State Office of Administrative Hearings

Lesli G. Ginn
Chief Administrative Law Judge

October 12, 2016

Mari Robinson, J.D.
Executive Director
Texas Medical Board
333 Guadalupe, Tower III, Suite 610
Austin, Texas 78701

VIA INTERAGENCY

RE: Docket No. 503-14-1342/Stanislaw R. Burzynski, M.D.

Dear Ms. Robinson:

Please find enclosed a Proposal for Decision in this case.

Exceptions and replies may be filed by any party in accordance with 1 Tex. Admin. Code § 155.507(c), a SOAH rule which may be found at www.soah.state.texas.gov.

Sincerely,

Roy G. Scudday
Administrative Law Judge

CATHERINE C. EGAN
ADMINISTRATIVE LAW JUDGE
STATE OFFICE OF ADMINISTRATIVE HEARINGS

RGS, CCE/et
Enclosures
xc: Amy Swanholm, Staff Attorney Texas Medical Board 333 Guadalupe, Tower III, Ste. 610, Austin, TX 78701 – **VIA INTERAGENCY**
Robin Etheridge, Hearings Coordinator, Texas Medical Board, 333 Guadalupe, Tower III, Ste. 610, Austin, TX 78701 (with 3 CDs; Certified Evidentiary Record –Staff's Exh. 5 boxes, Resp. Exh. 2 boxes, Transcripts 1 box, Depos. 2 boxes, 1 Envelope with Master List of Exhibits) – **VIA INTERAGENCY**
Melanie Rubinsky, Myers & Doyle, 7676 Woodway, Suite 350, Houston, TX 77063 – **VIA REGULAR MAIL**
J. Gregory Myers, Myers & Doyle, 7676 Woodway, Suite 350, Houston, TX 77063 – **VIA REGULAR MAIL**
Dan Cogdell, The Cogdell Law Firm, PLLC, 402 Main Street, 4th Floor, Houston, TX 77002 – **VIA REGULAR MAIL**

SOAH DOCKET NO. 503-14-1342.MD

TEXAS MEDICAL BOARD, Petitioner	§	BEFORE THE STATE OFFICE
v.	§	OF
STANISLAW R. BURZYNSKI, M.D., Respondent	§	ADMINISTRATIVE HEARINGS

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SOAH DOCKET NO. 503-14-1342.MD

TEXAS MEDICAL BOARD, **Petitioner**	§	**BEFORE THE STATE OFFICE**
v.	§	**OF**
STANISLAW R. BURZYNSKI, M.D., **Respondent**	§	**ADMINISTRATIVE HEARINGS**

PROPOSAL FOR DECISION

The staff (Staff) of the Texas Medical Board (Board) seeks to impose disciplinary action against Stanislaw R. Burzynski, M.D. (Dr. Burzynski/Respondent) for alleged violations of the Medical Practice Act[1] and the Board's rules[2] in his treatment of cancer patients.

This is a complex case involving a period of 13 years and Dr. Burzynski's treatment of 30 patients within that period. Staff initially offered 68 volumes of exhibits into evidence, but later reduced its exhibits to 59 volumes of documents that were admitted into evidence. Staff's exhibits included, among other things, the medical records for Patients A through G, 36 depositions, and portions of the medical records for Patients H through DD. Staff submitted over 19,870 pages of documentary exhibits.

The patients in issue were terminally-ill cancer patients who had either unsuccessfully tried conventional cancer treatment or had elected not to do so because of severe side effects with minimal prospect of curing the disease. Several of the patients were not expected to live for more than a year.

In the 1990s, Dr. Burzynski discovered and patented an anti-cancer drug for which the Food and Drug Administration (FDA) approved several clinical studies to determine its effectiveness in treating adults and children with advanced stages of cancer. Many of these patients elected to participate in the FDA-approved clinical studies, and others chose to

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[1] Tex. Occ. Code (Code), title 3, chapters 151-169.

[2] The applicable Board rules are located at 22 Texas Administrative Code (TAC) chapters 165, 179, and 190. In this proposal for decision, the Board rules are referred to as "Board Rule xx," or "22 TAC § xx," using the specific number of the rule.

participate in "personalized medicine" treatment that targeted the cause of the cancer rather than the location of the cancer. Because of Dr. Burzynski's treatments, several terminally ill patients recovered.

Staff makes allegations against Respondent ranging from standard of care violations to ethical violations in conducting clinical studies that are regulated by the FDA. Staff relied heavily on the testimony of three experts, one on ethics, one on billing issues, and another regarding the standard of care. The experts' qualifications will be discussed more fully later, but it is important to know that Staff's experts had not seen all the relevant records of the patients upon which they were asked to give an opinion. For example, Cynthia Wetmore, M.D., a pediatric oncologist, testified that Respondent had misrepresented Patient D's tumor response to ANP, when Patient D was not treated at the Clinic. Staff's reliance on the testimony of these experts cast doubt on the validity of its allegations.

The Board recognizes a patient's right to seek alternative or non-standard therapy and that physicians may provide such therapy. The alternative therapy provided by Dr. Burzynski during the period at issue has since become more accepted and mainstream. During the hearing, Staff took the position that the applicable standard of care regarding Dr. Burznyski's treatments was what was in effect at the time he provided the treatment, even if that treatment protocol has since become accepted in the medical community. Such an approach as taken by Staff would appear to discourage innovation in the treatment of advanced cancers.

In this context, based on the evidence, the Administrative Law Judges (ALJs) find that Staff proved some, but not most, of its allegations against Dr. Burzynski. The ALJs further find that there are mitigating and aggravating factors that the Board may consider in issuing a final decision.[3]

[3] Pursuant to Code § 164.007(a-1), the ALJs make findings of fact and conclusions of law, but do not make any recommendation regarding the appropriate sanction, if any, to impose.

I. JURISDICTION, NOTICE, AND PROCEDURAL HISTORY

The parties did not contest notice or jurisdiction except as discussed below.

On December 11, 2013, Staff filed an 8-page Complaint with the State Office of Administrative Hearings (SOAH). On July 10, 2014, Staff submitted a 202-page First Amended Complaint substantially increasing the charges alleged against Respondent. In response, Respondent filed an answer asserting two affirmative defenses: (1) collateral estoppel[4] and (2) lack of statutory authority to pursue claims regarding alleged violations of a clinical trial approved by the Food and Drug Administration (FDA) where there is no federal finding of a violation of federal law. On November 14, 2014, Staff filed a 48-page Second Amended Complaint (the Complaint) that contains Staff's notice of the current allegations against Respondent.

On August 21, 2014, Respondent filed a motion for summary disposition requesting that Staff's claims relating to alleged violations of federal regulations be dismissed. In response, Staff argued, among other things, that Texas Occupations Code (Code) §§ 164.052(a)(5) and 164.053(a)(1) authorizes the Board to sanction a licensee for any violation of state or federal law. The ALJs issued Order No. 7 on September 10, 2014, granting the motion in part. Pursuant to 22 Texas Administrative Code (TAC) § 190.8(2)(R), only alleged violations of the FDA-regulations that are criminal in nature are subject to disciplinary action by the Board under this section.[5] Staff did not assert any criminal violations, therefore any allegations related to 22 TAC § 190.8(2)(R) were disposed in Respondent's favor.

The hearing on the merits convened on November 19 through 20 and 23 through 25, 2015, January 19 and May 3 through 6, and 9 through 12, 2016, before ALJs Catherine Egan and

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[4] Respondent referenced Order No. 12 issued April 4, 2012, in SOAH Docket No. 503-11-1669, *Texas Medical Board v. Burzynski.*

[5] Order No. 7 (Sept. 9, 2014).

Roy G. Scudday in the William P. Clements Building, 300 West 15th St., Austin, Texas.[6] Attorneys Lee Bukstein, Amy Swanholm, Barbara Jordan, and Christopher Palazola represented Staff.[7] Attorneys Dan Cogdell, J. Dennis Hester, J. Gregory Myers, and Melanie Rubinsky represented Respondent. The record closed on August 15, 2016, with the filing of the parties' closing arguments and highlighted exhibits.[8]

II. BACKGROUND, ALLEGATIONS, AND APPLICABLE LAW

A. Background

1. Dr. Burzynski

Before immigrating to the United States in 1970, Respondent graduated from medical school in Poland in 1967 and received a Ph.D. in biochemistry in 1968. Between 1970 and 1977, Dr. Burzynski worked at Baylor College of Medicine doing cancer research. While there, he received funding from the National Cancer Institute to research the link between peptides in blood and cancer growth.[9] According to Dr. Burzynski, he has authored over 300 publications dealing with cancer and cancer research; however, many were not published in peer-reviewed publications.[10] He is a member of the American Medical Society, New York Academy of Sciences, and the American Academy of Medical Ethics, among other organizations.

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[6] During the proceeding, Dr. Burzynski's cardiac health issues required a delay in reconvening the hearing from January 19 to May 2016. On May 3, 2016, ALJ Egan had to leave the hearing due to a family emergency. The parties elected to proceed with the hearing with the understanding that ALJ Egan would read the transcript for that portion of the hearing that she was unable to attend. ALJ Egan affirms she has read the May 3, 2016 transcript.

[7] Mr. Bukstein retired from the Texas Medical Board (Board) and did not appear in this proceeding after January 19, 2016. Ms. Swanholm took over as Staff's lead counsel.

[8] Order No. 36 (Aug. 2, 2016).

[9] Tr. Vol. 7 at 30.

[10] Tr. Vol. 7 at 31, 36-37.

2. The Clinic

In 1977, Dr. Burzynski opened the Burzynski Clinic (Clinic), a private medical practice in Houston, Texas, to treat cancer patients.[11] Dr. Burzynski testified that approximately 95% of the Clinic's cancer patients have a terminal diagnosis. Many Clinic patients had tried conventional cancer treatment without success.[12] Beginning in 1990, Dr. Burzynski began adding gene-oriented treatment with personalized treatment to the Clinic's cancer patients. He explained that instead of treating the type of the cancer, he treats the cause of the cancer—the abnormal genes.[13] In his opinion, the "clue to success is a combination of a number of gene-targeted agents," sometimes using four or five gene-targeted agents.[14]

During the relevant periods from 2000 to 2013, the Clinic employed approximately 150 people.[15] This included three board-certified oncologists, Drs. Jai Joshi, Jose Valladares and Zanhua Yi; two internists, Drs. Robert Weaver and Gregory Burzynski; and one family practitioner, Dr. Alejandro Marquis.[16] All six were licensed to practice medicine in Texas during the time pertinent to this case. The Clinic also hired unlicensed foreign-trained doctors to assist the physicians as research associates. The Clinic assigned each patient to a team of health care providers that included an oncologist, an internist or family practitioner, and a research associate, all of whom met with the patient and Respondent at the initial consultation to discuss treatment options.[17]

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[11] Tr. Vol. 7 at 33.

[12] Tr. Vol. 7 at 36-37.

[13] Tr. Vol. 7 at 34.

[14] Tr. Vol. 7 at 34-35.

[15] Tr. Vol. 7 at 72.

[16] Tr. Vol. 7 at 72-74.

[17] Tr. Vol. 7 at 81-82.

3. Burzynski Research Institute/Institutional Review Board (BRI/IRB)

Dr. Burzynski testified that, based on his prior research, he discovered chemicals in the blood with anticancer activities.[18] In 1993, the FDA approved a clinical trial for the investigational drug, antineoplaston (ANP), in the treatment of cancer patients.[19] Over the years, Dr. Burzynski estimated, he engaged in 65 prospective clinical trials and one retrospective clinical trial.[20] Dr. Burzynski testified that BRI, of which he is the president and the owner of 80% of the shares, was created in 1983 to sponsor ANP clinical trials. According to Dr. Burzynski, BRI is not engaged in the practice of medicine.[21]

Dr. Burzynski testified that IRB was also created in 1983, but it is a separate entity from BRI. IRB was created to supervise the ethical conduct of clinical studies by approving or disapproving clinical trial protocols; to collect data on the toxicity and the response of the investigational agent; and to evaluate data on the efficacy of the investigational agent ANP.[22] IRB is not in the business of practicing medicine.[23] Neither Dr. Burzynski nor any of the Clinic's employees is a member of IRB. The IRB consists of 14 members. Carlton Hazelwood, M.D., a retired professor of pediatrics and physiology at the Baylor College of Medicine, is IRB's chairman.[24] Dr. Burzynski testified that he had no role in the selecting the board members.[25]

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[18] Tr. Vol. 7 at 33.

[19] Tr. Vol. 7 at 63.

[20] Tr. Vol. 7 at 45.

[21] Tr. Vol. 7 at 51-52.

[22] Tr. Vol. 7 at 41-42.

[23] Tr. Vol. 7 at 64.

[24] Tr. Vol. 7 at 41-43.

[25] Tr. Vol. 7 at 43.

