TEXAS STATE OFFICE OF ADMINISTRATIVE HEARINGS

SOAH DOCKET NO.503-14-1342 MD

TEXAS MEDICAL LICENSE NO. D-9377

IN THE MATTER OF THE	
COMPLAINT AGAINST	
STANISLAW R. BURZYNSKI, M.D.	

RESPONDENT'S ANSWER TO THE SECOND AMENDED COMPLAINT

TO THE HONORABLE ROY SCUDDAY AND CATHERINE EGAN:

COMES NOW RESPONDENT, STANISLAW R. BURZYNSKI, M.D., Ph.D. by and through his attorney and submits this ANSWER TO THE SECOND AMENDED COMPLAINT (the "Complaint") and would respectfully show the judges as follows:

GENERAL DENIAL

Pursuant to T.R.Civ. Pro. 92, Respondent generally denies each and every allegation in the Second Amended Complaint and demands strict proof thereof. In addition, Respondent states as follows:

I. INTRODUCTION

Denies that the relief requested is necessary to protect the health and public interest of the citizens of the state of Texas as alleged in the Introduction of the Complaint. In fact, the evidence will demonstrate that Respondent and his cancer clinic provide treatment which is extending and saving the lives of numerous terminally ill cancer patients. Protecting the health and public interest of the citizens of Texas

requires that this Complaint be dismissed in its entirety, *inter alia,* under 1090.15 (b)(5).

II. LEGAL AUTHORITY AND JURISDICTION

Admits the allegations in paragraphs 1, 2, 3, and 4 of this section.

BACKGROUND

Because of the factual complexity of this case, Respondent is providing the following background information:

1. The Burzynski Clinic (the "Clinic") treats advanced and terminal cancer patients. However, the Clinic does not diagnose cancer. Every patient presents to the Clinic with an established cancer diagnosis, including the stage of the disease. The diagnosis and staging are performed by the patients' prior treating oncologists and would include whatever histology, pathology, or tissue testing, radiology and laboratory tests that would be necessary to make a cancer diagnosis and provide a treatment recommendation to the patient. However, prior to coming to the Clinic after an initial cancer diagnosis, sometimes a patient may refuse another biopsy to confirm a recurrence which is what at least one of the patients did in this case, or an additional biopsy that is not medically necessary or that might endanger the patient's condition.
2. Every single patient who presented to the Clinic had no curative treatment option and/or had previously refused the treatment recommendations of their prior treating physicians, or at the very least, decided to explore treatment options beyond those offered by their prior treating oncologists.

3. The treatments offered by the Clinic are unique in that the exact treatment regimens can only be obtained or at least initiated at the Clinic. Since it is the TMB's intent to delicense Respondent and stop the Clinic from offering these treatments, this case has an impact beyond Respondent and his employees, namely the many, mostly terminal cancer patients still undergoing treatment, as well as future patients who desire a broader array of treatment options than what is currently available at even the most cutting-edge cancer treatment centers.

The Entities

Dr. Burzynski and the Burzynski Clinic

4. Respondent, Stanislaw Burzynski is the sole owner of the Clinic. In the "private practice" part, the Clinic treats patients with combinations of FDA approved drugs, many of which may be prescribed off label. The Clinic calls this approach personalized targeted therapy.
5. Since 1994, the Clinic has treated patients in FDA approved clinical trials with a family of drugs which Respondent has invented and has termed "antineoplastons." Dr. Burzynski is the principal investigator of essentially all of the clinical trials which provides his investigational drugs to patients at the Clinic.
6. A principal investigators ("PI") is an administrative position, and a PI is not required to personally administer the study drug to subjects of the investigation. The FDA imposes administrative and oversight responsibilities on a principal

investigator. These legal and regulatory obligations are set out in the code of federal regulations, 21 C.F.R. 312.60-69.

7. During the time patients A-G were treated (2010-2012), the Clinic had two to three board certified medical oncologists and two other licensed physicians delivering care to the patients.

8. In addition to nursing staff, the Clinic employs "Research Associates" who are unlicensed foreign medical school graduates and who work under strict supervision of licensed physicians. Their job is to act as a communications intermediary between the patients and the Clinic's licensed treating physicians who deliver the medical care to the patients. The Research Associates also coordinate testing and care coordination with other providers, and make sure that the Clinic's treating physicians are aware of all important changes in the patients' condition and new information like lab tests and imaging. They are also involved in maintaining the paperwork (i.e. medical records) in the clinical practice and the FDA required administrative paperwork for patients treated under clinical trial protocols.

9. None of the Research Associates make any diagnosis or treatment decisions for any patient, and hence, none of them are engaged in the practice of medicine as defined by Occ. Code 152.002(13). As a result, neither Respondent nor any other Clinic licensed physician assisted in the unlicensed practice of medicine, as alleged in the Complaint.

10. All patients, including the patients in this Complaint were informed at their initial visit to the Clinic that the Research Associates are foreign medical school graduates but are not licensed to practice and that they would not be making

medical decisions, but would communicate with them and their licensed treating physicians.

11. After Board Staff has completed discovery on the Research Associates' issues raised in the Complaint, Respondent intends to move for summary disposition dismissing all of these allegations and claims.

The Burzynski Research Institute, Inc.

12. The Burzynski Research Institute, Inc. ("INC.") is a publicly traded corporation engaged in research and development of antineoplastons. Respondent owns over 80% of the issued shares, and is the company's president and primary decision-maker.

13. INC. is the sponsor of the FDA approved clinical trials concerning antineoplastons. A drug sponsor has specific obligations in overseeing clinical investigations conducted by clinical investigators. A sponsor's administrative and oversight responsibilities are separate and distinct from the administrative responsibilities of a PI, and are separate and distinct from the clinical responsibilities of the investigator(s) who administer the study drug and treat the study patients. A drug sponsor's legal and regulatory obligations are set forth in federal regulations and specifically 21 CFR 312.50-59.

14. To the extent that the Complaint seeks to sanction Respondent based on INC.'s alleged failure to meet its regulatory obligations as sponsor of clinical trials, the effort is misconceived since a corporate sponsor is not and cannot engage in the practice of medicine. The sponsor's obligations as set forth in 21 CFR 312.50-59 are unrelated to the diagnosis and treatment of a disease or medical condition

which is the definition of the practice of medicine in Occ. Code 152.002.(13). It makes no statutory or logical sense for a professional board to attempt to seek to sanction a licensee for conduct which a business corporation/pharmaceutical research company allegedly failed to do, regardless of the close association between the company and the licensee.

