temodar.

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 patients 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 patients in this case by Respondent and his subordinates subject to his direction, supervision and control 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. Each of the patients in this case 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, supervision and control in treating these patients for cancer. Respondent and other health care providers under Respondent's direction, supervision and control violated the standard of care by treating the patients 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, supervision and control improperly referenced the case reports of other physicians not associated with the Burzynski Clinic as support for combined use of the drugs (other than antineoplastons) recommended and administered to the patients in this case. In those referenced case reports 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, supervision and control 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, supervision and control referenced case reports and literature as the basis of their medical rationale for the use of phenylbutyrate recommended and administered to the patients 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 patients in this case. In this regard, Respondent and other health care providers under Respondent's direction, supervision and control violated the standard of care by having an inadequate medical rationale for the use of phenylbutyrate.

5. Respondent and other health care providers under Respondent's direction, supervision and control referenced case reports and literature as the basis of their medical rationale for the use of antineoplastons recommended and administered to Patient B and Patient G in this case. (None of the other seven principal patients in this contested case received antineoplastons.) These case reports and literature were inadequate to support the use of antineoplastons as recommended and administered to Patient B and Patient G in this case. In this regard, Respondent and other health care providers under Respondent's direction, supervision and control violated the standard of care by having an inadequate medical rationale for the use of antineoplastons.

6. Respondent knowingly misled patients 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, supervision and control treated the patients 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.

7. 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 patients 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, supervision and control. This conduct constituted a violation of Sections 164.053(a)(8) and 164.053(a)(9) of the Act.

8. Respondent and other health care providers under Respondent's direction, supervision and control failed to meet the requirements of the standard of care for adequate medical rationale for the evaluation, diagnosis and treatment of the patients 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 patients in this case are as follows:

a. At the time that each 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 patients in this case, Respondent and other health care providers under Respondent's direction, supervision and control 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, supervision and control initiated treatment of each 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, supervision and control in these regards constituted a violation of the standard of care and/or constituted inadequate direction, supervision and control on or about each of the service dates listed on Appendix A.

c. Respondent and Burzynski Clinic employees acting under Respondent's direction, supervision and control violated the standard of care by failure to perform adequate physical and mental status examinations of each 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, supervision and control in these regards violated the standard of care and/or constituted inadequate direction, supervision and control on each of the service dates listed on Appendix A.

d. Respondent and Burzynski Clinic employees acting under Respondent's direction, supervision and control 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, supervision and control in these regards violated the standard of care and/or constituted inadequate direction, supervision and control 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 patients 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, supervision and control in these regards violated the standard of care and/or constituted inadequate direction, supervision and control on each of the service dates listed on Appendix A.

9. Inadequate medical documentation

Respondent and other health care providers under Respondent's direction, supervision and control 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 patients in this case;

b. an adequate treatment plan at the time that Respondent recommended and/or directed anti-cancer treatment for each of the patients 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 each 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 patients 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.

j. an adequate medical rationale for the use of antineoplastons in anti-cancer therapy (1) for Patient B after the initial office visit in February 2011, during the time period of office visits in February 2011, and early March 2011 through September 2011; and (2) for Patient G after the initial office visit in August 2012 during the time period of office visits in September 2012, and during the two month time period of October and November 2012.

10. Violations related to the conduct described in Section C.1 through Section C.9 occurred on or about each of the service dates listed on Appendix A.

11. <u>Individual Allegations: Violation of Standard of Care: Patient A</u>

a. In September 2010, Patient A received a diagnosis of "sigmoid colon carcinoma metastatic to the liver." Imaging studies revealed erosions indicative of multiple liver lesions, and a colonoscopy revealed a polypoid mass consistent with high-grade dysplasia and suspicious for invasive adenocarcinoma.

b. Patient A declined a local physician's recommendation of a biopsy and the FOLFOX[4] chemotherapy regimen, including the medication Avastin[5].

[4]Anti-cancer medication
[5]Anti-cancer medication

c. Patient A sought treatment at the Burzynski Clinic and met with Respondent on or about October 7, 2010.

d. Patient A had initially informed the health care providers at the Burzynski Clinic before he presented to the Burzynski Clinic that he wanted "antineoplaston" and FOLFOX/Vectibix therapies rather than classic or other chemotherapy treatments. Respondent was aware that at the Burzynski Clinic on or about October 7, 2010, Patient A informed Respondent and persons under Respondent's supervision, direction and control that Patient A wanted "antineoplaston" and FOLFOX/Vectibix therapies rather than classic or other chemotherapy treatments.

e. Respondent and/or employees under his direction, supervision and control immediately recommended, ordered and directed that Patient A start treatment with phenylbutyrate.[6] On or about October 11, 2010, Respondent prescribed phenylbutyrate to Patient A.

f. Respondent and/or employees under his direction, supervision and control later added a partially FOLFOX equivalent regimen (oral Xeloda[7] and intravenous Avastin) to Patient A's treatment.

g. Respondent and/or employees under his direction, supervision and control recommended, ordered and directed that Patient A continue various other substances for treatment (Respondent and/or employees under his direction, supervision and control ordered many of these medications to be taken simultaneously by Patient A), including:

(a) Votrient, (b) Oxaliplatin, (c) Avastin, (d), Xeloda, (e) Decadron, and (f) Xgeva.

h. Patient A showed an improvement in the size of his liver tumors during the initial eight months after treatment with oxaliplatin, Avastin, Xeloda and phenylbutyrate. In late April 2011, imaging of the affected area of the tissue revealed that the affected area was shrinking. In late April 2011, Respondent recommended, ordered and directed that the treatment be changed by eliminating some of the medications being used for Patient A by the Burzynski Clinic. In mid-May 2011, imaging of the affected area of the tissue revealed that the affected area had resumed growing larger. Respondent and/or employees under his direction, supervision and control failed to have and failed to document an adequate medical rationale for a change of therapy when Patient A's symptoms related to cancer appeared to be improving after late January 2011 and prior to late April 2011.

[6] Anti-cancer medication
[7] Anti-cancer medication

i. Patient A's initial results were not sustained after late April 2011, and Patient A's medical condition deteriorated as the tumor growth and spread worsened. Evaluation, diagnosis and treatment of Patient A by the Burzynski Clinic ended at the end of October 2011.

j. Respondent directed the unnecessary measurement of Patient A's oxygen saturation. Patient A had no significant pulmonary disease, and the medical records are without justification for this testing.

k. Respondent directed the unnecessary and costly laboratory testing for measures that are without demonstrable benefit to Patient A, including an echocardiogram, an assay of plasma VEGF, serum EGFR, and her-2.

l. 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.

13. <u>Individual Allegations: Violation of Standard of Care: Patient B</u>

a. In December 2010, Patient B received a diagnosis of a brain tumor. The brain tumor was removed surgically by craniotomy, followed by imaging that showed the complete removal of the tumor. Post-surgery radiation and chemotherapy treatment was recommended, but Patient B sought alternative treatment from Respondent at the Burzynski Clinic.

b. Patient B sought treatment at the Burzynski Clinic and met with Respondent and/or employees under his direction, supervision and control on or about February 1, 2011. Evaluation, diagnosis and treatment of Patient B by the Burzynski Clinic ceased at the end of September 2011.

c. Beginning on or about February 9, 2011, Respondent recommended, ordered and directed that Patient B start treatment with phenylbutyrate and other substances. On or about March 17, 2011, an MRI of Patient B's brain revealed moderate decrease in the size of the brain lesion. On or about March 21, 2011, Respondent first recommended, ordered and

directed that Patient B start treatment with antineoplastons. Respondent also recommended and/or directed that Patient B start treatment with the following substances:

(a) Votrient, (b) Avastin, (c) Phenylbutyrate, (d) Tarceva, (e) Afinitor, (f) Sprycel, (g) Nexavar, (h) Zolinza, (i) Antineoplastons.

d. Patient B appeared to show an improvement during the month after treatment with Votrient, Avastin and phenylbutyrate began under the direction, supervision and control of Respondent. After early March 2011, Respondent recommended, ordered and directed that Patient B stop taking phenylbutyrate and start taking antineoplastons. After early March 2011, Patient B's initial results were not sustained, and Patient B's medical condition and tumor growth and spread worsened. Respondent and/or employees under his direction, supervision and control failed to have an adequate medical rationale and failed to document an adequate medical rationale for a change of therapy when Patient B's symptom appeared to be improving in early March 2011.

e. Respondent and/or employees under his direction, supervision and control made additional representations to United States Customs agents that Patient B was being treated with antineoplastons in an FDA-approved clinical study. These representations were false.

f. Respondent directed the unnecessary measurement of Patient B's oxygen saturation. Patient A had no significant pulmonary disease, and the medical records are without justification for this testing.

g. Respondent directed the unnecessary and costly laboratory testing for measures that are without demonstrable benefit to Patient B, including, at the initial visit, an echocardiogram, an assay of plasma VEGF, serum EGFR, and her-2.

h. 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.

14. <u>Individual Allegations: Violation of Standard of Care Patient C</u>

a. In April 2010, Patient C received a diagnosis of mesothelioma. Imaging studies revealed submandibular metabolically active lymphadenopathy and mediastinal adenopathy.

b. Patient C declined a local physician's recommendation of chemotherapy and a surgical evaluation. His primary physicians recommended the anti-cancer medications cis-platin and pemetrexed.

c. Patient C sought treatment at the Burzynski Clinic and met with Respondent on or about May 11, 2010.

d. Respondent failed to document the patient encounter with Patient C at the Burzynski Clinic on or about May 14, 2010.

e. Respondent recommended, ordered and directed that Patient C start treatment with phenylbutyrate, Avastin, Tarceva and Nexavar beginning in May 2010. In November 2010, imaging indicated that tumor growth was inhibited and spread was minimal.

f. In and after November 2010, Respondent recommended, ordered and directed that Patient C's medications be changed to Votrient, Afinitor, Zolinza, and Vectibix. Patient C experienced disabling toxicities attributable to these drugs. Respondent failed to have and failed to document an adequate medical rationale for a change of therapy when Patient C's symptoms related to cancer appeared to be improving prior between May 2010 and April 2011. Respondent did not recommend or direct a change from those medications until imaging in April 2011 showed disease progression.

g. After reviewing the imaging from April 2011, Respondent only then recommended, ordered and directed that Patient C's medications be changed to carboplatin and pemetrexed.

h. After April 2011, Respondent recommended, ordered and directed that Patient C start various other substances for treatment including Nexavar, Tarceva, Avastin, Phenylbutyrate, and Dexamethasone. Respondent failed to have and failed to document an adequate medical rationale for these changes in therapy.

i. Evaluation, diagnosis and treatment of Patient C by the Burzynski Clinic ended at the end of January 2013.

j. Respondent directed the unnecessary and costly laboratory testing that were without demonstrable benefit to Patient C, including an echocardiogram, an assay of plasma VEGF, serum EGFR, and her-2.

k. Respondent directed the unnecessary repetition of laboratory tests for Patient C.

l. 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.