B. Staff's Allegations

Staff's allegations cover a period from 2000 through 2013. The issues in this case center on Respondent's cancer treatments, the marketing of his treatments, and his management of the Clinic's personnel and the clinical trials.[26] Staff's allegations against Respondent can be divided into the following general categories:

(1) Failing to treat Patients A through G according to the generally accepted standard of care;

(2) Engaging in unprofessional and dishonorable conduct that was likely to deceive the public by:

- failing to properly supervise unlicensed and unqualified medical personnel; improperly delegating professional medical responsibility to unlicensed personnel; and misleading patients about the Clinic's personnel;
- failing to provide adequate written informed consents for patients to review and sign;
- failing to disclose his ownership interest in pharmacies and a laboratory;
- overcharging patients; and
- deceptively marketing and advertising the Clinic's cancer treatments; and

(3) Violating ethical and professional responsibilities by:

- failing to protect patients in clinical trials, specifically Patients G and I through BB;
- engaging in unethical treatment of Patients A through F;
- treating Patients H through P without proper BRI-IRB approval;
- reporting inadequate or inaccurate therapeutic responses for Patients G and Q through BB;

[26] The ALJs will address the treatment dates that are in issue for each patient raised by the parties in their closing arguments. Order No. 34 (June 6, 2016).

- failing to train subordinates adequately about adverse events for Patients G and Q through U;
- failing to evaluate and report Patient G's reactions to corticosteroids and failing to inform her of additional costs imposed by the Clinic;
- providing inadequate or inaccurate case history for Patient CC; and
- violating federal regulations as the clinical investigator.

C. Applicable Law

The Board may take disciplinary action against a licensed physician who has violated a Board rule or the Code or failed to practice medicine in an acceptable professional manner consistent with public health and welfare.[27] Disciplinary actions include revocation, suspension (including a probated suspension), or reprimand.[28] Staff's allegations are based on the following provisions of the Act and the Board's rules:

1. Statutory Grounds for Disciplinary Action

Code § 164.052 states that a physician commits a prohibited practice, subjecting the physician to disciplinary action under Code § 164.051, if the physician engages in "unprofessional or dishonorable conduct that is likely to deceive or defraud the public or injure the public;"[29] uses false, misleading, or deceptive advertising;[30] or directly or indirectly aids or abets an unlicensed person in the practice medicine.[31] Code § 164.053 defines unprofessional or dishonorable conduct likely to deceive or defraud the public to include conduct in which the physician:

(1) commits an act that violates any state or federal law if the act is connected with the physician's practice of medicine;

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[27] Code § 164.051(a)(3),(6).

[28] Code §§ 164.001(a), .051(a).

[29] Code § 164.052(a)(5).

[30] Code § 164.052(a)(6).

[31] Code § 164.052(a)(17).

. . .

(5) prescribes or administers a drug or treatment that is nontherapeutic in nature or nontherapeutic in the manner the drug or treatment is administered or prescribed;

(6) prescribes, administers, or dispenses in a manner inconsistent with public health and welfare:

(A) dangerous drugs as defined by Chapter 483, Health and Safety Code; or

(B) 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.);

(7) violates Section 311.0025, Health and Safety Code;[32]

(8) fails to supervise adequately the activities of those acting under the supervision of the physician; or

(9) delegates professional medical responsibility or acts to a person if the delegating physician knows or has reason to know that the person is not qualified by training, experience, or licensure to perform the responsibility or acts.

According to Code § 157.001, a physician may delegate to a qualified and properly trained person any medical act so long as the person is acting under the physician's supervision and does not represent to the public that the person is authorized to practice medicine. The delegating physician is responsible for "the medical acts of the person performing the delegated medical acts."[33]

2. Board Rules

Board Rule 165.1 requires licensed physicians to maintain adequate medical records for each patient that are "complete, contemporaneous, and legible."[34] The patient's medical record must document, among other things, the following: (1) the reason for each visit, the patient's

[32] Texas Health & Safety Code § 311.0025(a) states that a health care professional may not submit to a patient a bill for treatment that the professional knows was not provided or knows was improper, unreasonable, or medically or clinically unnecessary.

[33] Code § 157.001(b).

[34] 22 TAC § 165.1.

relevant history, the physical examination findings, and prior diagnostic test results; (2) the physician's assessment, clinical impression, or diagnosis; (3) the plan of care; and (4) the date and "legible identity of the observer."[35] In addition, medical records should include, among other things, past and present diagnoses; the physician's rationale for and the results of diagnostic and other ancillary services; the patient's progress and response to treatment; and the relevant risk factors.[36]

As noted above, physicians are subject to sanctions for failing to practice medicine in an acceptable professional manner consistent with public health and welfare.[37] According to 22 TAC § 190.8(1), this includes, but is not limited to:

- failure to treat a patient according to the generally-accepted standard of care;[38]
- negligence in performing medical services;[39]
- failure to use proper diligence in one's professional practice;[40]
- failure to safeguard against potential complications;[41]
- failure to disclose reasonably foreseeable side effects of a procedure or treatment;[42]
- failure to disclose reasonable alternative treatments to a proposed procedure or treatment;[43] and
- 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,

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[35] 22 TAC § 165.1(a)(1)(A)-(D).

[36] 22 TAC § 165.1(a)(2)-(5).

[37] Code § 164.051(a)(6).

[38] 22 TAC § 190.8(1)(A).

[39] 22 TAC § 190.8(1)(B).

[40] 22 TAC § 190.8(1)(C).

[41] 22 TAC § 190.8(1)(D).

[42] 22 TAC § 190.8(1)(G).

[43] 22 TAC § 190.8(1)(H).

treatments, procedures, or autopsies as required under Chapter 49 of the Code of Criminal Procedure;[44]

Unprofessional and dishonorable conduct that is likely to deceive, defraud, or injure the public includes:

- referring a patient to a facility, laboratory, or pharmacy without disclosing the existence of the licensee's ownership interest in the entity to the patient;[45] and

- 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.)[46]

3. Board Rules Regarding Clinical Investigations

Physicians engaged in the clinical investigation of new drugs and procedures must comply with the ethical and professional responsibilities set out in Board Rule 200.3(7). Specifically, physicians are expected to conform to the following ethical standards:

(A) Clinical investigations, medical research, or clinical studies shall be part of a systematic program competently designed, under accepted standards of scientific research, to produce data that are scientifically valid and significant;

(B) A clinical investigator shall demonstrate the same concern and caution for the welfare, safety and comfort of the patient involved as is required of a physician who is furnishing medical care to a patient independent of any clinical investigation; and

(C) A clinical investigator shall have patients sign informed consent forms that are compliant with federal regulations, if applicable, and that indicate that the patients understand that they are participating in a clinical trial or investigational research.

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[44] 22 TAC § 190.8(1)(I).

[45] 22 TAC § 190.8(2)(H).

[46] 22 TAC § 190.8(2)(J).

4. Aggravating and Mitigating Factors

The Board's rules set out certain specified aggravating and mitigating factors relevant to determining whether more or less severe or restrictive action by the Board is warranted. Staff has the burden to present evidence regarding any aggravating factors that may apply in a particular case, and the physician has the burden to present evidence regarding any mitigating factors that may apply.[47]

III. OVERVIEW OF THE EVIDENCE

A. Staff's Evidence

Staff initially offered 68 volumes of exhibits into evidence, but later reduced its exhibits to 59 volumes of documents that were admitted into evidence. Staff's exhibits included, among other things, the medical records for Patients A through G, 29 depositions, and portions of the medical records for Patients H through DD. Staff also called the following witnesses:

- Norman Fost, M.D., M.P.H, a licensed pediatrician and bioethicist called as an expert witness;
- Elaine Kloos, R.N., NE-BC, MBA, a health care professional called as an expert witness;
- Cynthia Jean Wetmore, M.D., Staff's oncology expert;
- Patient F;
- Patient F's wife; and
- Patient A's wife.

B. Respondent's Evidence

Respondent introduced 28 exhibits that were admitted into evidence. Respondent also called the following witnesses:

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[47] 22 TAC § 190.15.

- Tomasz Janicki, M.D., Director of Medical Documentation of the Clinic and Vice President of Clinical Trials, called as an expert witness;
- Mark Levin, M.D., Respondent's oncology expert;
- Dr. Burzynski, who testified as both a fact witness and an expert witness;
- Gregory Burzynski, M.D., Dr. Burzynski's son and the Clinic's internist;
- Mary Michaels, the mother of a pediatric patient;
- Mary Jo Siegel; a patient;
- Mary Susan McGee; the mother of a pediatric patient;
- Lourdes DeLeon; a research associate at the Clinic;
- Alejandro F. Marquis, M.D. a family practitioner at the Clinic;
- Margaret Manning, a patient; and
- Robin Ressel, the mother of a pediatric patient.

C. The Experts

Staff called three expert witnesses to testify. Staff called Dr. Fost as an expert in physicians' ethical and professional responsibilities during a clinical investigation.[48] Ms. Kloos was designated as Staff's expert in medical billing practices.[49] Dr. Wetmore was designated as Staff's expert in the standard of care in the treatment of primarily adult cancer patients.[50] Respondent called two expert witnesses to testify: Dr. Janicki, designated as an expert in FDA-approved clinical trials for ANP;[51] and Dr. Levin, designated as an expert in the standard of care of treatment of cancer patients in a private setting.[52] Respondent also provided expert testimony

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[48] Dr. Fost's prefiled testimony was admitted into evidence as Staff Ex. 68.01.

[49] Ms. Kloos's prefiled testimony was admitted into evidence as Staff Ex. 68.02.

[50] Dr. Wetmore's prefiled testimony was admitted into evidence as Staff Ex. 68.03.

[51] Dr. Janicki's prefiled testimony was admitted into evidence as Resp. Ex. 158.

[52] Dr. Levin's prefiled testimony was admitted into evidence as Resp. Ex. 165.

regarding the standard of care; however, his testimony will be considered when addressing Staff's specific allegations.

1. Staff's Experts

a. Dr. Fost

Dr. Fost is a Wisconsin board-certified pediatrician and a bioethicist.[53] He completed his residency in 1967, was chief resident at Johns Hopkins Hospital from 1969 through 1971, and was an assistant professor in the Department of Pediatrics at Johns Hopkins Hospital from 1971 through 1973. Dr. Fost has been associated with the University of Wisconsin since 1973 in a number of positions including assistant professor in the Department of Pediatrics, Director of the Program in Bioethics, Professor of Pediatrics and Medical History & Bioethics, Chair of the Bioethics Advisory Committee, and Vice Chair of the Department of Medical History & Bioethics.[54] Dr. Fost is a member of the American Academy of Pediatrics, the American Society of Human Genetics, and the American Society of Bioethics and Humanities.[55] While at the University of Wisconsin, Dr. Fost practiced pediatric clinical medicine until June 2014.[56] Dr. Fost does not have specialty training in the treatment of patients with cancer.[57] He has served as a member of several institutional research boards, including as the chair of the University of Wisconsin Health Science Center's Institutional Review Board for 31 years.[58] He has never been a principal investigator in a cancer clinical trial.[59]

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[53] Staff Ex. 61.B.4 at 45152; Staff Ex. 68.01 at 1.

[54] Staff Ex. 61.B.4.

[55] Staff Ex. 61.B.4 at 45159.

[56] Staff Ex. 68.01 at 3.

[57] Tr. Vol. 1 at 97.

[58] Staff Ex. 68.01 at 4-5.

[59] Tr. Vol. 1 at 112-113.

b. Ms. Kloos

Ms. Kloos is a registered nurse and a certified Nurse Executive. She has worked over twenty years in oncology administration and women's health services at Shumpert Medical Center in Shreveport, Louisiana; Monmouth Medical Center in Long Branch, New Jersey; Hunterdon Medical Center in Flemington, New Jersey; Roper Saint Frances Healthcare in Charleston, South Carolina; and for the last nine years at the Oncology Management Consulting Group in Pipersville, Pennsylvania.[60] Ms. Kloos is a member of the Association of Cancer Executives.[61] She has been responsible for financial coding and billing for oncology centers since 1991, and is familiar with Current Procedural Terminology (CPT) codes and the CPT manual that are used for billing of medical services.[62]

c. Dr. Wetmore

Dr. Wetmore is board-certified in pediatrics and in pediatric hematology/oncology/bone marrow transplant.[63] She completed her residency in 1997, and was a professor at the Mayo Medical School and a consultant in the Department of Pediatrics at the Mayo Clinic from 2002-2010.[64] Since 2014, Dr. Wetmore has been the Director of the Center for Clinical and Translational Research for the Department of Pediatrics at Emory University School of Medicine where she cares for oncology patients in the outpatient as well as inpatient setting.[65] Dr. Wetmore is a member of the Medical Advisory Board for the Make-A-Wish Foundation, the Development Therapeutics Committee of the Children's Oncology Group, and the Lifespan Domain Task Force of the National Center for Advancing Translational Science.[66]

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[60] Staff Ex. 61.C.5 at 45222-45223.

[61] Staff Ex. 61.C.5 at 45223.

