HEARING CONDUCTED BY THE
TEXAS STATE OFFICE OF ADMINISTRATIVE HEARINGS
SOAH DOCKET NO. 503-11-1669.MD
LICENSE NO. D-9377

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

FIRST AMENDED COMPLAINT

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

COMES NOW, the Staff of the Texas Medical Board ("the Board"), and files this First Amended Complaint against Stanislaw R. Burzynski, M.D., ("Respondent"), based on Respondent's alleged violations of the Medical Practice Act ("the Act"), TEX. OCC. CODE ANN., Title 3, Subtitle B, and would show the following:

I. INTRODUCTION

The filing of this First Amended 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

1. Respondent is a Texas Physician and holds Texas Medical License No. D-9377, issued by the Board on January 13, 1973, which was in full force and effect at all times material and relevant to this Complaint. All jurisdictional requirements have been satisfied.

2. Respondent received notice of the Informal Settlement Conference ("ISC") and appeared at the ISC, which was conducted in accordance with §2001.054(c), GOV'T CODE and

§164.004 of the Act. All procedural rules were complied with, including but not limited to, Board Rules 182 and 187, as applicable.

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

III. FACTUAL ALLEGATIONS

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

1. Patient A[1]:

a. In approximately May of 2008, Patient A presented to Respondent with breast cancer that had metastasized to her brain, lung, and liver.

b. Respondent prescribed or directed the prescription of a combination of five drugs–phenylbutyrate, erlotinib, dasatinib, vorinostat, and sorafenib–which are not approved by the Food and Drug Administration ("FDA") for the treatment of breast cancer, and which do not meet the standard of care or are unjustified by supporting clinical data for the use of off-label drugs in breast cancer therapy.

c. The informed consent provided to Patient A for the use of sodium phenylbutyrate (PB) was misleading in that it stated that PB has been designated by the FDA for treatment of gliomas, among other things, when, in fact, it has an orphan designation for certain diseases or conditions but it does not meet the requirements for marketing approval and its safety and efficacy has not been established through adequate and well-controlled studies.

d. In combination with the five immunotherapy agents, Patient A was prescribed capecitabine, a chemotherapy agent. The concurrent prescription of five randomly selected immunotherapy agents in combination with a chemotherapy agent resulted in Patient A suffering unwarranted side effects. There is no recorded discussion about the experimental nature of the drugs or the combination of drugs used in Patient A's treatment.

[1] Board staff will provide the identification of the patients to the ALJ and Respondent by separate confidential document filed under seal.

e. Respondent over-read all the MRIs, as was the practice in his office and signed at least two progress notes for the patient. Respondent lists himself as the physician in charge of treatment in the consent form provided to the Patient in this case.

f. Respondent failed to conduct or record a detailed discussion with Patient A about the causes of fatigue she experienced and encourage her to complete her remaining treatments of conventional radiation therapy.

g. The Respondent failed to maintain adequate medical records that would allow the reader to determine whether adequate information had been given to the patient regarding her treatment options and the desirability of each one.

2. Patient B:

a. In approximately March of 2003, Patient B presented to Respondent with a diagnosis of esthesioneuroblastoma.

b. Respondent prescribed PB, an immunotherapy agent not approved by the FDA for the treatment of esthesioneuroblastoma and that does not meet the standard of care or is unjustified by supporting clinical data for off-label use.

c. Respondent did not inform Patient B that standard treatment has a better chance of success than experimental treatment in the treatment of potentially curable cancers, nor is any such discussion reflected in the medical records for Patient B.

d. Follow-up magnetic resonance imaging ("MRI") scans were conducted in approximately August and December of 2003, and March of 2004, which showed progressive disease. Respondent did not conduct interval evaluations. Patient B was continued on PB during this 11-month time period, and was not sufficiently informed about the drug's lack of efficacy on her disease. The standard of care requires that the physician monitor for toxicity and efficacy. If there is a lack of efficacy then recommend alternative treatment, which was not done.

e. The Respondent, upon determining based on his review of the MRI scans that there was a steady increase in the esthesioneuroblastoma, however, slight it may be, should have discussed the fact that the drug he was prescribing was not having a significant impact on her esthesioneuroblastoma and given her the option of stopping the treatment or continuing on; instead, he continued to prescribe the drug.

3. Both Patients A and B were treated with a particular therapy treating specific conditions without sufficient scientific safety and efficacy data to support their use and unnecessarily exposed the patients to known toxicities associated with PB.

4. Respondent controlled or had the right to control all or substantially all aspects of the care and treatment of both Patients A and B and is both directly and vicariously liable for deficiencies in their care, treatment and medical records in support of each.

5. Respondent's medical records for Patient B are inadequate because they do not reflect that Patient B gave her consent to the experimental therapy, or any other therapy proposed by Respondent, and do not identify any physician or physicians whose duty it was to manage her case and provide for her care.

6. Respondent failed to conduct and document in the medical record a Patient Assessment including, at a minimum: a review of conventional methods of diagnosis and discussion with Patient B of these options; the objectives, expected outcomes, or goals of the proposed treatment; the risks and benefits of the proposed treatment; and a statement that the treatment offered is an investigation article subject to clinical investigation standards.