15. After Board Staff has had an adequate opportunity for discovery, Respondent intends to move for summary disposition removing all claims, allegations and alleged violations relating to alleged federal regulatory violations by INC. as sponsor of the clinical trials.

BRI Institutional Review Board

16. In order to obtain FDA approval to do clinical trials, a sponsor has to retain the services of an oversight entity usually called an "institution review board" which oversees patient related issues.
17. The BRI Institutional Review Board ("BRI-IRB") is the IRB which oversaw the clinical trials in which BRI was the sponsor and Respondent was the principal investigator.
18. Neither the Respondent, nor any of Clinic's employees are currently, or were ever members of the BRI-IRB. However, as is common with IRBs overseeing clinical investigations, investigators or designated representatives often appeared at BRI-IRB meetings to answer questions or address issues raised by the BRI-IRB members.
19. Respondent does not control the operation of the BRI-IRB. Investigators or designated representatives are always excused from and absent during formal

decision-making of the IRB.

20. IRB's have regulatory imposed obligations and guidelines as to their oversight responsibilities concerning clinical trials which are delineated in the code of federal regulations and specifically 21 CFR part 56.

21. To the extent that the Complaint alleges that part 56 violations by the BRI-IRB can be the basis of sanctioning Respondent in this case, the effort is legally and factually flawed. After Board Staff has an adequate opportunity to conduct discovery on this issue, Respondent intends to move for summary disposition dismissing all claims and allegations concerning BRI-IRB's alleged violations of 21 CFR Part 56.

The Pharmacy

22. Like many oncology practices, the Clinic has an in-house pharmacy which dispenses medications to the Clinic's patients.

23. The pharmacy is just two rooms inside the Clinic's offices. Charges for the prescription drugs are included in the Clinic's billing statements to the patients and these charges are not separately identified as having been incurred by the in-house pharmacy. All patients are explained orally and in writing (as part of the treatment billing agreement) that they will be billed for medications dispensed to them at the Clinic.

24. Respondent is the sole owner of the in-house pharmacy.

25. There is no legal or ethical requirement for an oncology practice to separately or specifically notify a cancer patient that the practice's in-house pharmacy is owned by the oncology practice, and where the drugs dispensed are billed

through the practice's master billing statement.

26. After discovery has been completed on this issue, Respondent will move for summary disposition dismissing all claims relating to his alleged violations arising from his alleged failure to inform patients A-G that he owned the in-house pharmacy which supplied the prescription drugs to them.

The Treatments Offered at the Clinic

Personalized Multi-Agent Targeted Therapy

27. Currently, almost all Clinic patients receive what it calls personalized multi-agent targeted therapy or what is elsewhere called Personalized or Precision Medicine. In this new treatment paradigm, instead of planning treatment based on statistically validated data of treatment results from patient aggregates within clinical studies, individual cancers are analyzed using genomic and chemosensitivity tools and the resultant information is used to plan a personalized treatment regimen. Treatment successes resulting from this kind of personalized approach are routinely published by the proponents either as individual case reports or as a case series for a disease. This is exactly what Respondent and other Clinic physician have done and continue to do. [1]

28. All of the drugs prescribed by the Clinic under this treatment approach are FDA approved, but most of them are given off-label, i.e. that is to say for an

[1] The following are a few examples of case reports of successfully treated patients by the Clinic using targeted agents and case studies.
http://www.scirp.org/journal/PaperInformation.aspx?PaperID=6654
http://www.scirp.org/journal/PaperInformation.aspx?PaperID=7795
http://www.scirp.org/journal/PaperInformation.aspx?PaperID=19954
https://www.novapublishers.com/catalog/product_info.php?products_id=4240
https://www.researchgate.net/publication/266968450_The_coming_pandemic_of_liver_cancer_In_search_of_genomic_solutions
http://www.scirp.org/journal/PaperInformation.aspx?PaperID=51577
http://www.scirp.org/journal/PaperInformation.aspx?PaperID=50936
http://www.scirp.org/journal/PaperInformation.aspx?PaperID=50986

indication not specifically approved by the FDA.[2] As will be discussed in more detail *infra*, over the past dozen years, the Clinic has developed what it believes to be a safe and effective method of using combinations of drugs which target different genes or receptors on cancer cells, which combinations have a greater spectrum of activity than mono drug therapy (one drug at a time)[3]

29. Although the Clinic sometimes employs traditional cytotoxic chemotherapy drugs, most of the drugs it prescribes are small molecules or monoclonal antibodies which inhibit various parts of the cancer cell expansion process and work differently from interfering with a cancer cell's mitosis or cell division process (which is how cytotoxic cancer "chemotherapy" works).

30. In addition, virtually all patients receive sodium phenylbutyrate (PB), which is FDA approved for a non-cancer use, but has FDA recognized indicated uses for several types of cancer including gliomas. PB is not commonly used in cancer clinics outside of clinical trials.

31. PB is a histone deacetylase inhibitor, which is a class of agents that inhibits the growth of tumor cells by inducing cell cycle arrest, differentiation and/or apoptosis (i.e., normal programmed cell death). It is very closely related to Respondent's investigational drugs, antineoplastons, and works by the same mechanism of action. In fact, PB is basically a pro-drug of antineoplastons and is converted in the liver to two active ingredients of two of Respondent's antineoplastons. Therefore, practically and chemically speaking, all the targeted therapy patients

[2] Off label prescribing is very common in medical oncology and most other medical specialties. It has been estimated that as many as 70 percent of cancer patients receive at least one cancer medicine off label

[3] Respondent expects to offer into evidence all of the published case reports and best series reports reporting the successful results of the personalized targeted therapy approach and laboratory research reports.

in this case received the chemical equivalent of one of Respondent's antineoplaston formulation, at least after the patients' liver converted PB into the active ingredients of antineoplaston formulations.

32. A key aspect to this multi-agent targeted therapy approach ignored in the Complaint is that each drug in the combination is given at a substantially smaller dose than would have been provided under single agent or monotherapy, thereby reducing the possibility or severity of the drug's side effects at full dosage levels. Over the course of a dozen years, the Clinic has found and reported in the medical literature on these lesser, safe, and effective dosage levels.

33. As a further safeguard, drugs are added sequentially, and the patient's condition is closely monitored for unusual or intolerable side effects as the drugs are added.

34. The personalized aspect relates to the fact that a patient's blood, and if possible, the tumor is tested to identify possible cancer agents that might be useful to treat the patient. Tumor testing is rapidly becoming the standard of care at the most advanced cancer centers for late stage and difficult to treat patients, which is the Clinic's entire patient population.