15. **Individual Allegations: Violation of Standard of Care: Patient D**

a. In May 2010, Patient D received a diagnosis of brain tumor. A surgical removal of the tumor mass was performed on May 10, 2010. In November 2010, Patient D received imaging studies that revealed new lesions of the brain and spine. Patient D received radiation therapy and chemotherapy from an oncologist.

b. After Patient D experienced side effects from the chemotherapy medications, Patient D declined the oncologist's advice to continue chemotherapy at lower doses.

c. Patient D sought treatment at the Burzynski Clinic and met with Respondent on or about June 7, 2011.

d. Respondent recommended, ordered and directed that Patient D start treatment with phenylbutyrate, Temodar, Avastin, Tarceva, Afinitor, and Votrient.

e. Patient D decided to not initiate Respondent's recommendations and to not continue to obtain medical care from Respondent.

f. Respondent billed for services rendered by Dr. Robert Weaver, but Dr. Weaver did not provide any evaluation or care for Patient D.

g. Respondent directed the unnecessary measurement of Patient D's oxygen saturation. Patient D had no significant pulmonary disease, and the medical records are without justification for this testing.

h. Respondent directed the unnecessary and costly laboratory testing for measures that are without demonstrable benefit to Patient D, including, at the initial visit, an echocardiogram, an assay of plasma VEGF, serum EGFR, and her-2.

i. 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.

16. **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 carcinoma[8]. This is a relatively 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, supervision and control 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.

---

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

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, supervision and control 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, supervision and control 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, supervision and control failed to obtain informed consent from Patient E for simultaneous intake of Sutent and Afinitor.

k. Respondent and persons under Respondent's direction, supervision and control 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, supervision and control directed the unnecessary measurement of Patient E's oxygen saturation. Patient E had no significant pulmonary disease, and the medical records are without justification for this testing.

m. Respondent and persons under Respondent's direction, supervision and control 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, supervision and control 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.

17. **Individual Allegations: Violation of Standard of Care: Patient F**

a. In September 2009, Patient F received a diagnosis of pathologically benign hyperplastic fundic polyps. Imaging studies revealed a suspicious poorly marginated pancreatic mass and metastases to the liver. A biopsy performed on September 25, 2009, revealed poorly differentiated metastatic adenocarcinoma. Patient F declined a local physician's recommendation of chemotherapy.

b. Patient F sought treatment at the Respondent's clinic and met with Respondent on or about October 8, 2009.

c. Patient F did not present with a medical condition for which Valtrex[9] is an FDA-approved treatment. Respondent recommended, ordered and directed that Patient F be treated with Valtrex. The treatment of Patient F with Valtrex by Respondent and persons under Respondent's direction, supervision and control violated the standard of care and was non-therapeutic treatment. Respondent and persons under Respondent's direction, supervision and control failed to adequately document the medical rationale for treating Patient F with Valtrex.

d. Respondent recommended, ordered and directed that Patient F start treatment with phenylbutyrate. Although Dr. Weaver included this recommendation on the initial treatment plan for Patient F, Respondent initiated this recommendation and directed this treatment.

e. Respondent recommended, ordered and directed that Patient F start various other substances for treatment, including Xeloda, Avastin, Nexavar, Zolinza, Rapamune, Sutent, Afinitor, Xeloda, Gencitabine; Xgeva and Valtrex. Although Dr. Weaver included these recommendations on the treatment plans for Patient F, Respondent initiated these recommendations and directed this treatment.

f. Patient F soon experienced multiple side effects from the substances that Respondent recommended, ordered and directed for treatment of Patient F. Patient F canceled Respondent's treatments as of mid-November 2009.

g. Respondent directed the unnecessary measurement of Patient F's oxygen saturation. Patient F had no significant pulmonary disease, and the medical records are without justification for this testing.

[9] Anti-viral medication

h. Respondent directed the unnecessary and costly laboratory testing for measures that are without demonstrable benefit to Patient F. Respondent failed to document any medical rationale in Patient F's medical record to medically justify these laboratory studies.

i. 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.

18. <u>Individual Allegations: Violation of Standard of Care: Patient G</u>

a. In July 2012, Patient G received a diagnosis of suprasellar mass brain cancer and malignant astrocytoma of the optic nerve based on imaging studies and biopsy.

b. After Patient G experienced side effects from taking the anti-cancer medication Avastin, she declined a local physician's recommendation to begin radiation therapy and taking the anti-cancer medication Temodar.

c. Patient G sought treatment at the Burzynski Clinic and met with Respondent and persons under Respondent's direction, supervision and control on or about August 31, 2012.

d. In September 2012, Respondent recommended, ordered and directed antineoplastons to be administered and dispensed by the Burzynski Clinic to Patient G.

e. Respondent directed the unnecessary measurement of Patient G's oxygen saturation. Patient G had no significant pulmonary disease, and the medical records are without justification for this testing.

f. In mid-November 2012, Patient G decided to stop Respondent's recommended treatments and the antineoplaston therapy after imaging confirmed that the tumor had increased in size while she was taking the antineoplastons and after she experienced significant side effects from the medication and complications from the manner of administration.

<u>Patient G's Billing/Payment Dispute</u>

g. When initiating treatment, Respondent and Burzynski Clinic employees acting under Respondent's direction, supervision and control encouraged Patient G's parent to open an account whereby the public could read about Patient G's medical and financial crisis and

contribute money to that account. Respondent and Burzynski Clinic employees acting under Respondent's direction, supervision and control were aware that the website that hosted this contribution account would remit any donations directly to the Burzynski Clinic to pay for the costs of Patient G's treatment and that such costs had already been paid in advance by Patient G's parent.

h. When Patient G's parent had a billing dispute with Respondent and the Burzynski Clinic, Respondent and Burzynski Clinic employees acting under Respondent's direction, supervision and control rejected donations and refused to accept those donations as a credit on Patient G's account at the Burzynski Clinic. Respondent and Burzynski Clinic employees acting under Respondent's direction, supervision and control returned all of those donations to the website that had received the donations from donors as an intermediary.

i. Respondent and Burzynski Clinic employees acting under Respondent's direction, supervision and control informed Patient G's parent that since Patient G's parent had already paid in advance and did not have a balance owed at the time of the donations, the Burzynski Clinic would not accept donations on Patient G's account. Respondent and Burzynski Clinic employees acting under Respondent's direction, supervision and control returned a significant amount of donations that were made to help Patient G out with the cost of treatment by Respondent and Burzynski Clinic employees acting under Respondent's direction, supervision and control.

j. Additionally, Respondent and Burzynski Clinic employees acting under Respondent's direction, supervision and control received significant reimbursement payments from an insurance company on Patient G's behalf. Respondent and Burzynski Clinic employees acting under Respondent's direction, supervision and control refused to refund Patient G for those insurance benefits paid to the Burzynski Clinic.

k. 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.

19. Unprofessional Conduct

a. Inadequate Delegation and Inadequate Direction, Supervision and Control.

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 these 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) and Board Rules occurred as follows:

a) The evaluation, diagnosis and treatment of Patient A by the Burzynski Clinic after the initial office visit physical examination on or about October 7, 2010, during the time period of office visits in October 2010; at the time that Patient A returned to the Burzynski clinic beginning in August 2011; and during the nine month period between October 2010 and when Patient A returned to the Burzynski clinic in August 2011. These dates include the following specific dates: October 7, 2010, October 11, 2010, October 12, 2010, October 13, 2010, October 14, 2010, March 9, 2011, June 29, 2011, August 29, 2011, August 30, 2011, September 1, 2011, September 2, 2011, September 6, 2011, September 20, 2011, October 13, 2011, October 21, 2011.

b) The evaluation, diagnosis and treatment of Patient B by the Burzynski Clinic after the initial office visit physical examination in February 2011 during the time period of office visits in February 2011 and early March 2011; and during the nine month period between early March 2011 and when Respondent no longer made recommendations regarding Patient B's evaluation and treatment in September 2011. These dates include the following specific dates: February 7, 2011, February 8, 2011, February 9, 2011, February 10, 2011, February 11, 2011, February 12, 2011, February 14, 2011, February 15, 2011, February 16, 2011, February 17, 2011, February 18, 2011, February 21, 2011, February 22, 2011, February 23, 2011, February 24, 2011, February 25, 2011, February 28, 2011, March 1, 2011, March 2, 2011, March 3, 2011, March 4, 2011, March 21, 2011, May 24, 2011, June 16, 2011, June 17, 2011, July 1, 2011, July 5, 2011, July 6, 2011, July 7, 2011, August 19, 2011, and August 29, 2011.