7. Respondent has been the subject of a prior Board Order. 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 antineoplastons, in violation of state and federal laws. The 1994 Order terminated on October 19, 2004.

8. The actions of Respondent as specified above violate one or more of the following provisions of the Medical Practice Act:

a. Respondent is subject to disciplinary action pursuant to Section 164.051(a)(1) of the Act based on Respondent's commission of an act prohibited under Section 164.052 of the Act.

b. Section 164.051(a)(3) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's violation of a rule adopted under the Act, specifically:

a) Board Rule, 165.1, which requires the maintenance of adequate medical records, and;

b) Board Rule 200.3, regarding the standards for physicians practicing complementary and alternative medicine.

c. Section 164.051(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's failure to practice medicine in an acceptable professional manner consistent with public health and welfare, as further defined by: Board Rule(s): 190.8(1)(A), failure to meet the standard of care; 190.8(1)(B), negligence in performing medical services; 190.8(1)(C), failure to use professional diligence; 190.8(1)(D), failure to safeguard against potential complications; 190.8(1)(G), failure to disclose reasonably foreseeable side effects of a procedure or treatment; 190.8(1)(H), failure to disclose reasonable alternative treatments to a proposed procedure or treatment; 190.8(1)(I), failure to obtain informed consent from the patient or other person authorized by law to consent to treatment on the patient's behalf before performing tests, treatments, or procedures; and 190.8(1)(K), prescription or administration of a drug in a manner that is not in compliance with Chapter 200 of this title (relating to Standards for Physicians Practicing Complementary and Alternative Medicine) or, that is either not approved by the Food and Drug Administration (FDA) for use in human beings or does not meet the standards for off-label use, unless an exemption has otherwise been obtained from the FDA.

d. Section 164.053(a)(5) of the Act authorizes the Board to take disciplinary action against Respondent based upon Respondent's prescription or administration of a drug or treatment that is nontherapeutic in nature or nontherapeutic in the manner the drug or treatment is administered or prescribed.

e. Section 164.053(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based upon Respondent's prescribing, administering, or dispensing in a manner inconsistent with public health and welfare dangerous drugs as defined by Chapter 483, Health and Safety Code; or controlled substances scheduled in

Chapter 481, Health and Safety Code, or the Comprehensive Drug Abuse Prevention and Control Act of 1970, (21 U.S.C. Section 801 et seq.).

f. Section 164.052(a)(5) of the Act authorizes the Board to take disciplinary action against Respondent based upon Respondent's unprofessional or dishonorable conduct that is likely to deceive or defraud the public or injure the public, as further defined in 164.053(a)(8) failure to adequately supervise the activities of those acting under Respondent's supervision.

IV. AGGRAVATING FACTORS

Pursuant to Board Rule 190.15, this case includes the following aggravating factors:

1. Harm to one or more patients;
2. Severity of patient harm;
3. One or more violations that involve more than one patient;
4. increased potential of harm to the public;
5. Intentional, premeditated, knowing, or grossly negligent act constituting a violation; and
6. Prior similar violations.

V. APPLICABLE STATUTES, RULES, AND AGENCY POLICY

The following statutes, rules, and agency policy are applicable to the conduct of the contested case:

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. 1 TEX. ADMIN. CODE, CHAPTER 155 sets forth the rules of procedure adopted by SOAH for contested case proceedings.

4. 1 TEX. ADMIN. CODE, CHAPTER 155.507, requires the issuance of a Proposal for Decision ("PFD") containing Findings of Fact and Conclusions of Law.

5. Section 164.007(a) of the Act, Board Rule 187.37(d)(2) and Board Rule 190 et. seq., provides 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 WITHIN 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.

Filed with the Texas Medical Board on this 8th day of February, 2012.

Mari Robinson, J.D.
Executive Director
Texas Medical Board

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,

TEXAS MEDICAL BOARD

By: _____

John Heisler, Staff Attorney
Texas State Bar No. 09384100
Telephone: (512) 305-7172
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 John Heisler on this 9th day of February, 2012.

Cheryl A. Graham
Notary Public, State of Texas

CHERYL A. GRAHAM
Notary Public
STATE OF TEXAS
My Comm. Exp. 02-22-2014
Notary without Bond

CERTIFICATE OF SERVICE

I certify that on the 9th day of February, 2012, a true and correct copy of the foregoing document has been served as follows:

VIA FAX TRANSMISSION: (512) 322-2061
Docket Clerk
State Office of Administrative Hearings
William P. Clements Building
300 W. 15th Street, Suite 504
Austin, TX 78701-1649

VIA CERTIFIED MAIL #7008 2810 0000 1404 9334, RETURN RECEIPT REQUESTED and VIA FIRST CLASS MAIL
Stanislaw R. Burzynski, M.D.
9432 Katy Freeway, Suite 200
Houston, TX 77055

VIA FAX TRANSMISSION: (713) 626-9420
Richard Jaffe Attorney at Law
Phoenix Tower
3200 Southwest Freeway, Suite 3200
Houston, TX 77027

BY HAND DELIVERY:
Sonja Aurelius
Hearings Coordinator
Texas Medical Board
333 Guadalupe, Tower 3, Suite 610
Austin, TX 78701

By: _____
John Heisler