

HEARING CONDUCTED BY THE
TEXAS STATE OFFICE OF ADMINISTRATIVE HEARINGS
SOAH DOCKET NO. 503-14-1324.MD
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 STATE MEDICAL BOARD AND THE HONORABLE
ADMINISTRATIVE LAW JUDGE TO BE ASSIGNED:

COMES NOW, the Staff of the Texas Medical Board (Board staff), and files this 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

1. Respondent is a Texas Physician and holds Texas Medical License No. D-9377, issued by the Board on January 13, 1973.
2. Respondent's license was in full force and effect at all times material and relevant to this Complaint.

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

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

5. 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:

Respondent's internet-based advertising was false, misleading and violated federal law. Specifically, Respondent was notified by the Federal Drug Administration (FDA) that he must cease the dissemination of conflicting promotional materials for Antineoplastons, which are drugs that have been approved by the FDA only for investigational purposes. The advertising materials were found on multiple websites, and it was alleged that Respondent's websites violated the Federal Food, Drug, and Cosmetic Act and FDA regulation 21 CFR 312.7(a).

B. Specific Allegations:

1. Respondent, as 80% owner of the Burzynski Institute and 100% owner of the Burzynski Clinic, failed to adequately and appropriately scrutinize his advertisements and adhere to appropriate ethical standards for truth in advertising.

2. In a letter dated October 18, 2012, the FDA required Respondent cease the dissemination of improper promotional materials for antineoplastons.

3. The referenced materials were found on multiple websites belonging to or sponsored by Respondent.

4. Respondent's websites and/or websites sponsored by Respondent, violated the Federal Food, Drug, and Cosmetic Act and FDA regulation 21 CFR 312.7(a).

5. Since anitineoplastons are investigational new drugs, their safety and efficacy are unproven at the current time; therefore, promoting them as safe and effective is a violation of FDA regulations.

6. Respondent's advertisements violated federal law as they promoted these investigational agents as safe and effective, potentially causing consumers to have unjustified expectations about the safety and efficacy of the treatments.

7. Furthermore, Respondent never informed consumers that anitineoplastons have not been "proven" to cure cancer, and only stated that they were "not approved by the FDA."

IV. AGGRAVATING FACTORS

Board Rule 190.15 provides that aggravating factors may be considered by the Board in reaching a determination of sanctions. Aggravating factors applicable in this case include increased potential for 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. STATUTORY VIOLATIONS

The acts or omissions of Respondent as specified above violate one or more of the following provisions of the Medical Practice Act:

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

2. Section 164.051(a)(3) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's violation of a Board Rule 164.1, which prohibits the

dissemination of information that is false, deceptive or misleading and further requires each physician to scrutinize advertisements; 164.3, prohibiting the use of misleading or deceptive advertising; and 190.8(1)(C), failing to use proper diligence in one's professional practice.

3. Section 164.052(a)(5) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's unprofessional or dishonorable conduct that is likely to deceive or defraud the public, as provided by Section 164.053, or injure the public, and as further defined by Board Rules 190.8(2)(I), using false, misleading or deceptive advertising; and 190.8(2)(R), violation of federal or state law whether or not there is a complaint, indictment or conviction.

4. Section 164.052(a)(6) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's using an advertising statement that is false, misleading or deceptive.

5. Section 164.053(a)(1) of the Act authorizes the Board to take disciplinary action against Respondent based on Respondent's committing any act that violates state or federal law if that act is connected with the physician's practice of medicine, specifically, 21 CFR 312.7 (a).

VI. APPLICABLE STATUTES, RULES AND AGENCY POLICY

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

1. Section 164.007(a) of the Act requires that the Board adopt procedures governing formal disposition of a contested case before the State Office of Administrative Hearings.
2. 22 Tex. Admin. Code, Chapter 187 sets forth the procedures adopted by the Board under the requirement of Section 164.007(a) of the Act.
3. 22 Tex. Admin. Code, Chapter 190 sets forth aggravating factors that warrant more severe or restrictive action by the board.
4. 1 Tex. Admin. Code, Chapter 155 sets forth the rules of procedure adopted by SOAH for contested case proceedings.

5. 1 Tex. Admin. Code, Chapter 155.507, requires the issuance of a Proposal for Decision (PFD) containing Findings of Fact and Conclusions of Law.
6. Section 164.007(a) of the Act, Board Rule 187.37(d)(2) and, Board Rule 190 et. seq., provide the Board with the sole and exclusive authority to determine the charges on the merits, to impose sanctions for violation of the Act or a Board rule, and to issue a Final Order.

VII. 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.

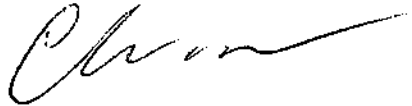
VIII. PRAYER

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



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THE STATE OF TEXAS

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COUNTY OF TRAVIS

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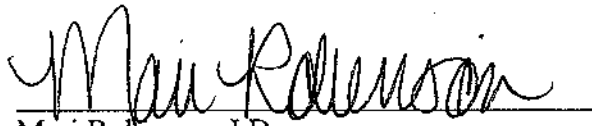
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SUBSCRIBED AND SWORN to before me by the said Christopher M. Palazola on this
11th day of December, 2013.



Notary Public, State of Texas

Filed with the Texas Medical Board on this 11 day of Dec, 2013.

A handwritten signature in cursive script that reads "Mari Robinson". The signature is written in black ink and is positioned above a horizontal line.

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

CERTIFICATE OF SERVICE

I certify that on the 11th day of December 2013, a true and correct copy of the foregoing document has been served as follows:

VIA EMAIL: docketing@soah.state.tx.us

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 0655

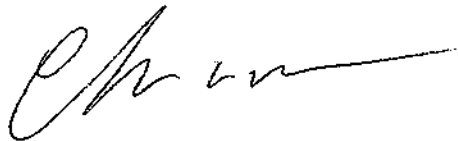
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Christopher M. Palazola, J.D.