35. Respondent has published the results of his personalized multi-agent targeted therapy approach for a variety of cancer types including most of the types of cancer of the patients who are the subject of this case. Respondent intends to demonstrate at the hearing that the approach he developed to treat these difficult cases is safe and at least as effective, if not more effective, as the treatments used at other cancer centers.

36. In addition, Respondent will also prove that other cancer facilities are starting to give combinations of small molecule treatment without phase III studies on the combinations, based on tumor and or blood genomic testing.[4]

37. Five of the patients discussed in detail in the Complaint (A, B C, E, and F) received multi-agent targeted therapy. Patients A, B and C had a documented objective response to the treatment in the form of tumor shrinkage. The documented objective response to treatment disproves all of the non-therapeutic related claims as well as many of the other claims relating to the alleged improper administration of the therapy to these patients.

38. Patient E only received treatment for eight days. Because of the short duration of treatment, the patient's response to the treatment was not evaluable.

39. Patient F was on the Clinic's combination therapy for several months and is still alive many years after his terminal prognosis.

40. Patient D only had a consultation where targeted therapy was discussed as a possible option, but the patient never started treatment.

Antineoplaston Therapy

41. One patient (Patient G) was treated with the investigational drug under what is called a "single patient protocol." This patient was not treated as part of the

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[4] Two examples of this approach at other oncology sites include:
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3921040/
Connolly, K., et al. "Anticancer activity of combination targeted therapy using cetuximab plus vemurafenib for refractory BRAFV600E-mutant metastatic colorectal carcinoma." *Current Oncology* 21.1 (2014): e151.
"In this report, we describe the clinical course of a heavily pretreated patient who elected to receive off-label dual-targeted braf- and egfr-inhibitory therapy with good tolerance and apparent clinical benefit."
http://www.tandfonline.com/doi/full/10.4161/cbt.25191#.VHxsUWotDX4
Al-Marrawi, Mhd Yaser, et al. "Off-label use of cetuximab plus sorafenib and panitumumab plus regorafenib to personalize therapy for a patient with V600E BRAF-mutant metastatic colon cancer." *Cancer biology & therapy* 14.8 (2013): 703-710.
Off-label use of cetuximab plus sorafenib and panitumumab plus regorafenib to personalize therapy for a patient with V600E BRAF-mutant metastatic colon cancer

clinical trials and Respondent was not the physician responsible for treating this patient, per the FDA approval[5]

42. The local physician of one foreign resident patient, (Patient B) received antineoplastons as part of multi-agent targeted therapy.

III. RESPONSE TO GENERAL ALLEGATIONS (pages 2-8):

1. There was no marketing of proprietary anticancer drug – Antineoplastons. Antineoplastons were provided free-of-charge for patients who participated in clinical trials or treated under Special Exception or Single Patient Protocols. The patients were charged for equipment, supplies, and services which are permitted by the FDA. Proper measures for patient's safety and evaluation of therapeutic values were observed.
2. The patients were not misled regarding availability of Antineoplastons. Only scientific information was shared with the public, which was based on the results of laboratory and clinical research presented at medical conferences and published in professional journals. Since 1994, when antineoplastons A10 and AS2-1 injections were available in clinical trials until January 2013, there were no restrictions for adult patients regarding access to antineoplastons under clinical trials and Special Exceptions and only adult patients are included in the Complaint. By then, the materials describing antineoplastons were removed from the internet. Until then, the FDA was freely permitting access of adult patients on the treatment with antineoplastons pending

[5] In this Complaint, there are also another twenty-one patients involved (patients H-BB). The claims involving these patients relate to FDA warning letters issued regarding alleged infractions of FDA regulations set forth in non-final agency action. The warning letters were the alleged to be violations of federal law which the Board sought to prosecute Respondent under 164.052 (5) and 164.053(1) (any violation of federal or state law…" As a result of the prior dismissal order dismissing these claims, in the Second Amended Complaint, a new legal theory is alleged, but it's still based on the same FDA issues and warning letters.

notification of the FDA about the admission under Special Exceptions within one week, or filing Single Patient Protocol (Patient G).

3. Only a single patient among seven cases reviewed by the TMB participated in Single Patient Protocol treatment with antineoplastons. The remaining patients were treated with FDA approved drugs. One patient received antineoplastons under the care of his German physician outside of the United States, which is consistent with the FDA law.
4. Respondent was not the treating physician of any patient listed by the TMB in the Complaint.
5. Respondent and the doctors of Burzynski Clinic did not violate the standard-of-care and complied with every bullet point listed under number 5 of the Complaint.
6. All of the patients listed in the Complaint came to the Clinic with a diagnosis of cancer. The evaluation of the patient's condition and the treatment was performed by one or more board-certified oncologists employed by the Clinic.

B. Applicable Standard of Care

1. The treatment with any drug is associated with adverse events, and the drugs used in cancer treatment have an even higher percentage of such events. This is typical for any oncology practice.
2. As evidenced by published data, the frequency and incidence of severe adverse events at Burzynski Clinic is lower than in a standard oncology practice.
3. The standard-of-care was fully explained by a board-certified oncologist to every patient coming to Burzynski Clinic, and in every case, either the patient specifically refused the standard-of-care or the standard-of-care was not available for the disease and stage.

   a., b., c. Respondent asserts that all allegations listed under these points are not true and

every aspect of ethics of standard oncology practice has been observed.

4. The treatment administered to the patients was therapeutic and resulted in elimination of symptoms, objective decrease in the tumor size, and extension of patient's lives (Patients C, E and F). It is well understood that only a limited percentage of advanced cancer patients in an oncology practice will respond to treatment. The patients are fully informed that no assurance of improvement during the treatment is given.

C. Violations of the Standard of Care

1.a. The patients were presented with standard of care options (if such existed) both prior to presenting at the Clinic and by the Clinic's medical oncologist. In the case of each patient in this Complaint, the patient either refused standard of care treatment, both before and while at the Clinic, or there was no standard of care treatment which would have been curative for the patient's disease.

b. There was no negligence in performing medical services, which in the case of the Respondent's actions primarily consisted of welcoming the patients to the clinic, introduction of the treatment team (including the Research Associates), an explanation of the general principles of the Clinic's treatment approach, and participating in the conferences with the patients and/or their local oncologists. Respondent also developed the protocols concerning the treatment dosages and timing for administration of PB.

d. The patients were safeguarded against potential complications.

e. The treatment was therapeutic in nature and based on sound scientific principles as indicated by laboratory and clinical research.

f. Medical personnel were adequately supervised by the treating physicians.