c) The evaluation, diagnosis and treatment of Patient C by the Burzynski Clinic after the initial office visit physical examination in May 2010 during the time period of office visits in May 2010; and during the 12-month time period between May 2010 and

the end of August 2011. These dates include the following specific dates: May 11, 2010, May 13, 2010, May 14, 2010, May 16, 2010, May 17, 2010, May 18, 2010, May 19, 2010, May 20, 2010, May 21, 2010, May 24, 2010, May 25, 2010, June 1, 2010, June 9, 2010, June 17, 2010, June 23, 2010, June 30, 2010, July 1, 2010, July 2, 2010, July 6, 2010, July 9, 2010, July 13, 2010, July 27, 2010, July 28, 2010, August 1, 2010, August 3, 2010, August 10, 2010, August 11, 2010, August 17, 2010, August 23, 2010, August 25, 2010, September 1, 2010, September 11, 2010, September 22, 2010, September 27, 2010, September 28, 2010, October 1, 2010, October 11, 2010, October 14, 2010, October 21, 2010, November 1, 2010, November 10, 2010, November 11, 2010, November 12, 2010, November 21, 2010, November 23, 2010, December 1, 2010, December 6, 2010, December 7, 2010, December 8, 2010, December 14, 2010, December 21, 2010, January 1, 2011, January 4, 2011, January 13, 2011, January 25, 2011, February 1, 2011, February 10, 2011, February 16, 2011, February 17, 2011, March 1, 2011, March 8, 2011, March 9, 2011, March 11, 2011, March 23, 2011, April 1, 2011, April 5, 2011, April 15, 2011, April 27, 2011, April 28, 2011, May 1, 2011, May 18, 2011, May 20, 2011, June 1, 2011, June 18, 2011, June 21, 2011, June 20, 2011, July 1, 2011, July 16, 2011, July 30, 2011, and August 31, 2011.

d) The evaluation, diagnosis and treatment of Patient D by the Burzynski Clinic at the time of evaluation of Patient D's medical condition on or about June 7, 2011, June 10, 2011, June 13, 2011, and July 1, 2011.

e) 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.

f) The evaluation, diagnosis and treatment of Patient F by the Burzynski Clinic at the time of evaluation of Patient F's medical condition on or about October 8, 2009, October 9, 2009, October 10, 2009, October 11, 2009, October 12, 2009, October 13, 2009, October 14, 2009, October 15, 2009, October 16, 2009, October 17, 2009, October 19, 2009, October 31, 2009, and October 11, 2009.

g) The evaluation, diagnosis and treatment of Patient G by the Burzynski Clinic at the time of evaluation of Patient G's medical condition on or about August 27, 2012, during the time period of office visits in August and September 2012, and during the two month time period of October and November 2012.

b. Aiding and Abetting the Unlicensed Practice of Medicine.

1) Respondent and other health care providers under Respondent's direction, supervision and control 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, supervision and control 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, supervision and control represented to the patients 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:

a) Tolib Rakhmanov and Muhamed Khan, persons were involved in the evaluation, diagnosis and treatment of Patient A, after the initial office visit physical examination on or about October 7, 2010, during the time period of office visits in October 2010; at the time that Patient A returned to the Burzynski clinic beginning in August 2011; and during the nine month period between October 2010 and when Patient A returned to the Burzynski clinic in August 2011.

b) Tolib Rakhmanov, Larisa Tikhomirova and Muhamed Khan were persons who were involved in the evaluation, diagnosis and treatment of Patient B by the Burzynski Clinic after the initial office visit physical examination in February 2011 during the time period of office visits in February 2011 and early March 2011; and during the nine month period between early March 2011 and when Respondent no longer made recommendations regarding Patient B's evaluation and treatment in September 2011.

c) Tolib Rakhmanov, Sheryll Acelar and Muhamed Khan, persons who were involved in the evaluation, diagnosis and treatment of Patient C by the Burzynski Clinic beginning with the initial physical examination in 2010, during the time period of office visits in May 2010; and during the 12-month time period between May 2010 and the end of August 2011.

d) Sheryll Acelar, a person who was involved in the evaluation, diagnosis and anticipated treatment of Patient D by the Burzynski Clinic at the time of evaluation of Patient D's medical condition on or about June 7, 2011, June 10, 2011, June 13, 2011, and July 1, 2011.

e) Tolib Rakhmanov, Lourdes DeLeon and Muhamed Khan, persons 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.

f) Larissa Tikhomirova and Muhamed Khan, persons who were not licensed physicians who were involved in the evaluation, diagnosis and anticipated treatment of Patient F by the Burzynski Clinic at the time of evaluation of Patient F's medical condition on or about October 8, 2009, October 9, 2009, October 10, 2009, October 11, 2009, October 12, 2009, October 13, 2009, October 14, 2009, October 15, 2009, October 16, 2009, October 17, 2009, October 19, 2009, October 31, 2009, and October 11, 2009.

g) Sheryll Acelar and Muhamed Khan, persons who were not licensed physicians who were involved in the evaluation, diagnosis and treatment of Patient G by the Burzynski Clinic at the time of evaluation of Patient G's medical condition on or about August 27, 2012 during the time period of office visits in September 2012, and during the two month time period of October and November 2012.

2) Respondent's actions and failures to inform the patients, patients' family members and other health care professionals who treated the patients 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, supervision and

control. 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, supervision and control participated in knowingly misleading the patients 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, supervision and control prescribed to the patients 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 patients in this case. Respondent and other health care providers under Respondent's direction, supervision and control failed to adequately discuss and document any discussion of the side effects of those combination of drugs.

3) Respondent and other health care providers under Respondent's direction, supervision and control also failed to adequately inform each 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 patients in this case for cancer.

4. The failure of Respondent and other health care providers under Respondent's direction, supervision and control 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), (H) 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 patients 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, supervision and control.

3) The failure by Respondent and other health care providers under Respondent's direction, supervision and control 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 Rule190.8(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, supervision and control 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, supervision and control 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, supervision and control 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 Rules190.8(2)(J), providing medically unnecessary services to a patient.

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

1) Respondent participated in marketing his 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 patients 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) The above-referenced published information was false, misleading and/or deceptive. Respondent and other persons under Respondent's direction, supervision and control participated in misleading patients knowingly by promoting antineoplastons as an attraction in advertising to bring patients to the medical practice when Respondent was aware that he could not legally include most of those patients in FDA-approved Phase 2[10] clinical trials of these proprietary anti-cancer drugs. Such promotion included information and links posted on the Burzynski Clinic and Burzynski Research Institute websites and statements made to the patients in this case and other health care providers. Respondent's appearance in this advertising constituted use of advertising statements under the circumstances. Prior to arrival of the patients in this case at the Burzynski Clinic, Respondent and/or employees under his direction, supervision and control failed to inform the patients about the FDA-approved criteria for treatment with antineoplastons in one of Respondent's sponsored clinical studies and about the likelihood that the patients would not receive antineoplaston therapy.

3). Respondent and/or employees of the Burzynski Clinic under his direction, supervision and control informed each patient that the patient would be considered for treatment with antineoplastons in one of Respondent's sponsored clinical studies. At the time Respondent and/or employees under his direction, supervision and control made this representation, Respondent and/or employees under his direction, supervision and control 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, supervision and control 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.

4) Each patient in this case initially informed Respondent and/or employees of the Burzynski Clinic under his direction, supervision and control 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

[10] 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 involve several thousand patients/subjects.

and the employees of the Burzynski Clinic under his direction, supervision and control 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, supervision and control recommended, ordered and directed treatments for each patient that did not include "antineoplaston" therapy.

a) For Patient A prior to the initial office visit in October 7, 2010, during the time period of office visits in October 2010; at the time that Patient A returned to the Burzynski clinic beginning in August 2011; and during the nine month period between October 2010 and when Patient A returned to the Burzynski clinic in August 2011.

b) For Patient C, prior to the initial office in May 2010, during the time period of office visits in May 2010; and during the 12-month time period between May 2010 and the end of August 2011.

c) For Patient D, prior to and during the time of evaluation of Patient D's medical condition in June and July 2011.

d) 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.

e) For Patient F on or about October 8, 2009, October 9, 2009, October 10, 2009, October 11, 2009, October 12, 2009, October 13, 2009, October 14, 2009, October 15, 2009, October 16, 2009, October 17, 2009, October 19, 2009, October 31, 2009, and October 11, 2009.

5) 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, supervision and control.

6) The above-described conduct of Respondent and other persons under Respondent's direction, supervision and control 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.

20. <u>Violation of Ethical and Professional Responsibilities Regarding Clinical Investigations</u> - <u>Clinical Investigations not approved by the FDA involving Patients A through F in this case and Clinical Investigations approved by the FDA (Patient G)</u>

a. Respondent was the only source of his proprietary drugs, antineoplastons, for any patient. Respondent was the principal clinical investigator conducting clinical studies of investigational new drugs (antineoplastons) 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 approved by the FDA and during the clinical studies not approved by the FDA:

1) Respondent failed to adequately protect the patients who were human subjects in the clinical investigations of antineoplastons that were FDA-approved. (Clinical investigations approved by the FDA involving Patient G and Patient I through Patient BB).

2) Respondent also failed to adequately protect the patients who were subjects in the clinical investigations of antineoplastons that were not FDA-approved (Patient B).

3) Respondent also failed to adequately protect the patients who were human subjects in the clinical investigations of drug combinations that were not approved by the FDA (Patients A through F).

4) 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 each 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 patients in this case.

c. Respondent was principal clinical investigator of the clinical study of antineoplaston therapy for Patient G that commenced on or about September 12, 2012. Respondent was a clinical investigator in the clinical study of antineoplaston therapy for Patient B that commenced on or about February 1, 2011.

d. The clinical studies of Patient G and Patient B were subject to federal law, Respondent's ethical and professional responsibilities expressed by federal regulations, the BRI-IRB investigation plan and the study protocols submitted for the study that included Patient G. FDA regulations 21 CFR 312.3(b), 21 CFR 312.50 and 21 CFR 312.60 applied to the clinical study in which Patient G was enrolled.

e. Respondent, as principal clinical investigator of the clinical study of antineoplaston therapy for any patient, including Patient G and Patient B, had ethical and professional responsibility:

- to ensure that risks to all patients who received antineoplastons were minimized and reasonable in relation to anticipated benefits;
- to report all adverse events that occurred for all patients who received antineoplastons;
- to ensure that persons under his direction, supervision and control providing care to all patients who received antineoplastons 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 G'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 antineoplastons that complied with Respondent's ethical and professional responsibilities expressed by federal regulations;
- to provide an adequate clinical protocol for all patients who received antineoplastons;
- to only report therapeutic responses based on how the all patients who received antineoplastons tumors responded to the study drug;

f. Respondent and health care providers under Respondent's direction, supervision and control evaluated, diagnosed and treated Patient B 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 B, because Respondent failed to treat Patient B 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. After Respondent was notified of adverse events for Patient G, he failed to adequately train or re-train those persons under his direction, supervision and control to prevent additional adverse events.