[62] Staff Ex. 68.02 at 2.

[63] Staff Ex. 68.03 at 4.

[64] Staff Ex. 61.A.3 at 45106.

[65] Staff Ex. 68.03 at 3.

[66] Staff Ex. 61.A.3 at 45107.

Dr. Wetmore is a pediatric oncologist and has not been the primary treating physician for adults with colon cancer,[67] mesothelioma,[68] kidney cancer,[69] or pancreatic cancer.[70] She stated that in preparation for her involvement in this case she relied on the National Comprehensive Cancer Network (NCCN) guidelines that pertained to the cancers Patients A through G and other adult patients had to form her opinions. However, the NCCN guidelines Dr. Wetmore relied on that were admitted into evidence were not published during the time these patients were being treated.[71]

The ALJs note that Dr. Wetmore also testified that Patient D "did not receive the standard of care and was exposed to medications that are not documented to cross the blood brain barrier . . . ."[72] She stated that Respondent had violated the standard of care in treating Patient D by failing to allow a "wash-out" period after discontinuing one drug before beginning another.[73] Contrary to Dr. Wetmore's testimony and report, Patient D received no treatment or therapy at the Clinic.[74]

2. Respondent's Experts

a. Dr. Levin

Dr. Levin is board-certified in internal medicine, oncology, and hematology. He completed his residency in 1987, and has practiced medical oncology and hematology in a variety of settings, including several academic institutions, for over 25 years.[75] He has served as

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[67] Tr. Vol. 3 at 28.

[68] Tr. Vol. 3 at 27-28.

[69] Tr. Vol. 3 at 20.

[70] Tr. Vol. 3 at 28.

[71] Tr. Vol. 3 at 99; Staff Ex. 63.

[72] Staff Ex. 68.03 at 49.

[73] Staff Ex. 68.03 at 48; Tr. Vol. 3 at 22.

[74] Tr. Vol. 3 at 22.

[75] Resp. Ex. 165 at 1.

the Chief of Hematology and Oncology at the Lincoln Medical Center; Director of the Hereditary Cancer Clinic and Director of Clinical Research at Holy Name Hospital; Acting Chief of Hematology and Oncology at the University Hospital in Newark, New Jersey; Director of the Sister Patricia Lynch Regional Medical Cancer Center at Holy Name Hospital; and the Director of the Cancer Center at the Generations and Northern Manhattan Network of the Health and Hospitals Corporation of New York City.[76]

Dr. Levin is currently in private practice in Cliffside Park, New Jersey.[77] He is President of Medical Review and Information Center, a consulting company, and is Chief Trustee of Knowledge is Power, a non-profit that supports a cancer information website and cancer education outreach.[78] He consults with insurance companies and hospitals, is certified in utilization review and quality assurance, and has conducted reviews of hundreds of oncology practices, similar to what he is doing in this case.[79]

Dr. Levin recognized Dr. Wetmore's expertise in pediatric oncology, but questioned her expertise in medical oncology (treating adult patients). According to Dr. Levin, medical oncology and pediatric oncology are two different medical specialties. He explained that adult cancers, such as renal cancer, colon cancer, pancreatic cancer, mesothelioma, and glioblastoma are rare among children. Similarly, most pediatric cancers are rare among adults. He stressed that even cancers that both children and adults experience, such as brain cancer, have different histologies and different standards and clinical approaches to treatment. Other differences exist between the two specialties. Typically, Dr. Levin noted, pediatric oncologists work in an academic practice setting (universities or research hospitals), but most medical oncologists work in a private practice setting. In addition, most children with cancer, he explained, are enrolled in Children's Oncology Group's clinical trials or other trials, but less than 2 to 5% of adult cancer patients are enrolled in clinical trials.[80]

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[76] Resp. Ex. 118 at 4.

[77] Resp. Ex. 118 at 6.

[78] Resp. Ex. 118 at 6.

[79] Resp. Ex. 165 at 3-4.

[80] Resp. Ex. 165 at 9.

b. Dr. Janicki

Dr. Janicki was licensed to practice medicine in Poland in 1992 and practiced in the pediatric cardiology and cardio-surgery department of the Hospital of Wroclaw from 1993-1996.[81] Dr. Janicki is not licensed to practice medicine in the United States. Beginning in 1997 he became Director of Medical Documentation for the Clinic, and in 2012 he was appointed vice president of Clinical Trials at the BRI.[82] He has been involved with the FDA-approved clinical trials for ANP since the late 1990's.[83]

IV. STANDARD OF CARE

The ALJs will discuss the issues using the outline set forth in the ALJ's Order No. 34, where possible, with the specific subjects addressed under the allegation most clearly applicable. The ALJs will add a brief summary of the patient's relevant medical history where appropriate. However, before discussing the specific allegations, the ALJs will address the weight to be given to the testimony of the oncology experts.

Dr. Wetmore's testimony regarding Patient D is troubling. According to Dr. Wetmore, she reviewed the Clinic's medical records carefully before preparing her expert report and her prefiled testimony. Yet, she accused Respondent of violating the standard of care in his treatment of Patient D, when Patient D received no treatment at the Clinic. Such inattentiveness to the accuracy of her report raises concerns about her credibility.

Dr. Wetmore is an accomplished oncologist, but her primary focus has been in pediatric medicine, not in treating adult patients with cancer. Her oncology practice has been in academic settings as reflected on her CV, and there is little evidence to show that she has practiced oncology in a private practice setting. Therefore, the ALJs find that Dr. Wetmore's expertise

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[81] Resp. Ex. 120 at 1.

[82] Resp. Ex. 120 at 1.

[83] Resp. Ex. 158 at 2.

about the treatment of adult cancer and the standard of care used by physicians in private practice is limited and will be given little weight.

A. General Allegations Regarding Patients A through G

Patients A through G were adult patients with terminal (Stage III and IV) cancer treated during the period from 2009 through 2012. Patient A was diagnosed with Stage IV colon cancer. Patients B, D, and G were diagnosed with brain cancer. Patient C was diagnosed with mesothelioma. Patient E had kidney (renal) cancer, and Patient F had Stage IV pancreatic cancer. Although none of these patients were enrolled in a clinical trial, Patient G was treated with ANP under an FDA-approved single patient protocol BT-09.[84] Patients A, B, C, E, and F were treated with sodium phenylbutrate (PB) in combination with other chemotherapy drugs, but were not treated with ANP. Patient B was treated with ANP in Germany by his local oncologist.[85]

1. Potential Toxicities of Combined Drugs

Staff argues that Respondent violated the standard of care and engaged in non-therapeutic prescribing by failing to "articulate a medical rationale for the initial treatment, the subsequent changes to this treatment, and for the decision to continue or discontinue the treatment." The parties agreed that "off-label" use of chemotherapy drugs and targeted agents is medically accepted and can be within the standard of care. In fact, the NCCN estimated that, in 2005, "50 percent to 75 percent of all uses of cancer therapy were off-label."[86] According to Dr. Wetmore, the standard of care in medicine is "what a reasonable physician would do in the same or similar circumstances."[87] She stated that when the cancer treatment involves the use of multiple anti-cancer agents, the physician must document an adequate rationale for the treatment plan, for any

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[84] Staff Ex. 7.01 at 2449-2464.

[85] Appendix A to this PFD sets forth a list of the brand and generic names of the drugs referred to in the PFD. For this PFD, the ALJs will use the brand name where possible.

[86] Tr. Vol. 11 at 158-159.

[87] Staff Ex. 68.03 at 8.

changes in the treatment plan, and for discontinuing the treatment.[88] This medical rationale, she maintained, must be based on peer-reviewed scientific evidence of safety and efficacy.[89]

When combining drugs for off-label purposes, including concurrent combinations of cytostatic (stop cells from dividing) and cytotoxic (kill cells) medications, Dr. Wetmore said that, because there is serious risk of unknown side effects, it is essential that patients receiving such drugs or combination of drugs be adequately monitored for any potential side effects.[90] In her opinion, Respondent failed to document his medical rationale for using multiple anti-cancer agents and failed to properly monitor the patients.

In addition, Dr. Wetmore testified that Respondent failed to meet the standard of care when he changed the patient's treatment without allowing time for the discontinued drug to "wash-out" of the patient's body before beginning another toxic drug. As an example, Dr. Wetmore testified that Respondent prescribed Avastin, a drug which stays in a patient's bloodstream for more than a month, to Patients A, B, C, and F. She stated that the standard of care requires waiting six weeks for Avastin to clear the body before starting treatment with another drug. Dr. Wetmore explained that this "wash-out" period is necessary to prevent harm and/or more toxicity to the patient from having both toxic medications in the body. Dr. Wetmore testified that Respondent discontinued the Avastin and started another drug without waiting for the Avastin to wash out of the patients' systems, and consequently exposed these patients to increased toxicity and adverse events.[91]

Dr. Fost referred to Respondent's treatment protocol as "innovative therapy" because the "drugs or combination of drugs" had not yet been studied for safety and efficacy. Consequently, Dr. Fost opined, Respondent exposed these patients to a substantial risk of harm.[92] Staff accepts that innovative therapy is not necessarily substandard care. However, Staff alleged that

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[88] Staff Ex. 68.03 at 9, 18.

[89] Staff Ex. 68.03 at 30.

[90] Staff Ex. 68.03 at 18.

[91] Staff Ex. 68.03 at 18-19.

[92] Staff Ex. 68.01 at 22-23.

Respondent failed to meet the basic standard of care requirements to show that the treatments were supported by rational, credible research and general consensus among physicians.[93]

Dr. Levin disagreed with Staff. He explained that Respondent provides personalized treatment for cancer patients based on genomic and chemo-sensitive tools that were analyzed to create a treatment plan unique to each patient. The pathways, not the name of the particular type of cancer the patient has, dictate the drugs to use. Dr. Levin acknowledged that this is a new treatment paradigm.[94] Except for Patient G, Patients A through C and E through F were being treated by Respondent with "Personalized or Precision Medicine" (personalized therapy) for terminally-ill cancer patients.[95] When using this approach, Dr. Levin clarified, the specific type of cancer (as well as the tumor's histology or morphology) is less important than "what targets, pathways, proteins, and other specific alterations the patient's tumor expresses."[96]

In Dr. Levin's opinion, personalized therapy is a reasonable medical approach for the treatment of advanced stages of cancer, and noted that this approach "has been around for the past half of a dozen years."[97] Dr. Levin also took issue with Dr. Wetmore's claim that failing to have a wash-out period when Respondent changed a patient's medication constituted a standard of care violation. He testified that the term "wash-out" is a research concept and is irrelevant in a clinical setting. Dr. Levin testified that when doing research "it is important to allow the previous drug to "wash out" so that, if there is a response to the experimental drug, the assessment is not compromised by . . . the effects of the prior drug."[98]

Dr. Levin stated that the use of PB outside of clinical trials is rare. However, he pointed out that the Clinic had used PB for at least 10 years and that PB is closely related to ANP, the drug Respondent invented. Moreover, the Clinic's patients typically had no curative treatment

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[93] Staff's Closing Argument at 5.

[94] Resp. Exs. 119 at 1; 165 at 24.

[95] Resp. Ex. 165 at 24-25.

[96] Resp. Ex. 165 at 28.

[97] Resp. Ex. 165 at 25.

[98] Resp. Ex. 165 at 10-11.

options left.[99] At this point, Dr. Levin opined, it is "the physician's duty, in consultation with the patient, to come up with the best possible treatment based on, in part, the physician's prior experience."[100] When based on the physician's prior experience, literature, and therapeutic rationale, the use of multiple targeted agents and other cancer drugs in advanced stage cancer patients is quite common, according to Dr. Levin.[101]

2. Inadequate Medical Rationale for Treatment with ANP, PB, and/or the Combined Use of Drugs

Staff asserts that Respondent violated the standard of care because he did not provide an adequate medical rationale for the use of ANP, PB, or combinations of drugs. As testified by Dr. Wetmore, the basic requirements of adequate medical rationale must include an adequate treatment plan clearly stating drug name, dose, and route of administration and monitoring. She stated that a physician must document an adequate medical rationale for nonstandard and unevaluated doses and combinations of cytostatic and cytotoxic medications. In her review of the patients' medical records, Dr. Wetmore concluded that for Patients A, B, C, D, E, and F, Respondent did not provide an adequate treatment plan documented in the medical records by listing the planned dosage for medications, addressing the reason for changes in dosages without any rationale or consideration of adverse side effects, making unreliable and inaccurate determinations of treatment response, and initiating and/or discontinuing the medications administered without giving a reason.[102]

Dr. Wetmore testified that the plasma tests Respondent required were not medically necessary because the tests needed to be performed on tumor tissue as opposed to blood.[103] However, she agreed that the use of blood biopsies for analysis of proteins as well as DNA is an

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[99] Resp. Ex. 165 at 32.

[100] Resp. Ex. 165 at 32.

[101] Resp. Ex. 165 at 34.

[102] Staff Exs. 61.01(A); 68.03 at 47.