2. None of the patients suffered toxicity any worse than what is generally expected from cancer treatment. This is proven by clinical research conducted by the Clinic and published data in peer-reviewed medical journals.

3. There was no improper citation of the research of the other physicians. It was always stated exactly what kind of treatment was used and what results were obtained by using therapeutic agents.

4. Respondent's laboratory and contracted universities conducted extensive research on the mechanism of action of phenylbutyrate including the study of the metabolites of phenylbutyrate on the entire cancerous genome and used data provided by other researchers who studied phenylbutyrate. There is adequate rationale based on laboratory data and clinical experience to prove that the use of phenylbutyrate in combination with other anticancer agents provides approximately twice as good overall survival of advanced cases of colon cancer, pancreatic cancer, malignant mesothelioma, and brain tumors.

5. The results of phase II clinical trials indicated that antineoplastons are safe and effective (based on phase II trial data) in the treatment of glioblastoma multiforme and astrocytoma, Grade 3 (anaplastic astrocytoma) diagnosed in patients B and G.

6. The information provided to patients was based on clinical research which was presented to the medical community and published in professional journals.

7. Neither the Respondent nor the employees of Clinic who are licensed physicians violated

the standard-of-care.

8.a. At the time that each patient in this case presented to Clinic, the patients had been diagnosed with incurable malignant disease.

b. Every patient had an adequate histological examination performed before starting treatment.

c. Every patient had adequate physical and mental status examinations, as needed by qualified physicians.

d. Every patient treatment has satisfied the treatment requirements for a treatment plan.

e. As proven by published data of the Clinic, the benefits of the treatment, which is markedly improved overall survival, outweigh the risk of the treatment provided to the patients.

9.a. Every patient had adequate medical rationale for treatment.

b. Every patient had an adequate treatment plan.

c. Every patient had an adequate physical examination.

d. Every patient had an adequate mental status examination or no such exam was needed. In addition every patient in the Complaint except patient E came with a close family member who participated in decision making process by the patient.

e. Every patient had an adequate medical rationale for simultaneous use of the agents as explained in the published data.

f. Every patient had an adequate rationale for the use of phenylbutyrate as evidenced by published data.

g. Every patient had an adequate histological examination.

h. Every patient had adequate pathological documentation of malignancy.

i. Every patient had adequate analysis of genomic screening and discussion, except Patient G who was treated under an FDA approved Single Patient Protocol and did not need genomic analysis.

j. There was an adequate medical rationale for the use of antineoplastons in the two patients who received it (B and G) as evidenced by published data.

Patient A (paragraph 11, pages 8-10)

1. The medical records set forth the basic medical facts of the case and Respondent respectfully refers the Court to these records. Denies all allegations in the Complaint contradicted or not supported by the records or otherwise not supported by the facts. Respondent expects to prove at the hearing as follows:
2. The patient was given a terminal cancer diagnosis of "sigmoid colon carcinoma metastatic to the liver," in September 2010 prior to coming to the Clinic. The diagnosis was supported by pathological analysis of the primary tumor performed on tissue taken from the colonoscopy. The patient refused his prior oncologist's recommendations for a further

biopsy and refused his treatment recommendations. The patient presented to the Clinic for more options.

3. At the Clinic, Patient A was given another standard of care oncology consultation by a medical oncologist employed by the Clinic. The patient refused the Clinic's oncologist's recommendation for a further biopsy and again refused standard of care treatment recommendations. However, he agreed to undergo a multi-agent targeted therapy approach also proposed by the Clinic, which approach included PB, a close analogue of Respondent's antineoplastons.
4. It would have been improper, inhumane and unethical for the Clinic to withhold treatment because of the patient's refusal to undergo another invasive surgical procedure (which is what a biopsy is) just to confirm that a terminal colon cancer patient with obvious progressive disease had cancer cells in his new tumors. Both the prior oncologist and the Clinic's oncologist did what they may have been required to do, at least for defensive medicine purposes, which was make the recommendation for a biopsy, and make a treatment recommendation based on the available evidence.
5. Most of the agents the patients received at the Clinic are FDA approved for colon cancer. The other agents used were supported by the medical literature for the patient's cancer and/or were supported by genomic studies performed on the patient's tumor.
6. The patient received verbal and written informed consent about the drugs recommended to him. There is no doubt that he was fully informed about

the treatment approach and that it was not conventional, and he specifically so stated in writing after he learned that a complaint was filed based on the Clinic's treatment of him.

7. In addition to his treatment team at the Clinic, the patient was followed by and received his treatment in part from the patient's two local board certified oncologists. These oncologists participated in the treatment regime and were supportive of the care and treatment recommended by the Clinic.
8. As admitted in paragraph h, (page 9) of the Complaint, the treatment initially benefited the patient in that there was a significant decrease in the size of the tumors. (see scans 1/28/11 and 4/28/11).
9. After June, 2011, a modified treatment regime was agreed to by the Clinic physicians and the local oncologist, and the local oncologist then took over the treatment of the patient based on the agreed-to modified treatment plan. The rationale for the change in the treatment is adequately documented in the medical records (see oncology consult note dated 6/29/11 (Clinic oncologist) and local oncologist note of 4/25/11 and 5/9/11).
10. The patient was satisfied with the treatment and care he received at the Clinic stating in November, 2011 that:

I have been a patient at the Burzynski clinic since October 2010. I am taking a regime of gene-targeted and other FDA approved drugs given to me off label. I understand that the treatment is unconventional and not supported by the conventional medical community, but I believe that the treatment has helped me, has stabilized my disease, and may be of further benefit in the future. I want to continue taking the treatment and I am satisfied with the care given to me by the Burzynski Clinic. I do not agree with or approve a complaint being filed against Dr. Burzynski, on my behalf nor do I support the complaint and I would like the investigation terminated as it concerns me.

11. The medical records for this patient contain a statement by the local oncologist that the patient did well on the treatment and that the patient's wife was satisfied with the progress. (8/18/11 email).
12. Respondent intends to prove at the hearing that his targeted approach has achieved long terms responses in patients with the same fatal disease and diagnosis as patient A.
13. Respondent wrote no prescriptions for this patient, nor was he the patient's treating physician. The treating physicians were a board certified medical oncologist and a family practitioner. The patient was also followed by various support staff including nurses and Research Associates (as discussed in the Background section and will not be repeated herein).
14. All of the testing and charges were medically necessary and appropriate given the patient's medical condition and prior history. Specifically,

O2 was needed to be tested and constantly monitored because he had pulmonary disease. A CT of September16, 2010 showed emphysematous changes within both lungs, and CT of Jan.28th showed 5 pulmonary nodules, scattered pneumatoceles and scarring. He was taking strong pain medications(opiates) which decreases breathing efficiency. An echocardiogram was required because

he had left ventricular diastolic dysfunction and targeted medications could make it worse. Blood tests for oncogenes were necessary to help design proper treatment plan which included Avastin which was justified by increased level of VEGF.