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

j. Ensuring that protocols were followed to isolate the impact of corticosteroids on Patient G'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 G.

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

l. Respondent and persons under Respondent's direction, supervision and control failed to assess Patient G's tumor response in accordance with the protocol requirements. This failure jeopardized Patient G's safety and welfare and raises concerns about the validity and integrity of the data collected in the clinical study.

m. The consent forms that Respondent directed for use in Patient G'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.

n. Failure to provide Patient G with information regarding any additional costs prior to obtaining her informed consent denied Patient G the opportunity to make an informed decision regarding their participation in the clinical investigation.

o. Respondent only presented a billing agreement to applicant Patient G after she had already consented to participate in the clinical studies.

p. Only physicians who had clinical expertise necessary to make the required information evaluation of potential risks and anticipated benefits could professionally evaluate applicant patients regarding enrollment criteria and protocols related to medical condition, risks of treatments and benefits of treatments.

q. Respondent, as principal clinical investigator, allowed persons who did not have the necessary clinical expertise to make an evaluation of the potential risks and anticipated benefits of antineoplaston therapy for Patient G.

r. Respondent, as principal clinical investigator, allowed persons who did not have the necessary clinical expertise to make an evaluation of the potential risks and anticipated benefits of antineoplaston therapy for Patient G was a violation of the standard of care, Respondent's ethical and professional responsibilities expressed by federal regulations, the Act and Board Rules.

s. Respondent's failure, as principal clinical investigator of the clinical study of antineoplaston therapy for Patient G, as regards allegations H.4 through H.19 above violated the standard of care, Respondent's ethical and professional responsibilities as expressed by federal regulations, the Act and Board Rules.

t. Respondent's failed to maintain adequate and accurate medical records for Patient G in that clinical study

u. The above-described conduct of Respondent, as principal clinical investigator of the clinical study of antineoplaston therapy for Patient G, 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, supervision and control 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.

v. Respondent's failure to meet his ethical and professional responsibilities as a clinical investigator as set out in Section H.1.B above is further demonstrated and supported by the following:

1) FDA inspections are designed to evaluate the conduct of FDA-regulated research to ensure that the data are scientifically valid and accurate, and to help ensure that the rights, safety and welfare of human subjects of those studies have been protected.

2) The FDA issued a "warning" letter dated September 23, 2013, to Respondent, as clinical investigator and sponsor, and BRI-IRB imposing restrictions on Respondent and BRI-IRB from enrolling patients as human subjects in clinical studies of antineoplastons. These restrictions were issued due to the failure of Respondent and BRI-IRB to adequately address allegations based on FDA inspection reports that Respondent and BRI-IRB had violated Respondent's ethical and professional responsibilities as expressed by federal regulations related to those clinical studies. These federal regulations are as follows: 21 CFR 312.7(a). 21 CFR 312.32(c); 21 CFR 312.50; 21 CFR 312.53; 21 CFR 312.55; 21 CFR 312.57, 21 CFR 312.60, 21 CFT 312.62; 21 CFR 312.64; 21 CFR 312.66; 21 CFR 312.110 and 21 CFR 312.120.

3) The FDA found Respondent's written responses dated February 28, 2013 and March 28, 2013, to the inspection report of early 2013 to be unacceptable.

4) The FDA informed Respondent and BRI-IRB that a corrective action plan was required to adequately address allegations based on FDA inspection reports that Respondent and BRI-IRB had violated Respondent's ethical and professional responsibilities as expressed by federal regulations related to Respondent's clinical studies of antineoplastons.

5) The federal regulatory requirements for approval of single patient protocols, special exemptions and expedited review for Phase 1 or Phase 2 clinical studies require ensuring that risks to patient/subjects are minimized and reasonable in relation to anticipated benefits.

6) Respondent and persons under his supervision, direction and control violated the signed agreement of the principal clinical investigator and investigation review board; (a) as relates to the evaluation and treatment of the patients whose records were reviewed as part of the FDA inspectors' 2013 reports issued during the period January 17, 2013, through March 15, 2013, and (b) as relates to the evaluation and treatment of the patients in this case who were treated with investigational new drugs, including

antineoplastons. This conduct constituted violation of Respondent's ethical and professional responsibilities as a clinical investigator as follows:

7) Improper initiation of treatment without proper BRI-IRB approval

a) Respondent used the expedited review process under federal regulations in violation of Respondent's ethical and professional responsibilities as expressed by federal regulations, inappropriately to submit protocols for patients who failed to meet enrollment criteria for antineoplaston therapy clinical studies.

b) The BRI-IRB approved several child patients for antineoplaston clinical studies without documentation that the study did not involve greater than a minimal risk to the patient/subject, that the study presented the prospect of direct benefit to the patient/subject, or any risk greater than minimal risk and that insufficient direct benefit to the patient/subject would still yield generalizable knowledge about the subject's disorder or condition.

c) Respondent failed to provide this information to the BRI-IRB when submitting these patients for approval prior to Respondent's initiation of the treatment of the following children: Patient I, Patient J, and Patient H.

d) Respondent violated his ethical and professional responsibilities as expressed by federal regulations when he placed patients for "provisional approval" before BRI-IRB members who were not physicians with adequate clinical experience and expertise to evaluate and to grant such approval. These illegally-initiated patients included: Patient H, Patient I, Patient J, Patient K, Patient L, Patient M, Patient N, Patient O, and Patient P.

e) The FDA rejected Respondent's proposal of an alternate procedure for BRI-IRB to circumvent the federal requirements for expedited review of applicants for clinical studies and for consideration of safeguards for children.

f) The FDA reiterated that these expedited reviews were limited to patients with serious or immediately life-threatening diseases or conditions who lack therapeutic alternatives.

g) The FDA placed a hold on BRI-IRB from approving any new clinical studies on children and any new clinical studies using the expedited review process.

8) Inadequate, inaccurate reports of therapeutic response

a) The investigational plans for clinical studies of antineoplastons designated as Protocols BT-09, BT-10, and BT-21 required Respondent, as a clinical investigator,

(1) to only report therapeutic responses based on how the patients/subjects' tumors respond to the study drug and (2) to report adverse response events of the patients/subjects.

b) Respondent assigned therapeutic responses incorrectly for 9 of 27 (one out of three) subjects reviewed during inspection, including the following:

Patient V, Protocol BT-10; Patient R, Protocol BT-10; Patient W, Protocol BT-09; Patient X, Protocol BT-21; Patient Y, Protocol BT-09; Patient Q, Protocol BT-10; Patient Z, Protocol BT-10; Patient AA, Protocol BT-10; Patient BB, Protocol BT-10

c) Respondent failed to adequately document adverse events for the following patients:

Patient Q, Protocol B-10; Patient R, Protocol B-10; Patient S, Protocol B-10; Expanded access Patient T, Protocol B-10; Patient U, Protocol AD-02.

9) Failure to adequately train/re-train subordinates after adverse events

a) After Respondent was notified of adverse events for some patients, he failed to adequately train or re-train those persons under his supervision, direction and control. Respondent violated Respondent's ethical and professional responsibilities expressed by federal regulations in this regard for the following patients:

Patient Q, Protocol B-10; Patient R, Protocol B-10; Patient S, Protocol B-10; Expanded access Patient T, Protocol B-10; and Patient U, Protocol AD-02.

10) Failure to properly consider and report the effect of corticosteroids

a) The investigational plans for clinical studies of antineoplastons designated as Protocols BT-09, BT-10, and BT-21 required Respondent, as a clinical investigator, to consider and report the effect of corticosteroids on patient responses to the investigational new drug and to ensure that protocols were followed to isolate the impact of corticosteroids on tumor response in order to obtain scientifically valid information from the clinical studies.

b) Respondent's failure to ensure that protocols were appropriately followed as regards to corticosteroid use constitutes a violation of Respondent's ethical and professional responsibilities as expressed by federal regulations.

11) Inadequate informed consent

a) The consent forms that Respondent approved for use in the clinical studies under Protocol B-10 and B-22 were inadequate and violated Respondent's ethical and professional responsibilities expressed by federal regulations due to the lack of a statement informing the patient of any additional costs.

12) Inadequate, inaccurate patient case histories

a) Respondent and persons under Respondent's direction, supervision and control provided the FDA inspectors with notably different records for Patient CC than were provided to the FDA previously.

b) Respondent's failure to maintain adequate and accurate medical records for patients/subjects in a clinical study violated Respondent's ethical and professional responsibilities expressed by federal regulations, the Act and Board Rules.

13) During the period January 17, 2013, through March 15, 2013, multiple violations of FDA regulations were cited by FDA inspectors in regard to the S.R. Burzynski Study Monitoring Plan after an inspection of documents of the Burzynski Clinic, Burzynski Research Institute, and Burzynski Research Institute-IRB, regarding the S.R. Burzynski Study Monitoring Plan MQA-001 Revision A (Monitoring Plan).

14) Respondent, as the principal clinical investigator of a clinical study, failed to ensure that Protocols BR-09, BT-10 and BT-21 were conducted according to the investigational plans.