[103] Tr. Vol. 4 at 29.

emerging trend, but only on an exploratory basis.[104] In regard to requiring blood tests, Dr. Levin testified that, while it is not common to use blood tests to detect targets, it is reasonable to use this type of testing to determine what drugs to utilize in patient treatment. This is particularly reasonable for terminally-ill patients because it can take weeks to get the results of tumor testing.[105]

Dr. Burzynski explained the phases of FDA clinical trials as follows: (1) Phase I clinical trials assess toxicity and try to determine the highest tolerated dose; (2) Phase II clinical trials seek to find out the treatment effectiveness based on the shrinkage of the tumor; and (3) Phase III clinical trials compare the effectiveness of the investigational medication and treatment with the best available conventional treatment based on survival rates.[106] He stated that ANP, which he discovered, affects approximately 100 genes that can cause cancer, which is enough to effectively treat some cancer, but not others.[107]

Dr. Burzynski testified that blood tests support the medical rationale for treatment because it identifies the proteins produced by genes, known as genetic markers, and finds fragments of abnormal genes that are causing cancer. He stated that this form of testing is easier because it does not require surgery to obtain tissue. In his opinion, this is less invasive, less expensive, and provides more information about cancer in the entire body.[108]

According to Dr. Burzynski, PB affects the group of enzymes called HDAC, which turns off the activity of tumor suppressor genes and promotes cancer.[109] Citing to a study of PB in the treatment of advanced cancer conducted by Dr. J. Gilbert, et.al., Dr. Burzynski testified that PB inhibits cancer cell division or multiplication.[110] He pointed out that the FDA has recognized

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[104] Tr. Vol. 14 at 81, 100.

[105] Resp. Ex. 165 at 46.

[106] Tr. Vol. 7 at 66-68.

[107] Tr. Vol. 7 at 72.

[108] Tr. Vol. 7 at 89-92.

[109] Tr. Vol. 7 at 98-99.

[110] Tr. Vol. 7 at 104-105.

that possibility that PB may be effective for treatment of malignant brain tumors and certain types of aggressive leukemia.[111]

As noted above, Dr. Levin testified that it is accepted in medical oncology to provide personalized or precision medicine outside of clinical trials even though the drugs used have not been tested together and are not part of an NCCN treatment recommendation. Dr. Levin explained that if a physician prescribed a targeting agent known to affect a particular pathway, then it was obvious to him, as a private practice oncologist, the reason why the drug was utilized. He was of the opinion that the standard of care does not require the physician to document that he prescribed drug X because it affects a certain pathway, and that the medical rationale is readily understood by medical oncologists.[112]

3. Inadequate Medical Rationale for the Evaluation, Diagnosis, and Treatment of the Patients

As noted above, Dr. Wetmore testified that the basic requirements of an adequate medical rationale include the following: (1) the treatment must be predicated on adequate histological diagnosis and pathologic confirmation of the cancer; (2) there must be an adequate and complete physical examination including mental status examination at each visit and prior to administering therapy, and (3) there must be an adequate treatment plan.[113] She maintained that establishing a baseline for a patient's mental function is critical when evaluating treatment for brain cancer.[114] She testified that an adequate mental status exam requires a general orientation to person, place, and time; an understanding of the diagnosis and purpose for which the patient is being seen; verification of the patient's ability to make decisions for themselves; the ability of the patient to take medication as prescribed; the awareness of the risks and side effects of medication; and the patient's frame of mind and general psychiatric condition.[115]

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[111] Tr. Vol. 7 at 99.

[112] Tr. Vol. 11 at 162-163.

[113] Staff Ex. 68.03 at 10-11.

[114] Staff Ex. 68.03 at 44.

[115] Staff Ex. 68.03 at 11.

Dr. Levin disagreed with Dr. Wetmore's opinion. He testified that it was not necessary or usual to perform a formal mental exam on a cancer patient unless the physician has some indication that the patient is not properly oriented. In his opinion, the interaction of the physician with the patient and family members is normally sufficient to determine whether the patient is adequately oriented to understand and consent to treatment.[116]

4. Inadequate Medical Documentation

Ms. Kloos reviewed the medical records for Patients A through G that Staff made available to her in order to determine whether they could support the CPT billing codes. She testified that she found numerous medical recordkeeping deficiencies. She noted that many of the medical records did not contain signatures, dates, or times of service from the provider who was seeing the patient.[117] Ms. Kloos testified that medical billing records must be authenticated by the provider to ensure the services rendered were accurately and appropriately documented, reviewed, and authenticated.[118]

In her expert report, Dr. Wetmore opined that the medical records for Patients A through G were inadequate, inconsistent, and missing portions. She stated that many pages had no date and time of service and that it was often impossible to tell who provided the care to a patient. For medications administered, it was unclear to her what dosage a patient received, the frequency of administration, and the concentration (for infusions). Handwritten orders were often unclear, improper, and used non-standard language when prescribing the chemotherapy drugs. She found numerous pages missing from the records she reviewed, such as progress notes. There was no underlying imaging for most of the diagnostic scans ordered by the Clinic, as well as imaging ordered prior to the patients' appearing at the Clinic. Imaging reports created by the Clinic

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[116] Resp. Ex. 165 at 41.

[117] Staff Ex. 68.02 at 11.

[118] Staff Ex. 68.02 at 103.

showed results inconsistent with outside radiology reports, with no explanation for the difference.[119]

Following his review of the medical records, Dr. Levin reported that the medical records of the Clinic were well organized, presented a clear picture, and contained all relevant laboratory, imaging, and pathology reports. He stated that he had no difficulty in understanding the development of the treatment plan over time, the basis for the treatment decisions, and the results for the treatment from the medical records of the Clinic.[120]

5. ALJs' Analysis

a. Potential Toxicities of Combined Drugs

Staff argued that, based on the testimony of Dr. Wetmore, Respondent violated the standard of care and engaged in non-therapeutic prescribing by failing to "articulate a medical rationale" for the initial treatment, subsequent treatment changes, and the decision to continue or discontinue the treatment. When combining drugs for off-label purposes, Dr. Wetmore stated that it was essential that patients receiving such drugs or combination of drugs be adequately monitored for any potential side effects.

The parties agree that "off-label" use of chemotherapy drugs and targeted agents is medically accepted and can be within the standard of care. Respondent argues that his medical rationale was based on the clinical judgment of the treating physicians, was explained to the patients with the potential risks and side effects discussed, and that the patients were monitored, all as reflected in the medical records. Additionally, Respondent asserts that the side effects were sufficiently documented in the written informed consent forms signed by the patients.

Dr. Wetmore stated that Respondent failed to meet the standard of care when each toxic drug used in the treatment of a patient was started without allowing time for the discontinued

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[119] Staff Ex. 61.01(A) at 45075, 45079, 45080-45081, 45085, 45087-45088, 45090-45091, 45092-45093.

[120] Resp. Ex. 165 at 43.

drug to "wash-out" of the patient's body. Dr. Levin disagreed that failing to have a wash-out period constituted a standard of care violation, because the term "wash-out" is a research concept and is irrelevant in a clinical setting, particularly when treating terminally ill cancer patients.

Staff alleged that Respondent failed to meet the basic standard of care requirements to show that the treatments were supported by rational, credible research and general consensus among physicians. Staff relied on Dr. Fost's testimony that Respondent exposed his patients to a substantial risk of harm because the drugs or combination of drugs had not yet been studied for safety and efficacy. Dr. Levin disagreed with Staff and asserted that Respondent's personalized treatment for cancer patients served to create a treatment plan unique to each patient. In Dr. Levin's opinion, personalized therapy is a reasonable medical approach for the treatment of advanced stages of cancer and, when based on the physician's prior experience, literature, and therapeutic rationale, the use of multiple-targeted agents, including PB and other cancer drugs, in advanced stage cancer patients is quite common for patients who were without curative treatment options, as were those patients of the Clinic.[121]

Dr. Levin's testimony was persuasive on this issue. The patients, for the most part, had received conventional treatment that had been unsuccessful. As noted by Dr. Levin, these patients had typically run out of treatment options when they appeared at the Clinic, or had chosen not to undergo further traditional treatments such as surgery, radiation, or conventional chemotherapy. The patients were made aware in the informed consent forms and in consultation with the treating physicians that the drugs and combinations of drugs could have side effects, both known and unknown. The medical records for the patients contain numerous accounts of discussions between the patients and Clinic personnel regarding side effects being experienced and changes in treatment to deal with those side effects. In addition, the research concept of a "wash-out" period so important to Dr. Wetmore is irrelevant in the private oncology clinic setting when treating patients with such poor prognoses. Accordingly, the ALJs do not find that

[121] Resp. Ex. 165 at 25.

Staff has established that there was a common failure to make Patients A through G aware of the potential toxicities of the combination of drugs.

b. Inadequate Medical Rationale for Treatment with ANP, PB, and/or the Combined Use of Drugs

Staff argued that Respondent prescribed nonstandard and unevaluated doses of multiple anti-cancer medications to these patients that went beyond the established off-label use of FDA-approved medications, without an adequate, documented medical rationale.

Respondent asserted that the medications chosen were based on one or more of the following factors: (1) type of cancer; (2) stage of cancer and curative options; (3) testing of malignant tissue that identified the affected pathway and medications with potential clinical benefits; (4) blood testing that measures proteins in the blood; (5) past experience and history with medications in the treatment of cancer; (6) case reviews and medical literature; and (7) the physician's training and clinical judgment.

However, Dr. Wetmore maintained that the patients' medical records did not meet the basic requirements of adequate medical rationale. She asserted that, in her opinion, the medical records must include adequate histological diagnosis and pathologic confirmation of the cancer; an adequate and complete physical examination; a treatment plan clearly stating the drug name, dose, and route of administration and monitoring; and documentation of an adequate medical rationale for nonstandard and unevaluated doses and combinations of cytostatic and cytotoxic medications.

As noted above, Dr. Levin disagreed that this standard as advocated by Dr. Wetmore is the generally accepted standard for private practice cancer clinics. He was of the opinion that the standard of care does not require the physician to document that he prescribed a certain drug because it affects a certain pathway because the rationale is understood by medical oncologists.

In regard to PB, Dr. Burzynski testified that PB affects the group of enzymes that turn off the activity of tumor suppressor genes and thus promote cancer. Dr. Levin supported this testimony, citing to what he considered to be a reliable and authoritative 2002 article in the Journal of Neuro-Oncology entitled "Complete Response of a Current, Multicentric Malignant Glioma in a Patient Treated With Sodium Phenylbutyrate." The article states, "Phenylbutyrate is a well-tolerated oral agent that shows potential for the treatment of malignant gliomas."[122] Dr. Burzynski testified that ANP adequately treats some cancers, but not others. The ALJs find this testimony to be persuasive.

As for the use of blood tests, the weight of the testimony is that they are more commonly used today, are less invasive, are less expensive, are quicker to analyze, and provide a more complete picture of the cancer.

Again, Dr. Levin's testimony appears to be more credible. He pointed out that it is accepted in medical oncology to provide personalized or precision medicine outside of clinical trials even though the use of drugs, such as ANP and PB, have not been tested together. He clarified that without a curative option, physicians in private practice have much greater flexibility in treating terminal patients and greater leeway in prescribing drugs. He stated that a private practice oncologist would understand the medical rationale for the specific drugs prescribed by the Clinic physicians. In addition, the use of blood tests by Respondent during the relevant period appears to now be a generally-accepted procedure. Accordingly, the ALJs do not find that Staff has established that there was a common failure to provide adequate medical rationale for treatment with ANP, PB, and/or the combined use of drugs to Patients A through G.

c. Inadequate Medical Rationale for the Evaluation, Diagnosis, and Treatment of the Patients

Staff argues that Respondent failed to meet the standard of care because the Clinic did not document an adequate and complete histological diagnosis of cancer and pathologic confirmation, an adequate and complete physical examination, and a mental status exam.

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[122] Tr. Vol. 11 at 166.

Staff asserts that although Patients A through G were given a physical exam on the first day the patients attended the Clinic, and sometimes on the patient's subsequent visits to the Clinic, there was no documentation of a physical exam aimed at the patient's area of concern. Staff argued that Respondent should have performed a physical evaluation of the patients each time a patient presented to the clinic, but that there is no documentation of anyone, licensed or unlicensed, performing physical evaluations of Patients A through G after the first day. Nor were physical exams performed when the patients were discharged from the Clinic. Staff asserts that this practice was inadequate to keep these patients' caregivers apprised of patients' progress, to monitor for potential side effects from the multiple drugs Respondent was prescribing and that were initiated during the patients' time at the clinic, and to address patients' documented complaints of physical symptoms while present at the Clinic. Staff argues that Respondent failed to perform adequate mental status exams on Patients B, C, D, and G, along with a physical exam each time the patient presented to the Clinic.