Patient B (Paragraph 13, pages 10-11)

The medical records of the patient set out the course of treatment both prior to and while under the care of the Clinic. In addition, Respondent will show**:**

1. This patient was diagnosed with glioblastoma multiform, ("GBM") one of the most virulent forms of brain tumors which carries a fatal diagnosis regardless of treatment. Standard of care treatment is surgical resection of the tumor followed by chemotherapy and radiation. Chemotherapy and radiation are given even if the surgery completely removes the tumor. However, regardless of treatment, the tumor invariably grows back and eventually kills the patient.
2. After an initial biopsy confirming the disease, Patient B's tumor was removed in December 2010. The patient refused radiation and chemotherapy.
3. The foreign patient presented to the Clinic in early February 2011 accompanied by his personal physician. A baseline scan on February 8, 2011 revealed that his tumor had regrown, as his previous physicians told him it would.

4. The notion that this patient needed another hole drilled in his head for a biopsy prior to further medical treatment, less than two months after he was recommended chemotherapy and radiation is absurd and shows an utter disregard of the patient's quality of life by the Board's medical experts.
5. The medical records document that Clinic physicians, his personal physician and the patient discussed various treatment options. The patient elected to initially receive the combination therapy of drugs which has shown efficacy in treating brain tumors at the Clinic.
6. It was also discussed and documented that the patient might eventually receive the investigational drug later on once he returned to Germany.
7. All of the drugs recommended to the patient are supported by the medical literature. Both before and after this patient was treated, Clinic physicians treated other GBM patients and achieved remarkable and unheard of results, exceeding the results from non-curative standard of care radiation/chemotherapy.
8. Respondent intends to prove at the hearing that his targeted approach to treating GBM achieves results superior to standard of care treatment.
9. Initially, the patient had a therapeutic, beneficial response to the treatment best described as a moderate decrease in the size of his tumor. However, after several months, the patient's tumors continued to grow somewhat. As a result of the tumor growth, another treatment plan was developed after performing genomic testing. Unfortunately, the treatment

failed to stop disease progression and the patient died of his disease in December 2011.

10. Although the Respondent made treatment recommendations to the Clinic treating physicians and his personal physician, he prescribed no drugs to the patient, issued no orders on the case and was not the patient's treating physician.

11. The patient, his wife, and his accompanying personal physician received extensive information about the proposed treatment and treatment options, including standard care options. The patient was fully and completely informed about his conventional and nonconventional options orally and in writing, and it was discussed that the patient would likely switch from taking oral Sodium Phenylbutyrate to intravenous (IV) antineoplastons therapy which drugs are closely related.

12. The personnel involved in the treatment of this patient included two successive medical oncologists, a board certified internist and a family practitioner, in addition to the patient's personal physician. In addition, the patient had contact with various members of the Clinic's nursing staff as well as research associates ("RA"), who, as previously explained, are foreign physicians, not licensed in the United States. The RAs collected data and acted as communication intermediaries between the Clinic's licensed physicians, the patient, his spouse and the patient's personal physician. Respondent denies that these research associates were practicing medicine as defined by Texas law or that they exercised any independent medical judgment.

13. All Clinic staff that have any contact with a patient or perform any service is required to write a note about the contact, and that includes research associates, even if they are merely gathering information or conveying orders from the treating physicians. As a result, in this and the other cases, the RA signed notes which are required to be part of the patient's medical file. As graduates of accredited medical schools, RAs are entitled to use the "MD" designation which means that the person graduated from a medical school and is entitled to be referred to as "Dr."
14. At all relevant times, the patient and the patient's treating physician knew and understood that the research associates were not licensed to practice medicine in the state of Texas.
15. Neither Respondent nor anyone else made any false representations to United States Customs agents in connection with the export to medications to the patient's physician abroad.
16. Respondent denies the allegations of billing for unnecessary services and or were not supported by the documentation as alleged in paragraphs f and g. All services were medical necessary and properly billed. Neither the patient nor his wife ever complained about the billing.
17. Clinic physicians and other staff performed all necessary physical and mental status exams appropriate for the patient's condition, and thus Respondent specifically denies any such allegation to the contrary.

Patient C (pages 11-13, paragraph 14)

1. The medical records set forth the basic medical facts of the case and Respondent respectfully refers the Court to these records. Denies all allegations in the Complaint contradicted or not supported by the records or otherwise not supported by the facts. Respondent expects to prove at the hearing as follows:
2. The patient suffered from advanced malignant pleural mesothelioma. The prognosis of this type of cancer is poor with median survival ranging from 9 to 12 months. When he came to the Burzynski Clinic 8 months later, in May 2010, he was terminal and had a short life expectancy.
3. The patient received an oncology consultation from Clinic oncologist and Chief Medical Officer Jai Joshi, M.D., who was assisted by Alejandro Marquis, M.D. The Respondent was not the treating physician of this patient and did not fail to document the patient encounter of May 14, 2010 because there is no evidence of such an encounter with the Respondent and because the Respondent was not responsible for maintaining the medical records for this patient.
4. The treating physician prescribed treatment with phenylbutyrate, Avastin, Tarceva, and Nexavar since the patient refused the recommendation of his local oncologist and Dr. Joshi for treatment with pemetrexed and carboplatin. After approximately 10 days at the Clinic, he was discharged home and from that time onwards, he was treated by his local oncologist.

5. In November 2010, the treatment plan was discussed with Dr. Waites (the local oncologist treating him) and the patient was prescribed Afinitor, Zolinza and Vectibix. According to Dr. Waites, the patient tolerated the first week of treatment extremely well. After two weeks of treatment, however, it was reported that he developed diarrhea, which was attributed to Vectibix. It was agreed with Dr. Waites to discontinue Vectibix due to adverse events. At that time, the patient was not seen at the Burzynski Clinic, but was under the care of his oncologist in Pennsylvania, Dr. Waites, who was documenting the changes in the treatment plan and the rationale for it.
6. It was the opinion of his local oncologist that further changes in the treatment plan were not recommended until April 2011. After that, it was mutually agreed with Dr. Waites that the patient's regimen should be changed to carboplatin and pemetrexed.
7. Medical testing procedures were necessary to identify if the patient could be treated with pharmaceutical agents which can contribute to cardiovascular adverse events. This required an echocardiogram since there was a 17% chance that Nexavar can cause cardiovascular adverse events. The assay of the most important oncogenes in the plasma and serum was necessary for the purpose of molecular profiling to guide the selection of the medications and the repetition of such tests was necessary to follow the patient's tolerance and response to treatment.
8. Despite the initial terminal prognosis, this patient is surviving over 4 ½ years since his diagnosis and suffered only reversible adverse events.