15) The FDA inspectors' reports in early 2013 had revealed that Respondent, in violation of FDA regulations, as an expression of Respondent's ethical and professional responsibilities as a clinical investigator, had not conducted the investigation evaluation, diagnosis and treatment of the patients in the clinical studies related to investigational new drugs in accordance with FDA regulations and the signed agreement of the principal clinical investigator and investigation review board due to the failure of Respondent and persons under his supervision, direction, and control:

- to follow investigation protocols;
- to report all adverse events experienced by study subjects during their participation in the studies to the sponsor as required by the study protocols;
- to protect the rights, safety, and welfare of subjects under his care;
- to prepare or maintain adequate case histories with respect to observations and data pertinent to the investigation;
- to report promptly to the IRB all unanticipated problems involving the risk to human subjects or others, such as study subjects/patients being admitted to hospital due to side effects of the investigational new drugs;
- to obtain adequate informed consent from the study subjects/patients, as the consent forms did not include a statement of any additional costs to the subject that might result from participation in the research;
- to maintain adequate records of the investigational drug disposition with respect to quantity and use by subjects;
- to conduct dynamic audits since 2005, as required by his Monitoring Plan; and to maintain adequate records required (FDA Form 1572) for "local physicians" who

participated in the clinical study activities involving evaluation, diagnosis and treatment of the study subjects/patients;

- to have QA (quality assurance) monitor the Monitoring Plan Section 7.2.1 regarding "monitor clinical trials including source document verification, query report general and final resolution, and drug accountability;"
- to monitor under Monitoring Plan Section 13.1 as required;
- to monitor as required by Monitoring Plan Section 16 which stated staff must "verify that information on all adverse events (AE) are "...summarized in the CRF's on monthly basis;"
- to timely report AE's experienced by study subjects, including 18 cases of hypernatremia;
- to ensure that a signed Form FDA 1572 and curriculum vitae (CV) are obtained from each "local physician:" and
- to provide upon request financial information for each of the sub-investigators participating in studies and to allow for complete and accurate certification or disclosure statements.

16) On or about December 3, 2013, the FDA issued a warning letter to Respondent citing the FDA inspectors' reports and that all of the inspectors' investigational findings were adopted by the FDA Office of Compliance considering the current investigation and history of past investigations.

17) Prior to January 17, 2013, Respondent and persons under his direction and control participated in the evaluation, diagnosis and treatment of multiple patients with investigational new drugs, including antineoplastons.

18) Respondent and persons under his supervision, direction and control violated federal laws that expressed Respondent's ethical and professional responsibilities as a clinical investigator (1) as relates to the evaluation and treatment of the patients whose records were reviewed as part of the FDA inspectors' 2013 report issued during the period January 17, 2013, through March 15, 2013, and (2) as relates to the evaluation and treatment of the patients in this case who were treated with investigational new drugs, including antineoplastons.

19) Respondent and persons under his supervision, direction and control violated federal laws, Respondent's ethical and professional responsibilities expressed by federal regulations and the clinical study agreements with the FDA connected with the practice of medicine, including the following: See 21 CFR 312.32(c); 21 CFR 312.50; 21 CFR 312.53; 21 CFR 312.55; 21 CFR 312.57, 21 CFR 312.60, 21 CFT 312.62; 21 CFR 312.64; 21 CFR 312.66; 21 CFR 312.110 and 21 CFR 312.120.

20) As regards the persons under Respondent's supervision, direction and control who evaluated, diagnosed and treated the patients who were the subject of the FDA warning

letter dated December 3, 2013, Respondent failed to adequately supervise these employees and delegated medical tasks to employees who were not appropriately trained and licensed to perform those tasks, including adequately documenting compliance with regulations.

21) Respondent's conduct and his failure to adequately supervise constituted a failure to meet his responsibilities as principal clinical investigator.

22) Respondent's above-described failures to maintain his ethical and professional responsibilities as a clinical investigator constituted the following violations of the Act and Board Rules:

- Section 164.051(a)(3) of the Act, based on Respondent's violation of Board Rules 165.1, adequate maintenance of medical records; 200.7(3), obligation to maintain ethical and professional responsibilities as a clinic investigator;
- Section 164.051(a)(6) of the Act, as further defined by Board Rules 190.8(1)(A); 190.8(1)(C);
- Section 164.052(a)(5) of the Act, unprofessional and dishonorable conduct;
- Section 164.053(a)(8) of the Act, failure to supervise adequately the activities of those acting under the supervision of the physician;
- Section 164.053(a)(9); and
- Section 164.053(a)(17).

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:

harm to one or more patients; severity of patient harm; one or more violations that involve more than one patient; increased potential harm to the public; prior similar violations, and previous disciplinary action by the Board, specifically, on August 20, 1994, the Board entered an Order (1994 Order) that suspended Respondent's medical license, stayed the suspension, and placed Respondent on probation for a period of 10 years. The Board's action was based on Respondent's treating patients with acquired immune deficiency syndrome and cancer with anitineoplastons, in violation of state and federal laws. The 1994 Order terminated on October 19, 2004.

V. APPLICABLE STATUTUES, 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.

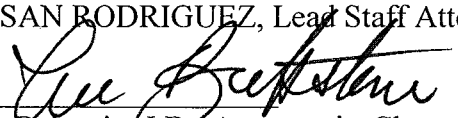
VI. NOTICE TO RESPONDENT

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
State Bar No. 03320300, lee.bukstein@tmb.state.tx.us
Telephone: (512) 305-7079, FAX # (512) 305-7007
333 Guadalupe, Tower 3, Suite 610, Austin, Texas 78701

THE STATE OF TEXAS §

COUNTY OF TRAVIS §

SUBSCRIBED AND SWORN to before me by the said Lee Bukstein on this 14th day of November, 2014.

Notary Public, State of Texas

JENNIFER L. TUCKER
MY COMMISSION EXPIRES
September 14, 2016

Filed with the Texas Medical Board on this 14th day of November, 2014.

Scott M Freshour for
Mari Robinson, J.D.
Executive Director
Texas Medical Board

CERTIFICATE OF SERVICE

I certify that on the 14th day of November, 2014, a true and correct copy of the foregoing document has been served as follows:

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

VIA FIRST CLASS MAIL AND CERTIFIED MAIL/RRR NO. 7008 2810 0000 1319 5940
Stanislaw Rajmund Burzynski, M.D.
9432 Katy Freeway
Houston, TX 77055

VIA FEDEX OVERNIGHT DELIVERY
Richard A. Jaffe, Esq.
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 – Dr. Stanislaw Burzynski - List of Service Dates:

1. For Patient A, after the initial office visit physical examination on or about October 7, 2010; during the time period of office visits in October 2010; at the time that Patient A returned to the Burzynski clinic beginning in August 2011; and during the nine month period between October 2010 and when Patient A returned to the Burzynski clinic in August 2011. These dates include the following specific dates: October 7, 2010, October 11, 2010, October 12, 2010, October 13, 2010, October 14, 2010, March 9, 2011, June 29, 2011, August 29, 2011, August 30, 2011, September 1, 2011, September 2, 2011, September 6, 2011, September 20, 2011, October 13, 2011, October 21, 2011.

2. For Patient B, after the initial office visit physical examination in February 2011 during the time period of office visits in February 2011 and early March 2011; and during the nine month period between early March 2011 and when Respondent no longer made recommendations regarding Patient B's evaluation and treatment in September 2011. These dates include the following specific dates: February 7, 2011, February 8, 2011, February 9, 2011, February 10, 2011, February 11, 2011, February 12, 2011, February 14, 2011, February 15, 2011, February 16, 2011, February 17, 2011, February 18, 2011, February 21, 2011, February 22, 2011, February 23, 2011, February 24, 2011, February 25, 2011, February 28, 2011, March 1, 2011, March 2, 2011, March 3, 2011, March 4, 2011, March 21, 2011, May 24, 2011, June 16, 2011, June 17, 2011, July 1, 2011, July 5, 2011, July 6, 2011, July 7, 2011, August 19, 2011, and August 29, 2011.

3. For Patient C, after the initial office visit physical examination in May 2010 during the time period of office visits in May 2010; and during the 12-month time period between May 2010 and the end of August 2011. These dates include the following specific dates: May 11, 2010, May 13, 2010, May 14, 2010, May 16, 2010, May 17, 2010, May 18, 2010, May 19, 2010, May 20, 2010, May 21, 2010, May 24, 2010, May 25, 2010, June 1, 2010, June 9, 2010, June 17, 2010, June 23, 2010, June 30, 2010, July 1, 2010, July 2, 2010, July 6, 2010, July 9, 2010, July 13, 2010, July 27, 2010, July 28, 2010, August 1, 2010, August 3, 2010, August 10, 2010, August 11, 2010, August 17, 2010, August 23, 2010, August 25, 2010, September 1, 2010, September 11, 2010, September 22, 2010, September 27, 2010, September 28, 2010, October 1, 2010, October 11, 2010, October 14, 2010, October 21, 2010, November 1, 2010, November 10, 2010, November 11, 2010, November 12, 2010, November 21, 2010, November 23, 2010, December 1, 2010, December 6, 2010, December 7, 2010, December 8, 2010, December 14, 2010, December 21, 2010, January 1, 2011, January 4, 2011, January 13, 2011, January 25, 2011, February 1, 2011, February 10, 2011, February 16, 2011, February 17, 2011, March 1, 2011, March 8, 2011, March 9, 2011, March 11, 2011, March 23, 2011, April 1, 2011, April 5, 2011, April 15, 2011, April 27, 2011, April 28, 2011, May 1, 2011, May 18, 2011, May 20, 2011, June 1, 2011, June 18, 2011, June 21, 2011, June 20, 2011, July 1, 2011, July 16, 2011, July 30, 2011, and August 31, 2011.

4. For Patient D, at the time of evaluation of Patient D's medical condition on or about June 7, 2011, June 10, 2011, June 13, 2011, and July 1, 2011.

5. 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.

6. For Patient F, beginning on or about October 8, 2009, October 9, 2009, October 10, 2009, October 11, 2009, October 12, 2009, October 13, 2009, October 14, 2009, October 15, 2009, October 16, 2009, October 17, 2009, October 19, 2009, October 31, 2009, and October 11, 2009.