Respondent's point, that there is no expert evidence that the standard of care requires a physical examination to be performed at *every* patient visit, is well-taken. Moreover, the diagnostic studies were routinely ordered by the treating team with the recommended treatment being based on the results of those studies.

Staff argues that the standard of care for the treatment of cancer requires an adequate histologic diagnosis and pathologic confirmation before creating a treatment plan or initiating treatment, as testified to by Dr. Wetmore, because treatment decisions vary based on the location of the primary tumor site and the disease advancement. However, as pointed out by Respondent, Patients A through G appeared at the Clinic after having been diagnosed with Stage 3 or 4 cancer and they were entitled to decline further invasive testing that they did not want or need.

There is insufficient evidence to establish that the standard of care requires that a physical exam be performed at every visit. The medical records indicate that the treating team for each patient monitored the patient's condition, discussed drug side effects, and otherwise remained aware of the patient's current condition. There is no evidence that the Respondent did not know

of the prior diagnosis as well as prognosis of each patient's disease that he treated. Staff pointed to no instance when any of the patients indicated at the time of treatment a lack of understanding as to the recommended treatment. There was no need for a mental exam because, as discussed below, Patient B was accompanied by his personal physician, Patient C was accompanied by his wife, and Patient G was accompanied by her mother, each of whom provided sufficient backup if any confusion developed in the mind of the patient about the treatment being recommended.[123] As noted above, Patient D was not even treated at the Clinic. Based on the record, Staff has failed to establish that there was a common failure to provide adequate medical rationale for the evaluation, diagnosis, and treatment of Patients A through G.

d. Inadequate Medical Documentation

Staff argues that Respondent failed to keep adequate, complete, and accurate medical records for these seven patients in violation of the standard of care.

As noted above, Ms. Kloos testified that many of the medical records that were made available were not authenticated by the provider to ensure the services rendered were accurately and appropriately documented, reviewed, and authenticated. Dr. Wetmore agreed with Ms. Kloos that the medical records for Patients A through G were inadequate, inconsistent, and incomplete. On the other hand, Dr. Levin testified that the medical records were well-organized, presented a clear picture, and contained all relevant laboratory, imaging, and pathology reports.

For example, on October 11, 2010, Patient A had a physical and neuro/psychiatric examination. Although the physician who performed the examination is not named in the examination report, Dr. Valladares signed the Oncology Report on that same date.[124] On February 7, 2011, Patient B had a physical examination. Although the physician who performed the examination is not named in the examination report, Dr. Valladares signed the Oncology

[123] Patients A, E, and F did not brain cancer and therefore did not require a mental exam.

[124] Staff Ex. 5.02.A at 712-716, 791-792.

Report on that same date.[125] On May 11, 2010, Patient C had a physical and neuro/psychiatric examination. Although the physician who performed the examination is not named in the examination report, Dr. Marquis signed the progress notes for that same date.[126]

There is evidence in the record as shown above that certain of the records did not have the provider name, although they did have the date the services were provided. However, in each case, contemporary documents indicate that the provider was either Dr. Valladares or Dr. Marquis. The prescription orders all had provider signatures some that illegible, but could be compared to the provider's signature on other forms where they were clearly identified. Accordingly, the medical records as a whole were adequate to ensure that the services were rendered and by whom they were provided. Based on the record, the ALJs determined that Staff failed to establish that there was inadequate medical documentation for Patients A through G.

B. Individual Allegations Regarding Patient A

On September 16, 2010, Patient A, a 67-year-old man, had a CT scan of his abdomen that showed "multiple poorly defined heterogeneously enhancing lesions within the liver most consistent with metastatic disease." On September 27, 2010, Patient A had a sigmoidoscopy of the colon and rectum and biopsy of a large polypoid mass partially blocking his colon. The pathology report showed that the mass was "suspicious for invasive adenocarcinoma."[127] Dr. Burzynski testified that Patient A had previously declined his local oncologist's recommendations of surgery and chemotherapy. He confirmed that the cancer from which Patient A suffered is uniformly fatal, with the medium survival rate being approximately five months.[128]

Patient A had an initial consultation at the Clinic on October 7, 2010.[129] On that same date, Patient A had a physical and neuro/psychiatric examination. While it is not clear from the

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[125] Staff Ex. 5.03.A at 1015-1017, 1062.

[126] Staff Ex. 5.04A at 1353-1355, 1440.

[127] Staff Ex. 5.02.A at 616, 639, 641,.

[128] Tr. Vol. 3 at 115-19.

[129] Staff Ex. 5.02.A at 718.

examination report who performed the examination,[130] Patient A's wife testified that Patient A was examined by Dr. Valladares and Tolib Rakhmanov, who was a research associate (RA). Senior Oncologist Dr. Valladares signed a history and physical report dated that same day that diagnosed Patient A with adenocarcinoma of the colon, invasive, with metastases to the liver.[131] On October 11, 2010, Respondent recommended that his treatment be initiated with a regimen of PB and hydrocodone for pain.[132] Patient A was treated by the Clinic from October 2010, through October 2011. Patient A died on November 4, 2011.

Patient A's wife, who was present during all but one of Patient A's visits at the Clinic, testified that Respondent met with them on the first day that they arrived. She testified that, after the first day, the only "doctor" they saw was RA Rakhmanov, whom she did not recall performing any physical examinations of Patient A subsequent to the first day.[133]

1. Inadequate Medical Rationale for Changing Therapy

In its Complaint, Staff alleges that in April 2011, there was no medical rationale for discontinuing some of the Patient A's medications because the radiology imaging of the affected area revealed that the tumor was shrinking, but that by mid-May 2011 radiology imaging showed that the tumor was growing larger.

On October 11, 2010, Patient A started receiving PB.[134] On October 13, 2010, Patient A started taking Xeloda (capecitabine).[135] Xeloda was placed on hold on October 14, 2010, due to a "non-conclusive pathology report of 9/27/10", but was restarted on October 17, 2010.[136] On October 15, 2010, Patient A began receiving Avastin, which he had been taking before his initial visit at the Clinic (oral dose of 25 mg/ml). At the Clinic, Avastin was administered

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[130] Staff Ex. 5.02.A at 712-716.

[131] Staff Ex. 5.02.A at 791-792.

[132] Staff Ex. 5.02.A at 718, 791-792.

[133] Tr. Vol. 5 at 16-22.

[134] Staff Ex. 5.02.A at 718.

[135] Staff Ex. 5.02.A at 720, 810.

[136] Staff Ex. 5.02.A at 492, 721, 807.

intravenously (IV) at a dosage of 2.5 mg/kg.[137] On October 19, 2010, Respondent complained of mild dizziness and generalized weakness.[138] On October 22, 2010, the Avastin dosage was doubled to 5 mg/kg.[139] On October 25, 2010, Patient A was discharged home to continue treatment under the care of his local oncologist, Lance Lassiter, M.D. Patient A was instructed to continue the same regimen including the PB, Xeloda, and Avastin. In addition, he was directed to start taking Eloxatin (oxaliplatin) if a new biopsy indicated the mass in his colon was adenocarcinoma.[140]

The notes from Patient A's local oncologist, Dr. Lassiter, from his January 31, 2011 office visit with Patient A indicated that the comparison of a CT scan taken on January 28, 2011, to a CT scan taken on September 16, 2010, showed Patient A had a positive response to the treatment and that the patient no longer experienced pain and fatigue.[141] On November 8, 2010, Dr. Lassiter had added Eloxatin (oxaliplatin) to Patient A's treatment regimen.[142] On April 11, 2011, Dr. Lassiter discontinued Eloxatin due to intermittent neuropathy, but continued the Xeloda (the dosage of which he wanted to increase) and Avastin.[143] On April 26, 2011, Dr. Marquis concurred with Dr. Lassiter's decision to increase the dosage of Xeloda.[144] On April 28, 2011, an enlarged nodule in the right upper lobe of Patient A's lungs was detected on a CT scan, and was later confirmed on a PET scan taken on August 3, 2011.[145]

Dr. Wetmore testified that, in general, combinations of drugs that are part of the medication regimen may have to be altered based on the patient's experience while on the regimen. She stated that reasons for such a change include: (1) the drugs utilized are ineffective;

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[137] Staff Ex. 5.02.A at 716, 722.

[138] Staff Ex. 5.02.A at 724.

[139] Staff Ex. 5.02.A at 727.

[140] Staff Ex. 5.02.A at 728, 845.

[141] Staff Ex. 5.02.A at 695-696.

[142] Staff Ex. 5.02.A at 704-705.

[143] Staff Ex. 5.02.A at 675-676.

[144] Staff Ex. 5.02.A at 750.

[145] Staff Ex. 5.02.A at 599-600, 618-619.

(2) better patient response is desired; (3) patient exhibits intolerance to the medications; and (4) untoward side effects occur.[146]

Dr. Levin testified that the initial treatment of Patient A initiated at the Clinic included oral CapeOx (Xeloda and oxaliplatin) and Avastin, which was an NCCN-recommended regimen and was considered standard therapy.[147]

Although, in its Closing Argument, Staff pointed to changes in therapy that occurred in August 2011, the only change in therapy set forth in Staff's Complaint is one in April 2011.[148] That change in therapy was made not by Respondent but by Dr. Lassiter, the physician in contact with Patient A who was observing how the patient was responding to the treatment. Dr. Marquis only concurred with Dr. Lassiter that an increase in the dosage of Xeloda was necessary. Accordingly, Staff has failed to establish that Respondent had an inadequate rationale for changing the therapy in April 2011.

2. Unnecessary Oxygen Saturation Measurements

Staff asserts that Respondent directed the unnecessary measurement of Patient A's oxygen saturation as the patient had no significant pulmonary disease.

Dr. Wetmore testified that cancer in one part of the body has the potential to affect multiple organ systems, including the lungs. She agreed that measuring a patient's oxygen saturation level is a way to evaluate lung function. Nevertheless, she stated that measuring Patient A's oxygen saturation level was not useful, relevant, or appropriate to guide his clinical care.[149] However, Staff has failed to point out any testimony by Dr. Wetmore to explain the basis of her opinion.

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[146] Tr. Vol. 3 at 52- 53.

[147] Resp. Ex. 165 at 42.

[148] *See* Tex. Gov't Code § 2001.052. Even if the issue had been included in the pleadings, the record indicates that the change in therapy on August 29, 2011, was based on concerns raised by Dr. Lassiter during his office visit with Patient A on August 22, 2011. Staff Ex. 5.02.A at 648-650, 785-789.

[149] Tr. Vol. 3 at 71-72; Staff Ex. 68.03 at 17-18.

Dr. Burzynski testified that patients with terminal diagnoses and who are elderly often experience pulmonary problems, infections such as bronchitis or pneumonia, pulmonary embolisms, or cancer that had spread to their lungs. He stated that oxygen saturation testing in these patients gives advance notice to the treating physicians of additional problems that could prove fatal. In addition, elderly patients are often immunosuppressed and have decreased respiratory function. Dr. Burzynski testified that 25% of elderly cancer patients die from pulmonary infections, and the oxygen saturation test helps identify those who need to be transferred to intensive care, where they can receive proper treatment for the pulmonary issues. This is why the Clinic routinely tested for oxygen saturation levels in patients such as Patient A, whose cancer metastasized to his lungs.[150]

Dr. Levin agreed with Dr. Burzynski that the Clinic used the oxygen saturation test as an "early trip wire" for progressive disease to the lungs or other lung problems that sometimes result from the cancer or its treatment. He stated that while the frequent use of such tests on Clinic patients was unusual, he opined that it was not unreasonable, given the Clinic's population of very sick patients.[151]

Based on the testimony of Dr. Burzynski and of Dr. Levin, as well as the general statements by Dr. Wetmore as to the benefits that can be gained from oxygen saturation testing to evaluate lung function, the ALJs do not find that Staff has established that oxygen saturation tests were medically unnecessary—particularly in view of the fact that the cancer had metastasized to Patient A's lungs.

3. Unnecessary and Costly Laboratory Testing without Demonstrable Benefit

Staff alleges that Respondent ordered and improperly relied upon testing that was unnecessary for Patient A's cancer.

Dr. Wetmore stated that, in most cases, testing was done on genes or proteins that were irrelevant to front-line therapy of Patient A's colon tumor. She stated that gene-related EGFR,

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[150] Tr. Vol. 7 at 115-116, Vol. 8 at 95-99.

[151] Resp. Ex. 165 at 38.