Patient D (pages 13-14, paragraph 15)

1. The medical records set forth the basic medical facts of the case and Respondent respectfully refers the Court to these records. Denies all allegations in the Complaint contradicted or not supported by the records or otherwise not supported by the facts. Respondent expects to prove at the hearing as follows:

2. Patient D suffered from a rare form of brain tumor, which involved both his brain and spinal cord. Respondent did not order and direct Patient D to start treatment with phenylbutyrate, Temodar, Avastin, Tarceva, Afinitor, and Votrient. As described in the medical records, (progress notes of June 13, 2011), the patient was advised by the doctors at the Clinic to continue temozolomide (Temodar) under the supervision of his local oncologist and wait for the results of the Caris tissue analysis. The allegation that Patient D decided to not initiate Respondent's recommendation and to not continue to obtain medical care from Respondent are not accurate. The recommendation from the doctors at the Burzynski Clinic was to continue chemotherapy with temozolomide under the supervision of the patient's local oncologist.

3. The Respondent did not order oxygen saturation measurement; however, such tests had been advised by the doctors of Burzynski Clinic due to pulmonary complications. The patient was under treatment for deep

venous thrombosis and pulmonary embolism as indicated in the history and physical examination of June 7, 2011. The patient also suffered from diabetes insipidus and hypernatremia, which causes significant fluid imbalance and imposes a burden on the cardiovascular system. In addition, he was considered for targeted agents, which may be contraindicated if he would not have abnormalities shown by the echocardiogram. For this reason, the echocardiogram was indicated as the baseline test. The result of plasma and serum oncogene testing were part of molecular profiling as a way to design the treatment plan with targeted agents.

Patient E (paragraph 16, pages 14-16).

1. The medical records of this patient will demonstrate the patient's treatment history. In short, this patient had a rare form of kidney cancer. His disease was metastatic to his liver and lung, and he had recently progressed on monotherapy. He presented to the Clinic for treatment options.
2. Because of the rarity of the patient's tumor, and because he progressed on prior monotherapy, there was no standard of care treatment available to this patient. The only thing a physician could do was search the medical literature for case reports or early stage clinical trials to see if someone had empirically tried some drug or combination which had some positive effect.

3. The patient was informed that there was a case report indicating that sequential use of Sutent followed by Afinitor produced a response in a patient with the same condition.
4. The Clinic also discussed with the patient a treatment plan consisting of a combination of Sutent and Afinitor based on a published Phase I clinical trial conducted at the Memorial Sloan Kettering Cancer Center which used these two drugs in combination on kidney cancer patients, including several patients who had Patient E's exact rare type of cancer. The results of the study showed that patients with chromophobe kidney cancer tolerated and responded to the treatment. This study directly and conclusively refutes the allegation of non-therapeutic prescribing as there is a direct evidence of efficacy of the combination.
5. Patient E was prescribed a dose consistent with the dosage prescribed to the patients in the study who responded to the treatment and tolerated the two drugs taken together.
6. The package insert of both drugs indicate that renal failure is not a contraindication, meaning that Patient E's prior renal disease was not a relevant consideration in determining whether the drugs can be used.
7. Patient E was also prescribed PB, because of its broad spectrum activity and because of its close relationship to antineoplastons therapy, which this patient wanted to take. The patient was advised that there was evidence of activity of PB in kidney cancer based on a clinical trial performed at the Johns Hopkins Medical Center. (Both studies will be offered into evidence at the hearing). The Johns Hopkins study in

conjunction with other evidence to be introduced at the hearing, in the form of studies showing the pathways of PB and other successfully treated kidney cancer patients treated with a similar drug combination refutes the non therapeutic allegations relating to this patient.

8. An injection of Xgeva was given to the patient which is standard therapy for bone metastases.
9. All testing and imaging and was medically necessary and justified and the patient was not overcharged. Specifically, O2 levels needed to be measured and constantly monitored because he suffered bronchospasm 2 x in the clinic, he had metastases to hilar lymph nodes and left lower lobe of the lung, and he was taking medications predisposing to pneumonia. Echocardiogram was necessary to exclude left ventricular dysfunction.(Sutent caused such adverse event in15% of patients ,and it would be contraindicated). A PET scan was necessary for establishing metabolic activity of patient's tumors. Determination of oncogenes in blood was part of molecular profiling necessary to design the treatment plan.

Patient F (pages 16 through 17, paragraph 17)

1. The medical records set forth the basic medical facts of the case and Respondent respectfully refers the Court to these records. Denies all allegations in the Complaint contradicted or not supported by the records or otherwise not supported by the facts. Respondent expects to prove at the hearing as follows:

2. Patient F was diagnosed with cancer of the pancreas with metastases to the liver. Respondent was not the patient's treating physician and he did not prescribe Valtrex, which was prescribed for the patient before his visit to the Clinic. The dose of Valtrex was increased by the patient's physician, Dr. Robert Weaver, due to acute HSV-type 2 infection. There is no evidence in the medical records that this patient was prescribed Sutent, Afinitor, gemcitabine, and Xgeva. He was prescribed Rapamune, Zolinza, Xeloda, Avastin, Nexavar, and phenylbutyrate, which is supported by data published in peer-reviewed journals including the article by the Respondent and his employees.
3. The patient did not suffer multiple side effects from the treatment; he only reported minor side effects possibly related to the treatment. The medical records indicate that on October 14, 2009 he did not report any new complaints. On October 15, 2009 he reported diarrhea x3, which is a classified as a minor Grade 1 toxicity. On October 16, 2009 he complained of intermittent headaches, which was disease related and were reported at the baseline examination. On October 19, 2009 he was complaining of intermittent headaches and urinary frequency which were present pretreatment. On October 23, 2009 the patient reported nausea and dizziness. The dizziness was a pretreatment condition and the nausea was categorized as a minor Grade 1 toxicity. In summary, he tolerated his treatment extremely well with minor Grade 1 rare toxicities. According to the information in the medical records, the patient decided

to discontinue the treatment due to financial constraints, and not due to adverse events.