7. For Patient G, beginning on or about August 31, 2012, September 10, 2012, September 12, 2012, September 13, 2012, September 2012, September 15, 2012, September 16, 2012, September 17, 2012, September 17, 2012, September 18, 2012, September 19, 2012, September 20, 2012, September 22, 2012, September 23, 2012, September 24, 2012, September 29, 2012, September 30, 2012, October 3, 2012, October 4, 2012, October 5, 2012, October 6, 2012, October 8, 2012, October 9, 2012, October 10, 2012, October 11, 2012, October 13, 2012, October 15, 2012, October 16, 2012, October 17, 2012, October 18, 2012, October 23, 2012, October 24, 2012, October 25, 2012, October 26, 2012, October 27, 2012, November 1, 2012, November 5, 2012, November 6, 2012, November 7, 2012, November 8, 2012, November 9, 2012, November 13, 2012, and November 14, 2012.

Appendix B List of Burzynski Improper Charges

Patient A		**Patient B (continued)**	
a.October 11, 2010		Addtl 30 min – Prolonged Ph	$100.00
Sodium Phenylbutyrate 500 mg	$60.00	Prolonged Phys Svc in ofc	$250.00
Sodium Phenylbutyrate 500 mg	$60.00	Molecular Diagnostics	40.00
b. October 12, 2010		Prolonged Serv. w/o contact	$150.00
Sodium Phenylbutyrate 500 mg	$120.00	Prolonged Serv. w/o contact	$350.00
Sodium Phenylbutyrate 500 mg	$120.00	Office Consultation	$1,000.00
c. October 13, 2010		b. February 8, 2011	
Sodium Phenylbutyrate 500 mg	$180.00	Sodium Phenylbutyrate 500 mg	$60.00
Sodium Phenylbutyrate 500 mg	$240.00	Dexamethasone Oral 0.25 mg	$34.80
Sodium Phenylbutyrate 500 mg	$240.00	Office/Outpatient Visit	$125.00
d. October 14, 2010		Measure Blood Oxygen Level	$35.00
Sodium Phenylbutyrate 500 mg	$180.00	c. February 9, 2011	
Sodium Phenylbutyrate 500 mg	$240.00	Measure Blood Oxygen Level	$35.00
Sodium Phenylbutyrate 500 mg	$240.00	Sodium Phenylbutyrate 500 mg	$120.00
e. March 18, 2011		Office/Outpatient Visit	$125.00
Monthly Case Management	$2,250.00	d. February 10, 2011	
f. March 24, 2011		Sodium Phenylbutyrate 500 mg	$240.00
Monthly Case Management	$2,250.00	Measure Blood Oxygen Level	$35.00
g. April 21, 2011		Office/Outpatient Visit	$125.00
Monthly Case Management	$2,250.00	e. February 11, 2011	
h. June 10, 2011		MG Magnesium	$50.00
Monthly Case Management	$2,250.00	Sodium Phenylbutyrate 500 mg	$2,160.00
i. August 3, 2011		Office/Outpatient Visit	$125.00
Monthly Case Management	$2,250.00	LD Lactate Dehydrogenase	$25.00
j. August 29, 2011		Lipid Panel	$50.00
Dr. Marquis office visit	$200.00	Measure Blood Oxygen Level	$35.00
Lipid Panel	$50.00	f. February 14, 2011	
Measure Blood Oxygen Level	$35.00	Office/Outpatient Visit	$125.00
CA 19-9 Cancer Antigen	$55.00	Measure Blood Oxygen Level	$35.00
k. August 30, 2011		g. February 15, 2011	
Measure Blood Oxygen Level	$35.00	Votrient 200 mg	$6,030.00
		Measure Blood Oxygen Level	$35.00
Patient B		Office/Outpatient Visit	$125.00
a. February 7, 2011		h. February 16, 2011	
VEG F Vascular Endothelial	$400.00	Votrient 200 mg	$6,030.00
Molecule Mutation Identify	$200.00	Measure Blood Oxygen Level	$35.00
Genetic Examination	$40.00	Office/Outpatient Visit	$125.00
EGFR Epidermal Growth Factor	$400.00	i. February 17, 2011	
Her-2/Neu	$350.00	Intravenous push, Single Or	$125.00
Add Supplies – A10	$1,080.00	Lipid Panel	$50.00

Patient B (continued)		**Patient B (continued)**	
Lithium batteries, AA	$10.22	Office/Outpatient Visit	$125.00
UA Urinalysis, Non-Auto W/	$25.00	p. February 28, 2011	
Therapeutic IV Push, Each A	$100.00	Measure Blood Oxygen Level	$35.00
Chemo, IV infusion 1 hr	$198.00	Office/Outpatient Visit	$125.00
MG Magnesium	$50.00	UA Urinalysis, Non-Auto W/	$25.00
LD Lactate Dehydrogenase	$25.00	MG Magnesium	$50.00
Office/Outpatient Visit	$125.00	Lipid Panel	$50.00
Avastin 10 mg	$1,237.34	LD Lactate Dehydrogenase	$25.00
Measure Blood Oxygen Level	$35.00	Office/Outpatient Visit	$125.00
j. February 18, 2011		Group Health Education	$60.00
Sodium Phenylbutyrate 500 mg	$1,440.00	q. March 1, 2011	
Measure Blood Oxygen Level	$35.00	Sodium Phenylbutyrate 500 mg	$1,440.00
Dr. Weaver/Office/Outpatient Visit	$125.00	Office/Outpatient Visit	$125.00
k. February 21, 2011		Measure Blood Oxygen Level	$35.00
Measure Blood Oxygen Level	$35.00	Office/Outpatient Visit	$125.00
Mg Magnesium	$50.00	r. March 2, 2011	
Intravenous push, Single Or	$125.00	Group Health Education	$60.00
Dr. Weaver/Office/Outpatient Visit	$125.00	Nutritional Medical Therapy	$400.00
Lipid Panel	$50.00	Office/Outpatient Visit	$125.00
UA Urinalysis, Non-Auto W/	$25.00	Measure Blood Oxygen Level	$35.00
Chemo, IV infusion 1 hr	$198.00	s. March 3, 2011	
Avastin 10 mg	$4,949.34	Votrient	$9,045.00
LD Lactate Dehydrogenase	$25.00	Measure Blood Oxygen Level	$35.00
Lithium batteries, AA	$10.22	Office/Outpatient Visit	$125.00
Parental infuse pump portable	$100.00	t. March 4, 2011	
l. February 22, 2011		Dressing change Hypafix	$120.00
Office/Outpatient Visit	$125.00	Lipid Panel	$50.00
Sodium Phenylbutyrate 500 mg	$1,080.00	MG Magnesium	$50.00
Measure Blood Oxygen Level	$35.00	Office/Outpatient Visit	$200.00
m. February 23, 2011		Intravenous push, Singe Or	$125.00
Measure Blood Oxygen Level	$35.00	External Ambulatory infuse pus	$4,500.00
Office/Outpatient Visit	$125.00	Continue Flo Solution Kit	$268.00
n. February 24, 2011		Measure Blood Oxygen Level	$35.00
Add supplies – BLF	$600.00	UA Urinalysis, Non-Auto W/	$25.00
Office/Outpatient Visit	$125.00	LD Lactate Dehydrogenase	$25.00
Measure Blood Oxygen Level	$35.00	Parenteral infuse. Pump portable	$100.00
Mg Magnesium	$50.00	Avastin 10 mg	$7,424.02
LD Lactate Dehydrogenase	$25.00	Chemo, IV infusion, 1 hr.	$198.00
Lipid Panel	$50.00	u. March 7, 2011	
o. February 25, 2011		Monthly Case Management	$3,511.00
Sodium Phenylbutyrate 500 mg	$1,440.00	v. March 21, 2011	
Measure Blood Oxygen Level	$35.00	Monthly Case Management	$3,511.00

Patient B (continued)		**Patient C (continued)**	
x. April 11, 2011		Chemo, IV Infusion 1 hr.	$198.00
Monthly Case Management	$3,511.00	Sodium Phenylbutyrate 500 mg	$240.00
y. April 28, 2011		g. May 18, 2010	
Monthly Case Management	$3,511.00	Sodium Phenylbutyrate 500 mg	$300.00
z. May 19, 2011		Dr. Marquis/Office/Outpatient Visit	$125.00
Monthly Case Management	$3,511.00	Dr. Marquis/Prolonged Serv in office	$350.00
aa. May 24, 2011		h. May 19, 2010	
Monthly Case Management	$3,511.00	Dr. Marquis/Office/Outpatient Visit	$125.00
bb. June 22, 2011		Sodium Phenylbutyrate 500 mg	$720.00
Monthly Case Management	$3,511.00	Nexavar 200 mg	$7,239.60
cc. July 21, 2011		i. May 20, 2010	
Monthly Case Management	$3,511.00	Dr. Marquis/ Office/ Outpatient Visit	$200.00
dd. September 6, 2011		Add supplies – A10	$360.00
Monthly Case Management	$3,511.00	Add supplies – A10	$72.00
Patient C		Add supplies – BL	$135.00
a. May 11, 2010		j. May 21, 2010	
Dr. Marquis/ Office Consultation	$1,000.00	Sodium Phenylbutyrate 500 mg	$1,440.00
Dr. Marquis/Prolonged Serv, W/O contact	$350.00	k. May 24, 2010	
VEG F Vascular Endothelial	$400.00	Sodium Phenylbutyrate 500 mg	$360.00
EGFR Epidermal Growth Factor	$400.00	l. May 25, 2010	
Her-2/Neu	$350.00	Sodium Phenylbutyrate 500 mg	$2,520.00
Molecular Mutation Identify	$200.00	m. June 1, 2010	
Genetic Examination	$40.00	Sodium Phenylbutyrate 500 mg	$2,880.00
b. May 13, 2010		n. June 9, 2010	
Tarceva 150 mg	$8,319.00	Sodium Phenylbutyrate 500 mg	$2,880.00
c. May 14, 2010		o. June 17, 2010	
Dr. Marquis/Office/Outpatient Visit	$125.00	Sodium Phenylbutyrate 500 mg	$2,520.00
Sodium Phenylbutyrate 500 mg	$60.00	p. June 23, 2010	
d. May 15, 2010		Phone E/M by Phys 5-10 min	$125.00
Sodium Phenylbutyrate 500 mg	$120.00	q. June 30, 2010	
e. May 16, 2010		Add supplies – A10	$360.00
Sodium Phenylbutyrate 500 mg	$180.00	r. July 1, 2010	
Measure Blood Oxygen Level	$35.00	Unidentified fee	$3,500.00
f. May 17, 2010		Sodium Phenylbutyrate 500 mg	$2,880.00
Dr. Marquis/Office/Outpatient Visit	$125.00	s. July 2, 2010	
Lithium batteries, AA	$10.22	Phone E/M by Phys 5-10 min	$125.00
Avastin 10 mg	$2,367.00		