VEGF and Her2 levels (testing for which was set out in the initial treatment plan) were unnecessary because these tests did not contribute to decisions made for treatment. She asserted that "it was already known in the medical community that mutation of a specific gene was not typically found in his tumor type."[152] In addition, she stated that Respondent improperly based treatment decisions on testing results from non-malignant tissue. In her opinion, the initial results of tissue testing for the KRAS mutation (a commonly mutated gene in cancer) came back negative because the tissue sample was from a non-malignant tissue specimen. She asserted that Respondent's treatment plan was based on this erroneous result.[153] She noted that a second biopsy taken later captured malignant tissue showing that the tumor contained the KRAS mutation.[154]

Dr. Levin testified that the use of the genomic blood and tissue testing was necessary, if not imperative, to obtain as much information as possible about the patient's tumor and, in particular, to provide guidance as to what targeted drugs to provide the patient. He pointed out that this personalized medicine approach differs from the older protocol approach relied on by Dr. Wetmore. Her approach does not consider that cancers in some patients have characteristics for which there are targeted agents that could be effective, even though not approved or even studied in the patient's type of cancer.[155]

The ALJs found Dr. Levin's testimony most persuasive. He pointed out that the use of genomic testing of blood and tissue by Respondent is necessary to determine what targeted agents should be used. This appears to be the non-conventional method of diagnosis contemplated by the Board Rule at 22 TAC §200.3(1). As for the two tissue samples, any error that may have occurred as a result of the first test was corrected by the second test. Accordingly, the ALJs do not find that Staff has established that Respondent used unnecessary and costly laboratory testing without demonstrable benefit in the treatment of Patient A.

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[152] Staff Ex. 68.03 at 18.

[153] Tr. Vol. 4 at 28-30.

[154] Staff Ex. 68.03 at 15-16.

[155] Resp. Ex. 165 at 45-46.

C. Individual Allegations Regarding Patient B

Patient B was a 56-year-old man who was diagnosed on December 12, 2010, with glioblastoma, grade IV, a fast-growing, aggressive type of central nervous system tumor that forms on the supportive tissue of the brain. He had debulking surgery on December 20, 2010, to remove as much of the tumor as possible. On February 7, 2011, Patient B and his personal physician, Dr. Demetri Brandt, traveled from the Ukraine and Germany to the Clinic to meet with Respondent. Dr. Valladares acknowledged in his initial oncology report that the standard of care treatment post-debulking is radiation therapy with Temodar (temozolomide) and an MRI of the brain every three months. Because Patient B had rejected this conventional treatment, Respondent recommended genetic testing, an MRI of the head, and administration of PB. Respondent also recommended considering therapy with Afinitor (everolimus), Votrient (pazopanib), Zolinza, Tarceva, and Avastin.[156] From February 8-17, 2011, Patient B consented to the administration of PB, Votrient, Avastin, and Tarceva, which were prescribed by Dr. Valladares.

On March 4, 2011, Patient B left the Clinic and returned to Germany under the care of Dr. Brandt. He was advised to continue treatment with PB, Votrient, and Avastin, but to discontinue the PB after four weeks and to start ANP treatments under the supervision of Dr. Brandt.[157] On March 17, 2011, an MRI of the patient's brain indicated a moderate decrease of the size of the enhancing lesion.[158] On March 21, 2011, after evaluating the MRI, Respondent recommended that Patient B discontinue the PB and start the ANP treatment.[159] On July 6 through 7, 2011, Patient B also consented to the administration of Afinitor, Sprycel (dastinib), and Nexavar (sorafenib).[160] Dr. Brandt stopped treating Patient B with ANP at the end of September 2011. Patient B died on December 18, 2011.

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[156] Staff Ex. 5.03.A at 1015-1023; 1062-1064.

[157] Staff Ex. 5.03.A at 1135-37.

[158] Staff Ex. 5.03.A at 978-979.

[159] Staff Ex. 5.03.A at 1065.

[160] Staff Ex. 5.03.A at 897-919.

1. Inadequate Medical Rationale for Using ANP

Staff alleges that Respondent made the treatment recommendation that Patient B receive ANP outside of a clinical trial or special exception and that, at least as of February 28, 2011, Patient B was receiving ANP in the United States without FDA approval. Staff asserts that there is no rationale in the medical records for Respondent's decision to train Patient B and/or his physician in the administration of ANP, or Respondent's decision to prescribe and provide ANP to Patient B.

A physician order dated February 11, 2011, states that Patient B was "in training for antineoplastons/private practice" and the treatment plan on that date includes considering Patient B for a clinical trial for ANP.[161] On February 17, 2011, Respondent wrote a letter stating that Respondent had approval to use ANP, a drug approved by the FDA for use in a clinical trial or as part of a special exception. The letter further states that Patient B would be taking ANP in Germany under Dr. Brandt's supervision.[162] On February 28, 2011, the treatment plan states that Patient B would continue receiving ANP. However, the actual starting of the administration of ANP was March 21, 2011, when the patient was in Germany.[163] Respondent shipped ANP to Dr. Brandt in Germany on March 21 and April 11, 2011, and to Patient B in the Ukraine from March 7 through August 31, 2011.[164]

Dr. Burzynski testified that in his initial meeting with Patient B, the patient indicated he was seeking ANP treatment from the Clinic.[165] He agreed that Patient B was not treated with ANP under a FDA-approved clinical study or as a single patient protocol, a compassionate exception, or a special exception.[166] He testified that the reason for the substitution of ANP for PB was that the patient requested in March that he be switched to intravenous ANP treatment

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[161] Staff Ex. 5.03.A at 1021, 1092.

[162] Staff Ex. 5.03.A at 1188.

[163] Staff Ex. 5.03.A at 1035, 1041.

[164] Staff Ex. 64.B at 45750-45755.

[165] Tr. Vol. 7 at 176-177.

[166] Tr. Vol. 8 at 189.

because he had difficulty tolerating the number of PB tablets he was required to take, and it was believed by the patient and his local oncologist that intravenous ANP treatment would be more powerful and effective.[167]

The record is clear that Patient B initially went to the Clinic in order to receive treatment with ANP. Instead, he was treated with PB until he returned to Germany, where Dr. Brandt started the ANP treatment. The reference to the continuation of ANP in the February 28, 2011 note referred to training the patient and Dr. Brandt in the administration of ANP rather than actual administering of ANP. No Clinic orders indicate that ANP was administered to Patient B until March 21, 2011, after he was in Germany. As noted above, Dr. Levin testified that patients have a right to utilize personalized or precision medicine outside of clinical trials. This is consistent with Board Rule 200.1 that "recognizes that patients have a right to seek complementary and alternative therapies." Accordingly, the ALJs find that the request of Patient B to be treated with ANP in Germany as allowed by the FDA, together with Respondent's experience with ANP, provided sufficient rationale for granting that request.

2. Inadequate Medical Rationale for Changing Therapy

In its Complaint, Staff alleges that Respondent failed to document an adequate medical rationale for the March 21, 2011 change from PB to ANP. This issue has been adequately discussed above. In addition, Patient B was directed to hold Votrient because he was suffering from blisters on his hands and feet, which appears to be a valid reason for doing so.[168]

In its Original Brief, Staff argued about changes in therapies that occurred on June 17 and July 1, 2011. Again, these latter two incidents were not included in the pleading and cannot be addressed.[169]

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[167] Tr. Vol. 7 at 172-173.

[168] Staff Ex. 5.03.A at 1041.

[169] Tex. Gov't Code § 2001.052. Even if the incidents had been included in the pleadings, the records indicate that the change in therapy adopted by Respondent on June 17, 2011, was based on the genetic testing previously discussed as well as progression of the tumor. Staff Ex. 5.02.A at 1060-1061; Tr. Vol. 7 at 174-175. As for the change on July 1, 2011, the physician order signed by Dr. Marquis indicates that the change was recommended by Dr. Burzynski, who testified that the change was again based on the genomic testing. Tr. Vol. 7 at 175-176.

3. Misrepresentations to United States Customs Agents

Staff alleges that Respondent misrepresented to United States Customs agents that Patient B was being treated with ANP in an FDA-approved clinical study. The February 17, 2011 letter was addressed "To Whom It May Concern" and stated that Patient B would be taking ANP in Germany under Dr. Brandt's supervision. It also stated that Respondent had approval to use ANP in clinical trials and on a special exception basis, which was true. While it does not say that Patient B was in such a clinical trial or on such a special exception basis, a reasonable person could conclude that such a representation was the purpose for including the statement in the letter in the first place. However, there was no harm done because Patient B did not need to be in a clinical trial in order for Respondent to ship ANP to Germany, in that the FDA did not require that it give its approval for shipments of ANP to Germany.

On the other hand, Respondent did ship ANP to the Ukraine, a location to which Respondent was not allowed by FDA regulations to export ANP.[170] Dr. Wetmore agreed that Respondent did not need FDA approval to ship APN to Germany, but opined that he violated the FDA protocols when he exported them to the Ukraine.[171]

Respondent points out that this issue was the subject of a query by the FDA inspector. Specifically, in his 2013 investigation report, Inspector Joel Martinez discussed the procedure by which Respondent exported ANP to physicians outside the country whose patients were not entered into a study protocol. The document does not indicate that the shipments to Patient B were part of this discussion.[172]

Respondent further points out that in the Warning Letter dated December 3, 2013, Thomas N. Moreno, Acting Office Director of the Office of Scientific Investigations of the Office of Compliance of the Center for Drug Evaluation and Research of the FDA, did not

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[170] Staff Ex. 65, Vol. 13.09D.02. at 45686-45687.

[171] Staff Ex. 68.03 at 33; Tr. V. 3 at 149-151.

[172] Staff Ex. 65, Vol. 14.09L.09. at 46082-46085.

include the export of ANP outside the country as a violation.[173] Accordingly, the ALJs find that any FDA concerns regarding exports of ANP to unauthorized countries that were resolved to the satisfaction of FDA (as indicated by the fact that Mr. Moreno did not reference the issue raised by Mr. Martinez) cannot alone serve as the basis of any violations within the scope of this case.

4. Unnecessary Oxygen Saturation Measurements

For the same reasons as set forth in Section IV(B)(2) above, specifically due to the benefits that can be gained from oxygen saturation testing to evaluate lung function, the ALJs do not find that Staff has established that the tests were medically unnecessary.

5. Unnecessary and Costly Laboratory Testing without Demonstrable Benefit

Staff alleges that the unnecessary and costly genomic testing of Patient B that Dr. Valladares ordered had no demonstrable benefit. Because Patient B had rejected conventional treatment, Respondent recommended genetic testing be performed by Caris Life Sciences (Caris). On March 2, 2011, Caris reported on several tests ordered by Dr. Valladares for Patient B. These included a C-Kit mutational analysis from a formalin-fixed paraffin-embedded tumor sample.[174] Dr. Wetmore testified that this test was improperly performed from a plasma specimen because the specimen should have been from the tumor tissue.[175]

In that same report, Caris reported the results of VEGF and HER2 tests.[176] Dr. Wetmore testified that HER2 and VEGF tests are not tests on oncogenes but tests on normal proteins present in the blood. In addition, Dr. Wetmore opined that this type of testing was irrelevant to Patient B's tumor type.[177]

Dr. Levin testified that the testing of EGFR, HER2, and plasma VEGF by Caris were necessary under the personalized medicine concept. He stated that the Caris tests examine the

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[173] Staff Ex. 12 at 7136-7164 .

[174] Staff Ex. 5.03.A at 997.

[175] Staff Ex. 68.03 at 27.

[176] Staff Ex. 5.03.A at 989-1002.

[177] Staff Ex. 68.03 at 27.

genetic and molecular changes of a patient's tumor so that treatment options may be matched to the tumor's molecular profile. In his opinion, Respondent used these tests as a diagnostic tool and never meant them to be the only basis for the treatment prescribed.[178]

For the same reasons as set forth in the discussion in Paragraph B3 above, specifically because these tests appear to be the non-conventional methods of diagnosis contemplated by the Board Rule 200.3(1), the ALJs do not find that Staff has established that Respondent used unnecessary and costly laboratory testing without demonstrable benefit in the treatment of Patient B.

D. Individual Allegations Regarding Patient C

Patient C was a 42-year-old man who was diagnosed with Stage II A nodular sclerosing Hodgkin's disease in 1986, for which surgical and radiotherapy were successful. On April 19, 2010, Patient C was diagnosed with cancer in his left lung. Patient C's oncologist recommended chemotherapy in April 2010. Patient C then chose to consult with the Clinic on May 11, 2010.[179] From May 14 through 19, 2010, pursuant to Dr. Joshi's directions, Dr. Marquis prescribed the administration of PB (in combination or concurrently with) the medications Avastin, Decadron (dexamethasone), Nexavar, and Tarceva.[180] Patient C was discharged home on May 20, 2010, with directions from Dr. Marquis to continue the regimen of PB, Tarceva, Nexavar, Avastin, and Decadron under the care of Dr. Thomas Waits, his local oncologist.[181]

1. Failure to Document May 14, 2010 Office Visit

Staff alleges that Respondent failed to document Patient C's May 14, 2010 office visit, and that an outpatient physician order for treatment with PB had no physician's name or

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[178] Resp. Ex. 165 at 46, 50-51.

[179] Staff Ex. 5.04A at 1353-1355, 1440.

[180] Staff Ex. 5.04.A at 1436-1439.