4. Patients with advanced pancreatic cancer undergoing treatment with chemotherapeutic and targeted agents are vulnerable to developing pneumonia. This patient already had an active viral infection which is further causing an immunosuppressive effect. For this reason, Dr. Weaver ordered an oxygen saturation test to be able to monitor possible changes leading to pneumonia.
5. All laboratory tests ordered by the patient's treating physician, Dr. Robert Weaver, were necessary. It should be noted that this case is one of out of a million patients with aggressive pancreatic cancer and liver metastases who survived over 5 years.

Patient G (Paragraph 18, pages 17-19)

1. This patient was treated with the Clinic's two investigational drugs from early September 2012 until mid November 2012, pursuant to FDA permission under a single patient protocol ("SPP").
2. Respondent was not listed as the physician responsible for the treatment in the FDA SPP documents. He did not examine the patient, signed no notes for the patient, nor did he sign any prescription orders. The dosages of the drugs were administered pursuant to FDA approved protocol BT-09. Respondent is the principal investigator for the IND (Investigational New Drug Application) covering protocol BT-9.

3. Respondent saw the patient briefly during her first day at the Clinic to greet the patient and introduce her to her treatment team. Respondent was not a member of the treatment team.
4. The patient's family had two billing/financial issues with the clinic. The patient's family created a web site to solicit donations to help pay the costs of the treatment. However, the web site falsely stated that the patient owed the clinic $35,000 in unpaid expenses, even though there was no balance due on the account.
5. Clinic personal repeatedly requested the family to remove the false statements from the web site. These requests were made orally and in writing via email.
6. It was also explained that the Clinic could not accept donations for her treatment since the account showed a zero balance. It was suggested that the web site direct that donations be made to the family directly. The family refused to make the requested changes.
7. The Clinic received one check for $12.50 and returned it to the sender because as stated, there was a zero balance on the account.
8. Second, per the billing agreement signed by the patient, the patient agreed to pay a monthly deposit covering a portion of the costs of the services and supplies relating to the administration of the drug. The billing agreement stated that the patient's insurance carrier would be billed the full amount of the charges and that the patient would only receive a refund if all the charges were paid by the carrier. The carrier made some partial payments, but the patient insisted that she was entitled

to a refund of her deposit because of her carrier's partial payment. After the Clinic refused to refund all monies paid by her to the Clinic and as a result of the Clinic's return of the $12.50 donation, the patient's family filed a complaint with the TMB based on the above.

19. Unprofessional Conduct (page 19)

a. Inadequate Delegation and Inadequate Direction, Supervision and Control. (page 19)

1. All clinic personnel were adequately trained and supervised for the tasks assigned to them.
2. To the extent these allegations related to unlicensed medical doctors whose job description is "Research Associate," none of them engaged in the practice of medicine as defined by Texas law.
3. Every patient including the patients A-G were told that the research associates assigned to their treatment team was not a licensed physician and their job was, inter alia, to act as a communication intermediary between the licensed physicians on the treatment team and the patient and his/her family members.
4. The research associates made no independent medical decision making and conveyed to the patient that medical decisions would have to be made by the licensed physicians.
5. However, the fact that graduates of medical schools were interacting with patients, rather than nurses and untrained medical assistants benefited the patients in the Complaint and all the Clinic's patients because they are much more

knowledgeable than nurses and other non-physician licensed medical staff.

6. All clinic personnel who have interaction with the patient or a family member are required to make a note concerning the contact. Notes from the research associates sometimes incorporate information concerning the patient's diagnosis and/or current or past treatment as a matter of routine, but the information in these notes is taken from prior notes signed by licensed physicians.

b. Aiding and Abetting the Unlicensed Practice of Medicine. (page 20)

1. Texas law defines "practicing medicine" as "the diagnosis, treatment , or offer to treat a mental or physical disease or disorder or a physical deformity or injury by any system or method, or the attempt to effect cures of those conditions…." (Tex. Occ. Code 151.002(13). None of the unlicensed research associates engage in any activity included in the above definition of practicing medicine.

2. Texas law does not prohibit a graduate of a medical school to be referred to as "Doctor" or use the designation "M.D."

3. No research associate listed in this case represented to any of the patients listed in this case that he/she was licensed to practice medicine in Texas.

4. All Clinic patients are informed at their first visit that their treatment team will include an unlicensed foreign medical school graduate, and all of the patients in this case were so informed.

5. The First Amended Complaint alleged that the research associates were practicing medicine without a license. As a result of discovery which demonstrated that they

did no such thing, in the current Complaint the Board has changed the factual allegation to being "involved in the evaluation, diagnosis and treatment" of the listed patients. (See page 21 a-g). However, many licensed and unlicensed Clinic personnel are in some way "involved" in such activities including transcriptionists, secretaries, financial counselors and other personnel. Being "involved" in the diagnosis and treatment of a patient is not within the definition of the practice of medicine and hence is not a violation of Texas law prosecutable by the Board.

c. <u>Failure to Disclose Reasonably Foreseeable Side Effects and Failure to Obtain Adequate Informed Consent.</u> (Page 22)

1. The patients treated in the Clinic's private practice (Patients A-C and E-F) were treated with multi-agent targeted therapy based on the Clinic's past history and use of combinations of drugs as refined by blood and tumor testing which added a personalized or individualized component to the treatment approach. Patients were provided with whatever information was available concerning the drugs being administered and signed written informed consent forms for each drug.
2. The dosages of each drug administered were substantially less than the dosage of the drug for monotherapy. Side effects were explained to the patients, and drugs were introduced sequentially and the patients were closely monitored.

