

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

IN THE MATTER OF THE
COMPLAINT AGAINST:

STANISLAW R. BURZYNSKI, M.D.

BEFORE THE

TEXAS MEDICAL BOARD

COMPLAINT

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

COMES NOW, the Staff of the Texas State Board of Medical Examiners ("the Board"), and files this 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 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 A¹:
 - 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 a combination of five immunotherapy agents—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 FDA’s regulations for the use of off-label drugs in breast cancer therapy.
 - c. In combination with the five immunotherapy agents, Patient A was prescribed capecitabine, a chemotherapy agent. The concurrent prescription of five immunotherapy agents in combination with a chemotherapy agent resulted in Patient A suffering unwarranted side effects.
 - d. Respondent owned the clinic pharmacy from which the multiple drugs were ordered. Respondent failed to affirmatively disclose to Patient A his ownership interest in the pharmacy.
2. Patient B:
 - a. In approximately March of 2003, Patient B presented to Respondent with a diagnosis of esthesioneuroblastoma.

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

b. Respondent prescribed sodium phenylbutyrate, an immunotherapy agent that is not approved by the FDA for the treatment of esthesioneuroblastoma and that does not meet the FDA's regulations for off-label use.

c. Follow-up magnetic resonance imaging ("MRI") scans were conducted in approximately August and December of 2003, and March of 2004, which showed progressive disease. Patient B was continued on phenylbutyrate during this 11-month time period, and was not sufficiently informed about the drug's lack of efficacy on her disease.

3. 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.

4. The actions of Respondent described above constitute one or more of the following, but are not limited to: failure to meet standard of care; negligence; lack of diligence; lack of informed consent; unprofessional conduct; and non-therapeutic prescribing.

5. 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)(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.

c. 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 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. "Improper" means the billing statement is false, fraudulent, misrepresents services provided, or otherwise does not meet professional standards.

d. 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, to wit: Section 311.0025 of the Texas Health and Safety Code.

e. 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.

f. 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.).

g. Section 164.053(a)(7) of the Act authorizes the Board to take disciplinary action against Respondent based upon Respondent's- violation of Section 311.0025 of the Texas Health and Safety Code, specifically, improper billing practices.

IV. AGGRAVATING FACTORS

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

1. Harm to one or more patients;
2. Economic harm to any individual or entity and the severity of such harm;
3. Severity of patient harm;
4. One or more violations that involve more than one patient; increased potential 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.

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:



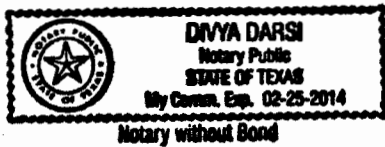
John Heisler, Staff Attorney
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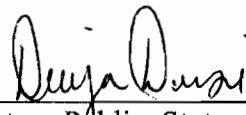
THE STATE OF TEXAS

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COUNTY OF TRAVIS

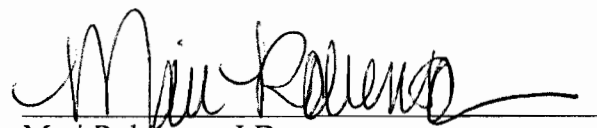
SUBSCRIBED AND SWORN to before me by the said John Heisler on this 8th day of December, 2010.





Notary Public, State of Texas

Filed with the Texas Medical Board on this 7th day of Dec, 2010.



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

CERTIFICATE OF SERVICE

I certify that on the 8th day of December, 2010, a true and correct copy of the foregoing document has been served as follows:

VIA EMAIL TO DOCKETING@SOAH.STATE.TX.US:

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

VIA FIRST CLASS MAIL, CERTIFIED, RETURN RECEIPT REQUESTED:

7008 2810 0000 1404 8603

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Austin, TX 78701

By: _____


John Heisler