[181] Staff Ex. 5.04.A at 1578-1580.

signature. However, the Progress Notes on that same date signed by Dr. Marquis indicate the patient's vitals and direct that the administration of PB would begin that day. Dr. Marquis's signature appears on both the Progress Notes and the Physician Order.[182]

Based on the above-referenced documents, Staff has failed to establish that Respondent did not document the May 14, 2010 visit with Patient C.

2. Inadequate Medical Rationale for Changing Therapy

On November 17, 2010, Respondent recommended to Sheryl Acelar, a research associate who is not licensed to practice medicine in the United States, to change Patient C's regimen by decreasing the PB, adding Zolinza (vorinostat), and switching Avastin for Vectibix (panitumumab), based on a high EGFR result.[183] Staff alleges that Respondent failed to document an adequate rationale for this change in therapy, particularly in light of the fact that Patient C's cancer symptoms appeared to have been improving. Staff argues that the rationale given for this change—based on a high EGFR result from a plasma sample—was inadequate. However, as discussed above, genomic test results provide an adequate rationale for treatment decisions.

On December 6, 2010, Patient C reported to the Clinic that he had a rash on his forehead and around his nose, and that he was going to see Dr. Thomas Waits, his local oncologist, to address the problem.[184] On December 9, 2010, Patient C's wife contacted the Clinic to determine if the Vectibix dosages should be reduced as suggested by Dr. Waits. Ms. Acelar informed Dr. Waits that the Vectibix dosage should be reduced, which Dr. Waits did.[185] Although Staff did not allege in its Complaint that this specific change in therapy was a violation, clearly the rationale for the change was to resolve the rash.

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[182] Staff Ex. 5.04.A at 1245, 1439.

[183] Staff Ex. 5.04.A at 1432-1433.

[184] Staff Ex. 5.04.A at 1370.

[185] Staff Ex. 5.04.A at 1430-1431. The issue regarding RA Acelar's giving medical directions is discussed below.

On March 9, 2011, Dr. Waits contacted the Clinic to report that the Vectibix appeared to be causing Patient C to have diarrhea.[186] On March 11, 2011, a teleconference was held with Respondent, Dr. Joshi, Dr. Marquis, and Patient C. Respondent recommended starting Alimta (pemetrexed), discontinuing the Vectibix, and considering a surgical evaluation.[187] Dr. Waits last administered Vectibix on March 14, 2011. Subsequent communications from Dr. Waits indicate that he did not understand until March 18, 2011, that Vectibix was to be discontinued.[188] He began the administration of Alimta on May 2, 2011.[189] Again, although Staff did not allege in its Complaint this specific change in therapy was a violation, clearly the rationale for the change was to resolve the patient's diarrhea.

Finally, in its Complaint, Staff alleged that after April 2011, Respondent directed that Patient C start other substances, including Nexavar, Tarceva, Avastin, PB, and Decadron, without providing a medical rationale for the addition of each drug. However, Staff has not pointed to any documentation in the record to indicate such changes in therapy were made. In addition, it is clear from the record that Dr. Marquis prescribed PB, Decadron, Nexavar, Tarceva, and Avastin to Patient C from May 14 through 20, 2010, well before April 2011.

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[186] Staff Ex. 5.04.A at 1427.

[187] Staff Ex. 5.04.A at 1390.

[188] Staff Ex. 5.04.A at 1425, 1502.

[189] Staff Ex. 5.04.A at 1493, 1501.

3. Unnecessary and Costly Laboratory Testing without Demonstrable Benefit

This allegation has been previously discussed in Section IV(B)(3) above, and for the same reasons, the ALJs do not find that Staff has established that Respondent used unnecessary and costly laboratory testing without demonstrable benefit in the treatment of Patient C.

E. Individual Allegations Regarding Patient D

Patient D was a 28-year-old male who was diagnosed on May 13, 2010, with brain cancer, specifically pleomorphic xanthoastrocytoma, grade II, for which he had a surgical resection. Imaging studies taken on November 26, 2010, showed new lesions were present in his brain and spine.[190] On January 10, 2011, Patient D's oncologist recommended treatment with Temodar, an oral chemotherapy drug, and radiation, which treatment was continued through April 6, 2011. It was stopped due to adverse reactions (abnormally low sodium in the blood).[191]

Due to adverse reactions to conventional treatment, on June 7, 2011, Patient D visited the Clinic for a consultation, during which Dr. Joshi conducted an oncology assessment. Dr. Joshi opined that, absent any further progression of the cancer, Patient D should continue with his current treatment with Temodar. Should future scans show progression, Dr. Joshi indicated that he would recommend a second-line standard of care treatment with Avastin.[192]

On July 1, 2011, after receiving the results of Caris tests, Respondent recommended Patient D to be treated with Tarceva, Afinitor, and Avastin.[193] Patient D declined to follow Respondent's recommendations and no further treatment was considered.

1. Improper Billing for Dr. Weaver's Services

Staff alleges that Respondent improperly billed for services provided by Dr. Weaver. The medical records for Patient D do not show any such billings.[194]

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[190] Staff Ex. 5.01.A at 423-430.

[191] Staff Ex. 5.01.A at 383, 453-458.

[192] Staff Ex. 5.01.A at 387.

[193] Staff Ex. 5.01.A at 370, 417.

2. Unnecessary Oxygen Saturation Measurements

For the same reasons as set forth in Section IV(B)(2) above, specifically due to the benefits that can be gained from oxygen saturation testing to evaluate lung function, the ALJs do not find that Staff has established that the tests were medically unnecessary.

3. Unnecessary and Costly Laboratory Testing without Demonstrable Benefit

On June 7, 2011, Respondent ordered Profile III, HER2, VEGF, EGFR, C-KIT, amino acid level, and Caris testing.[195] On June 7, 2011, Patient D agreed in writing to undergo the various tests including blood and urine analyses, nuclear medicine tests, scans, and x-rays that the Clinic ordered so that the physicians could develop a treatment plan.[196]

This allegation has been previously discussed in Section IV(B)(3) above, and for the same reasons, the ALJs do not find that Staff has established that Respondent used unnecessary and costly laboratory testing.

F. Individual Allegations Regarding Patient E

Patient E was a 67-year-old male with chromophobic type renal cell carcinoma (kidney cancer) with multiple recurrences who was first seen at the Clinic on September 7, 2011, during which visit he had an oncology consultation with Dr. Yi. Dr. Yi recommended treatment with Sutent to be followed with Afinitor if Patient E's cancer progressed. Dr. Yi also noted that Xeloda (capecitabine) plus Gemzar (gemcitabine) in combination was an option because this combination was reported to work in renal cell carcinoma. On that same date, Respondent recommended that Patient E be evaluated for appropriate personalized treatment including the consideration of Sutent, Afinitor, and Xgeva.[197]

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[194] Staff Ex. 5.01.B at 464-465.

[195] Staff Ex. 5.01.A at 373-376.

[196] Staff Ex. 5.01.A at 312.

[197] Staff Ex. 5.05.A at 1619-1625.

Rather than follow Dr. Yi's recommendation, Patient E chose to follow Respondent's recommendation. On September 8, 2011, Patient E began receiving PB; on September 13, 2011, Patient E began receiving Xgeva (denosumab); on September 14, 2011, Patient E began receiving Afinitor; and on September 15, 2011, Patient E began receiving Sutent.[198] Patient E was discharged from the Clinic on September 15, 2011. On October 4, 2011, Patient E informed Respondent's Staff that he had discontinued the PB because of a skin rash. Respondent stopped all treatment of Patient E on October 16, 2011.[199]

1. Non-Therapeutically Prescribing Combinations of Two Targeting Agents

Staff alleges that there is no rationale in Patient E's medical record for Respondent's recommendation that Sutent and Afinitor (everolimus) should be taken at the same time rather than in succession as Dr. Yi recommended. Staff asserts that the untested combination of these drugs brought with it the risk of unknown side effects caused by interactions between these drugs, including the risk of renal failure. Staff further alleges that there is no documented medical rationale for prescribing PB.

In her expert report, Dr. Wetmore noted Patient E had already experienced toxicity with a prior drug (Votrient) that had similar tyrosine kinase parameters as Sutent. She opined that it was irresponsible for Respondent to prescribe combinations of those agents without proper monitoring and documenting of toxicities.[200]

Dr. Burzynski testified that a 2009 report of a study conducted by a team at Memorial Sloan Kettering Cancer Center showed that the combination of Sutent and Afinitor showed positive responses for patients with renal cell carcinoma. He stated that because the prescribed combination of the two targeting therapy agents had previously been demonstrated to be

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[198] Staff Ex. 5.05.A at 1632-1638.

[199] Staff Ex. 5.05.A at 1605-1608.

[200] Staff Ex. 61.A.01 at 45087-45088.

effective in patients with this type of cancer, it was proper to prescribe them in combination to Patient E.[201]

Dr. Levin explained that Afinitor is an active drug in chromophobe renal cell cancer and that its concurrent treatment with Sutent was reasonable in a situation such as that of Patient E where no standard approach existed. He opined that prescribing the two drugs followed the principles of personalized medicine and could not in any way be represented as having no medical rationale.[202]

The testimony of Dr. Levin and Dr. Burzynski constitute sufficient evidence that the combination of the two drugs had therapeutic validity for Patient E. However, Dr. Wetmore's report makes clear that the medical records do not document the risk factors related to Sutent, particularly in light of the prior problems Patient E had with the similar drug, Votrient. Therefore, on that aspect alone, the ALJs find that Respondent failed to meet the standard of care, in violation of 22 TAC § 165.1(a)(5).

The discussion regarding the prescribing of PB is set forth in Section IV(A)(5)(b) above. For the same reasons set out in that section, the ALJs do not find that Staff has established that there was a failure to provide adequate medical rationale for treatment of Patient E with PB.

2. Inadequate Medical Rationale for Prescribing Multiple Targeting Agents

Staff alleges that there is no rationale in Patient E's medical record for Respondent's recommendation that the four targeting agents (Sutent, Afinitor, Xgeva, and PB) should be taken concurrently. Dr. Wetmore opined that the four-drug combination Respondent prescribed to Patient E did not have sufficient peer-reviewed scientific evidence to establish safety and efficacy. In her opinion, Respondent failed to allow a washout period, which was needed if the

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[201] Tr. Vol. 7 at 233-234, 237.

[202] Resp. Ex. 165 at 58-60.

drugs were administered at the same time, and improperly documented adverse events.[203] Dr. Burzynski justified his treatment by referring to a 2001 Johns Hopkins study showing that the use of PB in combination with other agents stabilized renal carcinoma in three of six patients in the study.[204]

Again, because Patient E had experienced prior problems with Votrient, Respondent should have documented that he reviewed the risk factors in prescribing Sutent in combination with the other targeting agents. Therefore, on this issue, the ALJs find that Respondent failed to meet the standard of care in violation of 22 TAC § 165.1(a)(5).

3. Inadequate Informed Consent

For a general discussion of the issue of informed consent, see Section VI(B).

Staff alleges that Respondent failed to obtain informed consent from Patient E for the simultaneous intake of Sutent and Afinitor.

The prescriptions for Afinitor and Sutent were signed on September 13, 2011.[205] The informed consent form for Afinitor was signed that day, while the signed informed consent for Sutent was dated September 14, 2011.[206] As noted above, the Afinitor was not administered until September 14, 2011, and Sutent was not administered until September 15, 2011, both after the signing of the informed consent forms.

The first paragraph of the informed consent for Afinitor states that the document contains information about treatment with Afinitor and other unnamed agents. The "purpose of the treatment" section in the form describes Afinitor as a kinase inhibitor indicated for the treatment of patients with advanced renal cell carcinoma after failure of treatment with Sutent or sorafenib.

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[203] Staff Ex. 68.03 at 53-55.

[204] Tr. Vol. 7 at 231-233.

[205] Staff Ex. 5.05.A at 1645.

[206] Staff Ex. 5.05.A at 1786-1791.

The "purpose of the treatment" section in the Sutent form describes Sutent as an oral multi-kinase inhibitor also indicated for the treatment of patients with advanced renal cell carcinoma.[207]

Staff asserts that the informed consents that were signed for these medications do not take into account the potential side effects from the medication's being taken at the same time, but only address side effects that could be attributed to the drugs being taken individually. Staff argues that the statement in the forms that "the regimen might involve risks of which we are not currently aware" is not enough to explain the dangers of taking two untested chemotherapy drugs at the same time.

Dr. Wetmore opined that the standard of care required that "[t]he informed consent process should be completed after [the physician's] discussion with the patient; and as part of that discussion, the side effects, risks, benefits and alternatives should be relayed to the patient, and the informed consent should be signed prior to the order to give any medication."[208]

Dr. Levin testified that it is not necessarily an obligatory practice to obtain consent for a combination of drugs for several reasons. Medications are often used concurrently in everyday practice even when full toxicity profiles are not well-worked and without patient consent to combinations. He was of the opinion that separate consents for concurrent use of Sutent and Afinitor are sufficient.[209]

The ALJs agree with Dr. Levin that separate informed consents for two drugs used concurrently is, in general, within the standard of care, the Afinitor informed consent form represented that it should be used if treatment with Sutent failed. That statement was misleading because treatment with Afinitor began before the administration of the Sutent, after which they were administered together. This treatment of Patient E is clearly a deviation from the procedure

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[207] Staff Ex. 5.05.A at 1786-1791.