3. By its very nature, personalized targeted therapy which treatment decisions include consideration of results of genomic blood and tumor testing is not amenable to controlled clinical trials. This is the new model for treating advanced cancer patients.
4. Prior to presenting to the Clinic, all patients had received a standard of care treatment recommendation and received another standard of care recommendation at the Clinic by a Clinic employed board certified medical oncologist. Thus, every patient in this case at least twice received and rejected standard of care treatment options and instead chose to undergo personalized multi-agent targeted therapy based on the Clinic's prior experience and a discussion of treatment options and benefits and possible side effects of the different types of treatment. That is all the Clinic was required to do.

d. Inadequate Disclosure [Regarding Respondent's ownership of the pharmacy

(Pages-22-23)

1. As indicated previously (pages 7-9) the Clinic has an in-house pharmacy consisting of two rooms inside the Clinic. The pharmacy dispenses the drugs ordered by the Clinic's physicians and the charges are listed on the Clinic's statements. Patients understand that the pharmacy is a part of the Clinic. Respondent expects to move for summary disposition on this issue after discovery is completed.

e. Improper Charges (page 23)

1. Board Staff appears to take the position that none of the charges the Clinic billed

were reasonable and necessary, presumably because of its view that the treatment was non-therapeutic and otherwise improper. Respondent contends that the patient charges attached as an exhibit to the Complaint were reasonable, medically necessary based on the patient's condition and adequately documented.

f. <u>False, Misleading and/or Deceptive Advertising and Marketing Conduct</u> (pages 23-25)

1. In the late 1960s, Respondent discovered a group of medium chain size peptides and amino acid derivatives which seemed to work as molecular switches on cancer cells. For the next decade or two, conventional wisdom was that these compounds were just "cellular debris."
2. However, that all changed and by the 1990s these compounds started to attract widespread attention and were viewed as potentially effective compounds for a variety of diseases. NCI and a pharmaceutical company patented a weak component of one of Respondent's antineoplastons; another company patented and obtained FDA approval for a non-cancer use of a pro-drug of Respondent's patented compounds, to wit sodium phenylbutyrate or PB.
3. Respondent then started using PB in cancer patients because it was an FDA legal way to treat patients based on his discovery in the 1960s and without the need for subjecting patients to clinical trials obligations (like blood tests three times a week).
4. In fact, Respondent has FDA approval to manufacture PB under the FDA's generic drug rules. People coming to the Clinic who want to be treated based on

Respondent's discoveries and theory get antineoplastons, (Atengenal (A10) and Astugenal (AS2-1), which are their formal drug names and numeric designations) if they qualified for the clinical trials. If the patients do not qualify for the clinical trials, they receive PB, which the body converts into the two active components of Astugenal. All patients are explained the close connection between PB and antineoplastons (Atengenal and Astugenal). But at the end of the day, all patients who reject standard of care treatment and want to be treated with the class of compounds which Respondent claimed more than 40 years ago could effectively treat cancer are receiving treatment based on Respondent's discoveries.

20. <u>Violation of Ethical and Professional Responsibilities Regarding Clinical Investigations - 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>

Initial General Response:

1. This section of the Complaint is based mainly on the facts alleged in Claim H in the First Amended Complaint, which claims had previously been dismissed by this Court, namely alleged violations of federal law relating to FDA informal communications with Respondent, INC. and BRI-IRB.
2. Last time, the alleged violation was "violation of any federal or state law…" Occ. Code 164.052 (a)(5) and 164.053(a)(1). This time the

alleged violation is Board Rule 200.3(7) dealing with the "ethical and professional responsibilities" of clinical investigations and sponsors as set forth in various sections of the code of federal regulations. (See Complaint at page 25 a through page 26).

3. These allegations appear to apply to all patients listed in the Complaint, to wit, A-F (page 26 b. 3) and G-BB (Id. at 1), or 28 total patients which are now the subject of this case, or 21 additional patients beyond the standard of care cases.
4. Patients A-F were not treated under a clinical trial or under a clinical trial protocol. Rather, they were treated in Respondent's regular clinical practice. Hence, none of what follows in the Complaint about clinical investigations applies to them. Respondent expects to move for summary disposition on these claims with respect to the private practice patients.
5. Respondent asserts that the federal CFR provisions which are the predicate of these claims are not ethical or professional guidelines which can be the basis of an alleged violation of Board Rule 200.3(7). After discovery on these and related issues, Respondent intends to file a motion for summary disposition striking all such claims from the Complaint and other legal, factual and jurisprudential reasons. If the motion is denied, Respondent will provide a detailed response in answer to the allegations in this section.

IV. AGGRAVATING FACTORS

1. Denies that there are any aggravating factors relevant to this case as alleged in IV of the Complaint.

V. APPLICABLE STATUTES, RULES AND AGENCY POLICY

1. Admits the allegations in paragraph 1.

2. Admits the allegations in paragraph 2.

3. Admits the allegations in paragraph 3.

4. Admits the allegations in paragraph 4.

5. Denies that SOAH issues proposals for decisions which are reversible by the board in terms of findings of fact, as alleged or implied by paragraph

6. Denies that the Board has "sole and exclusive authority to determine the charges on the merits…" to the extent this implies that the Board has no limitations on its power to overrule an ALJ's findings of fact, conclusions of law. Whether or not the Board had such powers might be debatable, but Texas law now provides that the Board has no power to overrule an administrative law judge's findings of fact and conclusions of law. Its only remedy is to challenge such findings and conclusions in state district court. (Texas Board Rule 187.37(d)).

VII. DEFENSES, AFFIRMATIVE DEFENSES AND MITIGATING FACTORS

1. Respondent's websites contain truthful and accurate information concerning the investigational agents known as antineoplastons and the results of the clinical trials. To the extent that the FDA regulation which is the basis of the informal FDA letter prohibits truthful speech under the FDA rule against "promotion" of an investigational drug, it is a violation of Respondent's First Amendment rights.
2. Pursuant to Texas Medical Board Rule 190.15 (b) the following mitigating factors are applicable and will be proven at the hearing.
    1. 190.15(b)(5) prior community service and present value to the community as follows:
        a. Prior Community Service

            Respondent and his cancer clinic have cured or benefited hundreds of terminally ill or very advanced cancer patients.

            By definition, a patient with terminal cancer is not expected to survive his/her disease. And yet Respondent has documented many dozens of cures to many forms of cancer, most especially brain tumors. Many of these cured patients received his investigational drug as part of clinical trials over the past 18 years; other cured and benefited patients received the drug prior to the clinical trials. Finally the multi-agent targeted therapy offered by the Clinic over the past dozen years has also cured and benefited dozens of patients.

            In support of this mitigating factor, Respondent intends to adduce

testimony from a number of previously diagnosed terminally ill cancer patients who have been cured of cancer by the treatment received at the Clinic and physicians participating in or following the care given to patients.

b. Present Value to the community: Respondent intends to adduce evidence from patients currently undergoing treatment at the Clinic and who will be adversely affected if the Board revokes Respondent's medical license.

WHEREFORE PREMISES CONSIDERED, based on the foregoing, Respondent requests that before or after a hearing on this matter this Court dismiss the Complaint in its entirety.

Respectfully Submitted,

s/_____

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Certificate of Service

On this 4th day of December 2014, I certify that a true and correct copy of this Respondent's

Answer to the Second Amended Complaint has been served on the following individuals by fax:

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s/_____
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