Patient C (continued)		**Patient C (continued)**	
t. July 6, 2010		nn. October 11, 2010	
Unidentified fee	$4,500.00	Sodium Phenylbutyrate 500 mg	$3,600.00
u. July 9, 2010		oo. October 14, 2010	
Sodium Phenylbutyrate 500 mg	$3,600.00	Add Supplies – A10	$360.00
v. July 13, 2010		Unidentified fee	$4,500.00
Phone E/M by Phys 5-10 min	$125.00	pp. October 21, 2010	
w. July 19, 2010		Sodium Phenylbutyrate 500 mg	$3,960.00
Sodium Phenylbutyrate 500 mg	$2,520.00	qq. November 1, 2010	
x. July 27, 2010		Sodium Phenylbutyrate 500 mg	$3,600.00
Phone E/M by Phys 5-10 min	$125.00	rr. November 10, 2010	
y. July 28, 2010		Add Supplies – A10	$324.00
VEG F Vascular Endothelial	$400.00	Add Supplies – A10	$180.00
EGFR Epidermal Growth Factor	$400.00	xx. November 11, 2010	
Add supplies – A10	$360.00	Sodium Phenylbutyrate 500 mg	$3,600.00
z. August 1, 2010		VEG F Vascular Endothelial	$400.00
Sodium Phenylbutyrate 500 mg	$3,600.00	Her-2/Neu	$350.00
aa. August 3, 2010		yy. November 12, 2010	
Unidentified fee	$4,500.00	EGFR Epidermal Growth Factor	$400.00
bb. August 10, 2010		zz. November 21, 2010	
Phone E/M by Phys 5-10 min	$125.00	Sodium Phenylbutyrate 500 mg	$1,440.00
cc. August 11, 2010		aaa. November 23, 2010	
Sodium Phenylbutyrate 500 mg	$2,520.00	Phone E/M by Phys 5-10 min	$125.00
dd. August 10, 2010		Unidentified fee	$4,500.00
Phone E/M by Phys 5-10 min	$125.00	bbb. November 21, 2010	
ee. August 17, 2010		Sodium Phenylbutyrate 500 mg	$1,080.00
Sodium Phenylbutyrate 500 mg	$2,520.00	ccc. December 1, 2010	
ff. August 23, 2010		Sodium Phenylbutyrate 500 mg	$1,080.00
Phone E/M by Phys 5-10 min	$125.00	ddd. December 6, 2010	
gg. August 25, 2010		Phone E/M by Phys 5-10 min	$125.00
Sodium Phenylbutyrate 500 mg	$2,520.00	eee. December 7, 2010	
hh. September 1, 2010		Sodium Phenylbutyrate 500 mg	$2,160.00
Add Supplies – A10	$360.00	fff. December 8, 2010	
Sodium Phenylbutyrate 500 mg	$3,600.00	Add Supplies – A10	$324.00
Unidentified fee	$4,500.00	Add Supplies – A10	$180.00
ii. September 11, 2010		ggg. December 14, 2010	
Sodium Phenylbutyrate 500 mg	$3,600.00	Phone E/M by Phys 5-10 min	$125.00
jj. September 22, 2010		hhh. December 21, 2010	
Sodium Phenylbutyrate 500 mg	$2,520.00	Phone E/M by Phys 5-10 min	$125.00
kk. September 27, 2010		iii. January 1, 2011	
Phone E/M by Phys 5-10 min	$125.00	Sodium Phenylbutyrate 500 mg	$2,160.00
ll. September 28, 2010		jjj. January 4, 2011	
Sodium Phenylbutyrate 500 mg	$1,080.00	Add Supplies – A10	$240.00
mm. October 1, 2010		Add Supplies – A10	$120.00
Sodium Phenylbutyrate 500 mg	$3,600.00	Unidentified fee	$4,500.00

Patient C (continued)		**Patient C (continued)**	
kkk. January 13, 2011		cccc. April 28, 2011	
Sodium Phenylbutyrate 500 mg	$2,160.00	VEG F Vascular Endothelial	$400.00
lll. January 25, 2011		Her-2/Neu	$350.00
Phone E/M by Phys 5-10 min	$125.00	dddd. May 1, 2011	
mmm. February 1, 2011		Sodium Phenylbutyrate 500 mg	$2,700.00
Sodium Phenylbutyrate 500 mg	$2,700.00	eeee. May 18, 2011	
nnn. February 16, 2011		Add Supplies – A10	$240.00
Sodium Phenylbutyrate 500 mg	$2,340.00	Add Supplies – A10	$120.00
ooo. February 10, 2011		Unidentified fee	$4,500.00
Add Supplies – A10	$240.00	ffff. May 20, 2011	
Add Supplies – A10	$120.00	Sodium Phenylbutyrate 500 mg	$2,160.00
Unidentified fee	$4,500.00	gggg. June 1, 2011	
ppp. February 16, 2011		Sodium Phenylbutyrate 500 mg	$3,600.00
EGFR Epidermal Growth Factor	$400.00	hhhh. June 18, 2011	
qqq. February 17, 2011		Unidentified fee	$15,665.61
VEG F Vascular Endothelial	$400.00	iiii. June 21, 2011	
Her-2/Neu	$350.00	Sodium Phenylbutyrate 500 mg	$1,800.00
rrr. March 1, 2011		jjjj. June 20, 2011	
Sodium Phenylbutyrate 500 mg	$1,440.00	Unidentified fee	$4,500.00
sss. March 8, 2011		kkkk. July 1, 2011	
Phone E/M by Phys 5-10 min	$125.00	Sodium Phenylbutyrate 500 mg	$2,700.00
ttt. March 9, 2011		llll. July 16, 2011	
Add Supplies – A10	$240.00	Sodium Phenylbutyrate 500 mg	$2,160.00
Add Supplies – A10	$120.00	mmmm. July 30, 2011	
uuu. March 9, 2011		Sodium Phenylbutyrate 500 mg	$24.00
Sodium Phenylbutyrate 500 mg	$2,520.00	nnnn. August 31, 2011	
vvv. March 11, 2011		Monthly Case Management	$4,500.00
Online E/M by Phys	$200.00	**Patient D**	
xxx. March 23, 2011		a. June 7, 2011	
Sodium Phenylbutyrate 500 mg	$1,620.00	EGFR Epidermal Growth Factor	$400.00
yyy. April 1, 2011		Dr. Marquis/Office Consultation	$1,000.00
Sodium Phenylbutyrate 500 mg	$2,520.00	Molecule Isolate Nucleic	$142.00
zzz. April 5, 2011		Dr. Marquis/Prolonged Ser. W/O Contact	$150.00
Unidentified fee	$4,500.00	Her-2/Neu	$350.00
aaaa. April 15, 2011		Molecular diagnostics	$40.00
Sodium Phenylbutyrate 500 mg	$2,880.00	VEG F Vascular Endothelial	$400.00
bbbb. April 27, 2011		Molecular Mutation Identify	$200.00
EGFR Epidermal Growth Factor	$400.00	Dr. Marquis/Prolonged Ser. W/O Contact	$350.00
		Genetic Examination	$40.00
		Electrolyte Panel	$25.00

Patient D (continued)		**Patient E (continued)**	
b. June 8, 2011 through July 1, 2011		f. September 12, 2011	
All services which were not itemized in billing sent to Patient D		Sodium Phenylbutyrate 500 mg	$300.00
(Billing for these dates is missing from Patient D's billing records)		g. September 13, 2011	
Patient E		Therapeutic or Diagnostic Inj	$100.00
a. September 7, 2011		Sodium Phenylbutyrate 500 mg	$360.00
Genetic Examination	$40.00	Xgeva 1 mg	$3,300.00
VEG F Vascular Endothelial	$400.00	h. September 14, 2011	
Her-2/Neu	$350.00	Afinitor	$473.88
Prolonged Ser. W/O Contact	$350.00	Sodium Phenylbutyrate 500 mg	$360.00
Molecular Diagnostics	$600.00	Office/Outpatient Visit	$100.00
Prolonged Ser. W/O Contact	$150.00	Measure Blood Oxygen Level	$35.00
Molecular Diagnostics	$40.00	i. September 15, 2011	
Office Consultation	$1,000.00	Lipid Panel	$50.00
Molecular Mutation Identify	$200.00	Measure Blood Oxygen Level	$35.00
EGFR Epidermal Growth Factor	$400.00	LD Lactate Dehydrogenase	$25.00
b. September 8, 2011		Dr. Burzynski/Office/Outpatient Visit	$125.00
Office/Outpatient Visit	$100.00	Monthly Case Management	$4,500.00
Measure Blood Oxygen Level	$35.00	Sodium Phenylbutyrate 500 mg	$360.00
Dr. Burzynski/Nutritional Medical Therapy	$300.00	Mg Magnesium	$50.00
Sodium Phenylbutyrate 500 mg	$60.00	j. September 16, 2011	
c. September 9, 2011		Dr. Burzynski/Office/Outpatient Visit	$125.00
Office/Outpatient Visit	$100.00	Measure Blood Oxygen Level	$35.00
Measure Blood Oxygen Level	$35.00	**Patient F**	
Sodium Phenylbutyrate 500 mg	$120.00	a. October 8, 2009	
d. September 10, 2011		Dr. Burzynski/ Prolonged Eval. & Mgmt before or	$350.00
Medical services after hours	$95.00	Dr. Burzynski/ Prolonged Eval. & Mgmt each add	$150.00
Sodium Phenylbutyrate 500 mg	$180.00	Dr. Burzynski/ Consultation - Comprehensive	$1,000.00
Measure Blood Oxygen Level	$35.00	Her-2/Neu	$350.00
Office/Outpatient Visit	$75.00	EGFR Epidermal Growth Factor	$400.00
e. September 11, 2011		VEG F Vascular Endothelial	$400.00
Medical services after hours	$95.00	Genetic Examination	$40.00
Office/Outpatient Visit	$75.00	b. October 9, 2009	
Sodium Phenylbutyrate 500 mg	$240.00	Dr. Burzynski/Follow up Visit	$125.00
Measure Blood Oxygen Level	$35.00	Measure Blood Oxygen Level	$35.00

Patient F (continued)		**Patient F (continued)**	
Sodium Phenylbutyrate 500 mg	$60.00	k. October 19, 2009	
Add supply – supplement	$360.00	Sodium Phenylbutyrate 500 mg	$360.00
c. October 10, 2009		Dr. Burzynski/Follow up Visit	$200.00
Sodium Phenylbutyrate 500 mg	$120.00	Measure Blood Oxygen Level	$35.00
Rapamune 1 mg	$738.90	Sodium Phenylbutyrate 500 mg	$360.00
d. October 11, 2009		l. October 31, 2009	
Sodium Phenylbutyrate 500 mg	$180.00	Sodium Phenylbutyrate 500 mg	$4,320.00
Zolinza 100 mg	$5,646.00	m. November 11, 2009	
e. October 12, 2009		Sodium Phenylbutyrate 500 mg	$3,960.00
Dr. Burzynski/Follow up Visit	$125.00	**Patient G**	
Measure Blood Oxygen Level	$35.00	a. August 31, 2012	
Sodium Phenylbutyrate 500 mg	$240.00	Dr. Valladares/ Office Consultation	$1,250.00
f. October 13, 2009		b. September 10, 2012	
Dr. Burzynski/Follow up Visit	$125.00	Pregnancy Test	$30.00
Measure Blood Oxygen Level	$35.00	Pt Prothrombin Time with INR (duplicated)	$25.00
Sodium Phenylbutyrate 500 mg	$300.00	c. September 12, 2012	
Xeloda 500 mg	$2,385.60	LD Lactate Dehydrogenase	$25.00
g. October 14, 2009		Group Health Education	$60.00
Dr. Burzynski/Follow up Visit	$125.00	Dexamethasone	$12.50
Measure Blood Oxygen Level	$35.00	Measure Blood Oxygen Level	$35.00
Sodium Phenylbutyrate 500 mg	$180.00	External ambulatory infuse pump	$5,500.00
Nexavar 200 mg	$8,419.80	Chemo, IV Push, Single Drug	$170.00
h. October 15, 2009		Lipid Panel	$50.00
Lithium Batteries AA	$14.22	Special Reports and Treatment	$400.00
MG Magnesium	$50.00	Patient Education Materials	$35.00
Lipid Profile	$50.00	MG Magnesium	$50.00
Lactate Deydrogenase	$25.00	Chemo Prolong Infuse w/p	$395.00
Avastin 10 mg	$2,915.00	d. September 13, 2012	
Dexamethasone	$4.80	Group Health Education	$60.00
Chemotherapy administration IV	$198.00	Measure Blood Oxygen Level	$35.00
Dr. Burzynski/Follow up Visit	$125.00	Dr. Marquis/Office/Outpatient Visit	$125.00
Measure Blood Oxygen Level	$35.00	Chemo Prolong Infuse w/p	$395.00
Sodium Phenylbutyrate 500 mg	$360.00	e. September 14, 2012	
i. October 16, 2009		Chemo Prolong Infuse w/p	$395.00
Dr. Burzynski/Follow up Visit	$125.00	Lipid Panel	$50.00
Measure Blood Oxygen Level	$35.00	LD Lactate Dehydrogenase	$25.00
Sodium Phenylbutyrate 500 mg	$360.00	Group Health Education	$60.00
Office outpatient visit, New	$410.00	MG Magnesium	$50.00
j. October 18, 2009		Measure Blood Oxygen Level	$35.00
Sodium Phenylbutyrate 500 mg	$720.00	Electrolyte Panel	$25.00

Patient G (continued)		**Patient G (continued)**	
Dr. Valladares/ Office/ Outpatient Visit	$125.00	Chemo Prolong Infuse w/p	$395.00
f. September 15, 2012		k. September 20, 2012	
Chemo Prolong Infuse w/p	$395.00	Electrolyte Panel	$25.00
Medical Services after Hrs.	$95.00	Dr. Marquis/ Office/ Outpatient Visit	$125.00
Electrolyte Panel	$25.00	Chemo Prolong Infuse w/p	$395.00
Measure Blood Oxygen Level	$35.00	Group Health Education	$60.00
Dr. Burzynski/Office/Outpatient Visit	$75.00	Measure Blood Oxygen Level	$35.00
g. September 16, 2012		l. September 21, 2012	
Chemo Prolong Infuse w/p	$395.00	Group Health Education	$60.00
Measure Blood Oxygen Level	$35.00	Chemo Prolong Infuse w/p	$395.00
Medical Services after Hrs.	$95.00	UA Urinalysis, Non-Auto W/	$25.00
Dr. Burzynski/Office/Outpatient Visit	$75.00	Measure Blood Oxygen Level	$35.00
h. September 17, 2012		Dr. Marquis/ Office/ Outpatient Visit	$125.00
UA Urinalysis, Non-Auto W/	$25.00	m. September 22, 2012	
Measure Blood Oxygen Level	$35.00	Chemo Prolong Infuse w/p	$395.00
Group Health Education	$60.00	Measure Blood Oxygen Level	$35.00
MG Magnesium	$50.00	Dr. Burzynski/Office/Outpatient Visit	$75.00
LD Lactate Dehydrogenase	$25.00	n. September 23, 2012	
Chemo Prolong Infuse w/p	$395.00	Dr. Burzynski/ Office/ Outpatient Visit	$75.00
Lipid Panel	$50.00	Measure Blood Oxygen Level	$35.00
Dr. Marquis/Office/Outpatient Visit	$125.00	Medical Services after Hours	$95.00
i. September 18, 2012		o. September 24, 2012	
Dr. Burzynski/ Office/ Outpatient Visit	$125.00	Lipid Panel	$50.00
Group Health Education	$60.00	Measure Blood Oxygen Level	$35.00
Measure Blood Oxygen Level	$35.00	UA Urinalysis, Non-Auto W/	$25.00
Nutritional Medical Therapy	$300.00	Electrolyte Panel	$25.00
Chemo Prolong Infuse w/p	$395.00	LD Lactate Dehydrogenase	$25.00
j. September 19, 2012		Dr. Marquis/ Office/ Outpatient Visit	$125.00
LD Lactate Dehydrogenase	$25.00	p. September 25, 2012	
Lipid Panel	$50.00	Continue Flo Solution Kit	$268.00
Group Health Education	$60.00	Y adapter 2-way	$285.48
MG Magnesium	$50.00	Body Guard Dual Tubing/ Car	$3,360.00
Dr. Marquis/ Office/ Outpatient Visit	$125.00	Sodium Chloride Flush 5 cc	$358.80

Patient G (continued)		**Patient G (continued)**	
Dr. Burzynski/ Office/Outpatient Visit	$200.00	ll. October 24, 2012	
q. September 29, 2012		Chemo Prolong Infuse w/p	$395.00
Chemo Prolong Infuse w/p	$395.00	mm. October 25, 2012	
r. September 30, 2012		Chemo Prolong Infuse w/p	$395.00
Chemo Prolong Infuse w/p	$395.00	nn. October 26, 2012	
s. October 1, 2012		Chemo Prolong Infuse w/p	$395.00
Chemo Prolong Infuse w/p	$395.00	oo. October 27, 2012	
t. October 2, 2012		Chemo Prolong Infuse w/p	$395.00
Chemo Prolong Infuse w/p	$395.00	pp. November 1, 2012	
u. October 3, 2012		Chemo Prolong Infuse w/p	$395.00
Chemo Prolong Infuse w/p	$395.00	Y adapter 2-way	$219.60
v. October 4, 2012		Body Guard Dual Tubing/Car	$1,890.00
Chemo Prolong Infuse w/p	$395.00	Sodium Chloride Flush 5 cc	$358.80
x. October 5, 2012		Dr. Burzynski/Office/Outpatient Visit	$200.00
Chemo Prolong Infuse w/p	$395.00	qq. November 5, 2012	
y. October 6, 2012		Chemo Prolong Infuse w/p	$395.00
Chemo Prolong Infuse w/p	$395.00	rr. November 6, 2012	
z. October 8, 2012		Chemo Prolong Infuse w/p	$395.00
Chemo Prolong Infuse w/p	$395.00	ss. November 7, 2012	
aa. October 9, 2012		Chemo Prolong Infuse w/p	$395.00
Chemo Prolong Infuse w/p	$395.00	tt. November 8, 2012	
bb. October 10, 2012		Chemo Prolong Infuse w/p	$395.00
Chemo Prolong Infuse w/p	$395.00	uu. November 9, 2012	
cc. October 11, 2012		Chemo Prolong Infuse w/p	
Chemo Prolong Infuse w/p	$395.00	vv. November 12, 2012	
dd. October 12, 2012		Chemo Prolong Infuse w/p	
Chemo Prolong Infuse w/p	$395.00	xx. November 13, 2012	
ee. October 13, 2012		Chemo Prolong Infuse w/p	
Chemo Prolong Infuse w/p	$395.00	yy. November 14, 2012	
ff. October 15, 2012		Chemo Prolong Infuse w/p	
Chemo Prolong Infuse w/p	$395.00		
gg. October 16, 2012			
Chemo Prolong Infuse w/p	$395.00		
hh. October 17, 2012			
Chemo Prolong Infuse w/p	$395.00		
ii. October 18, 2012			
Chemo Prolong Infuse w/p	$395.00		
jj. October 19, 2012			
Chemo Prolong Infuse w/p	$395.00		
kk. October 23, 2012			
Chemo Prolong Infuse w/p	$395.00		