[208] Tr. Vol. 6 at 10.

[209] Resp. Ex. 165 at 60-61.

indicated in the Afinitor form that was signed by the patient, and there is nothing to indicate that Respondent or a qualified person explained the purpose for this deviation and for the simultaneous use of both agents. As a result, Patient E was not given the opportunity to give his informed consent to that simultaneous use. Accordingly, the ALJs find that Staff has established that Respondent is in violation of 22 TAC § 190.8(1)(I).

4. Unnecessary Oxygen Saturation Measurements

For the same reasons as set forth in Section IV(B)(2) above, specifically due to the benefits that can be gained from oxygen saturation testing to evaluate lung function, the ALJs do not find that Staff established that the tests were medically unnecessary.

5. Unnecessary and Costly Laboratory Testing without Demonstrable Benefit

On September 7, 2011, Respondent recommended that Patient E have the following tests: "Profile III, VEGF, EGFR, HER-2, C-Kit, B12, PSA level, TSH, and amino acid assay."[210]

This allegation has been previously discussed in Section IV(B)(3) above, and for the same reasons, the ALJs do not find that Staff established that Respondent used unnecessary and costly laboratory testing without demonstrable benefit in the treatment of Patient E.

G. Individual Allegations Regarding Patient F

On September 21, 2009, Patient F, a 66-year-old male, was diagnosed with pancreatic cancer. The treatment recommended by his oncologist was chemotherapy. Patient F and his wife chose to consult with Respondent and the treatment team at the Clinic on October 8, 2009.

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[210] Staff Ex. 5.05.A at 1623-1625.

The treatment plan developed by the team and presented by Dr. Weaver on that date recommended treatment with PB (started on October 9), Rapamune with grapefruit juice (started on October 10), Zolinza (started on October 11), and Xeloda (started on October 13.) At the time, Patient F was also being treated for a herpes outbreak with Valtrex. On October 9, 2009, Dr. Weaver increased Patient F's Valtrex dosage.[211] On October 14, 2009, the dosages of PB and Xeloda were increased, Avastin with premedication of Benadryl and Decadron were started, and Nexavar was scheduled to begin the next day.[212]

On October 19, 2009, Patient F was discharged home with his treatment plan of PB, Rapamune, Zolinza, Nexavar, Xeloda, and Avastin.[213] On October 23, 2009, Patient F complained that he had been nauseous and dizzy for the previous two days.[214] On November 13, 2009, a progress note states that "The patient wants to discontinue our treatment due to financial constraints. He received his last dose of [PB] on 11/11/09."[215]

1. Inadequate Documented Medical Rationale for Valtrex in Treatment

In her report, Dr. Wetmore stated that it was a violation of the standard of care to initiate chemotherapy and PB while Patient F was having an active herpes outbreak for which he was being treated with Valtrex. She opined that Respondent should have waited until the herpes outbreak had cleared up and Patient F had enough time to wash out the Valtrex before initiating Respondent's treatment plan.[216] However, Dr. Wetmore did not provide any scientific basis for her opinion as to why an anti-viral medication had to wash out before the administration of the anti-cancer targeting agents.

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[211] Patient F was being treated with Valtrex for a herpes outbreak prior to visiting the Clinic. Staff Ex. 6.01.A at 2032-2035; 2049; 2066; 2071.

[212] Staff Ex. 6.01.A at 2047.

[213] Staff Ex. 6.01.A at 2044.

[214] Staff Ex. 6.01.A at 2084-2085.

[215] Staff Ex. 6.01.A at 2041.

[216] Staff Ex. 61.A.01 at 45090.

As discussed above, based on the opinion of Dr. Levin, a wash-out period is irrelevant in a clinical setting. Accordingly, Staff has failed to establish that the initiation of anti-cancer drugs while Patient F was being treated with an anti-viral medication was a violation of the standard of care.

2. Unnecessary Oxygen Saturation Measurements

For the same reasons as set forth in Section IV(B)(2) above, specifically due to the evidence of benefits that can be gained from oxygen saturation testing to evaluate lung function, the ALJs do not find that Staff has established that the tests were medically unnecessary.

3. Unnecessary and Costly Laboratory Testing without Demonstrable Benefit

On October 8, 2009, Dr. Weaver recommended numerous tests, including Profile III, HER 2, VEGF, EGFR, C-Kit, CA 15-3, ammonia level, PSA, a full body PET/CT scan, a head MRI, and an echocardiogram.[217]

This allegation has been previously discussed in Section IV(B)(3) above, and for the same reasons, the ALJs do not find that Staff has established that Respondent used unnecessary and costly laboratory testing without demonstrable benefit in the treatment of Patient F.

H. Individual Allegations Regarding Patient G

Patient G was a 26-year-old woman who was diagnosed with suprasellar mass brain cancer and malignant astrocytoma of the optic nerve on July 5, 2012. She underwent surgery on August 3, 2012, and received treatment with Avastin on August 24, 2012. Her plan of treatment after surgery included radiation therapy and Temodar (temozolomide). Patient G was informed by her oncologist that the adverse side effects of the recommended conventional treatment

[217] Staff Ex. 6.01.A at 2032-2035.

included edema, headaches, and probable blindness. Patient G determined not to follow this recommendation.

Patient G went to the Clinic on August 31, 2012. Respondent recommended that she be evaluated for ANP in a single patient protocol.[218] The checklist for inclusion in Respondent's ANP study under protocol BT-09 states that she was ineligible to participate in the clinical trial for ANP because she had previously received chemotherapy.[219] On September 4 and 5, 2012, Respondent submitted an application to request permission for approval for Patient G to receive ANP under a single patient protocol, which was approved by IRB and the FDA on September 6, 2012.[220] On September 6, 2012, Respondent submitted Patient G's informed consent document for the single patient protocol to IRB, which was approved on that date.[221]

1. Inadequate Medical Rationale for Use and Promotion of ANP

On September 12, 2012, the first day of the ANP infusion, Patient G reported dizziness, discomfort, and fatigue.[222] Nevertheless, her dosage was increased. On September 14, 2012, she reported adverse fatigue, headaches, and "pressure." Tests showed she had abnormally low potassium levels. Dr. Marquis increased her Decadron (a steroid) dose, which had initially been decreased, back to her original dosage and prescribed a potassium supplement.[223] Patient G reported on September 15, 2012, having edema in both feet and increased blurred vision. Dr. Marquis increased dosages of ANP and potassium and maintained the dosage of Decadron.[224] On September 16, 2012, she reported similar symptoms and again Dr. Marquis

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[218] Staff Ex. 7.01 at 2434-2438.

[219] Staff Ex. 7.01 at 2469-2470.

[220] Staff Ex. 7.01 at 2461-2467.

[221] Staff Ex. 7.01 at 2449-2461.

[222] Staff Ex. Vol. 7.01 at 2534.

[223] Staff Ex. Vol. 7.01 at 2532.

[224] Staff Ex. Vol. 7.01 at 2531.

increased the ANP and potassium dosages. She continued to have abnormally low potassium levels.[225]

On September 17, 2012, Patient G reported that her vision was getting worse, as were her headaches. The edema was still present and worsened at night and with activities. Dr. Marquis advised her to elevate her feet and monitor for pain in the back of her calves. ANP and steroids were both increased on that day. September 18, 2012, Patient G reported that her vision was getting worse, and that her eye pain and headaches remained unchanged.[226] Dr. Marquis increased her potassium and ANP. On September 19, 2012, she reported having no eye pain but still had blurred vision in her right eye together with agitation and increased anxiety. Pursuant to Dr. Yi's direction, Dr. Marquis recommended that one of the types of ANP and potassium be increased.

On September 20, 2012, a note signed by Dr. Yi stated that she was doing much better, had no anxiety or agitation, had no eye pain in her right eye, but still had blurred vision in her left eye. Dr. Yi recommended that one type of the ANP be increased. On September 21, 2012, Dr. Yi again recommended that one type of the ANP be increased.

On September 22 and 23, 2012, Dr. Yi recommended that she stop taking the ANP due to her increased potassium level. On September 25, 2012, Dr. Marquis counseled with Patient G and her mother about her edema, which she reported was decreasing. He instructed her to remain off the ANP that she had not taken since September 23, to decrease her potassium, and to receive more Decadron via IV STAT. On September 26, 2012, since she was planning to leave the Clinic to go home, Dr. Marquis instructed her to stay off ANP and prescribed an increased dosage of Decadron for her headaches.[227]

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[225] Staff Ex. Vol. 7.01 at 2530.

[226] Staff Exs. Vol. 7.01 at 2528; Vol. 33 at 22528.

[227] Staff Ex. Vol. 7.01 at 2520-2534.

The next day Patient G was admitted to a hospital in the patient's home city after waking up in the night with extreme leg pain. The hospital staff attributed it to an adverse reaction to her medications.[228] Over the next two days, Patient G's leg pain and edema went away. Patient G restarted ANP on September 29, 2012. On October 2, 2012, her lower extremity pain returned. The edema steadily increased as Patient G increased the ANP dosage over the next few days, and she remained on the elevated steroid dosage.[229]

On October 19, 2012, Patient G was instructed by Clinic staff to hold ANP due to her reporting having severe bilateral knee and lower leg pain. Staff told her to go to the emergency room of the hospital in her home city for assessment. On October 22, 2012, Dr. Yi directed that she restart ANP, which she did.[230]

On October 26, 2012, Dr. Marquis told Patient G's mother that a recent MRI showed significant tumor growth and if the tumor grew more than 50%, Patient G might have to be terminated from the protocol. On October 28, Patient G stopped taking the ANP due to her edema. On November 1, 2012, Dr. Marquis noted that the Clinic had received the radiology imaging showing that the tumor had grown 33%. Patient G elected to continue with the ANP treatments.[231] Patient G discontinued treatment at the Clinic on November 26, 2012, due to persistent edema.[232]

Dr. Wetmore testified that the standard of care for Patient G's cancer was optimal surgical resection followed by radiation therapy with Temodar (temozolomide), with adjunctive Avastin. She opined that Respondent violated the standard of care when Patient G did not receive this first-line therapy.[233]

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[228] Staff Ex. Vol. 7.01 at 2813-2821.

[229] Staff Ex. Vol. 7.01 at 2513-2519.

[230] Staff Ex. Vol. 7.01 at 2512-2513.

[231] Staff Ex. Vol. 7.01 at 2507-2510.

[232] Staff Ex. Vol. 7.01 at 2502.

[233] Staff Ex. 68.03 at 64-65.

In December 2012, Patient G began treatment in her home town with radiation, Temodar and Avastin.[234] The patient's records indicate that she experienced edema, severe headaches, and other severe side effects, including a hospital admission with sepsis, while on this first-line conventional treatment regimen.[235]

Staff's allegation raises the issue of whether the patient has the right to continue an alternative treatment that does not appear to be working rather than undergo a conventional treatment the side effects of which are known and clearly adverse—in this case total blindness. The preface to 22 TAC § 200.3 states the following:

> A licensed physician shall not be found guilty of unprofessional conduct or be found to have committed professional failure to practice medicine in an acceptable manner solely on the basis of employing a health care method of complementary or alternative medicine, unless it can be demonstrated that such method has a safety risk for the patient that is unreasonably greater than the conventional treatment for the patient's medical condition.

In this case Staff has not established that the safety risk for Patient G in following the ANP treatment was unreasonably greater than that of the conventional treatment. Patient G was diagnosed with a terminal illness; she was aware of the adverse effects of conventional treatment; and despite the effects of edema, blurred vision, and headaches, some of which were attributable to the alternative medications she was receiving and some of which were attributable to her disease, she continued to choose to follow the alternative treatments until she made the decision to stop them. The ALJs agree that Patient G had full knowledge of the consequences of her decisions and that Respondent did not violate the standard of care by following her wishes.

2. Unnecessary Oxygen Saturation Measurements

For the same reasons as set forth in Section IV(B)(2) above, specifically due to the benefits that can be gained from oxygen saturation testing to evaluate lung function, the ALJs do not find that Staff established that the tests were medically unnecessary.

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[234] Staff Ex. 7.01 at 2830.

[235] Staff Ex. Vol. 7.01 at 2823; 3030-3033.

3. Improper Billing and Collection Practices

In its Complaint, Staff alleged that Respondent rejected donations made to Patient G's website, refused to credit those donations against Patient G's account, and returned the donations to the donors. Staff further alleges that Respondent refused to refund payments received from Patient G's insurance company that were paid to Patient G's account.

Because Staff did not address this allegation in its closing arguments, pursuant to Order No. 34 the allegation is deemed to be waived.

I. Summary of ALJs' Analysis

Based on the above discussion, the ALJs do not find that Staff established violations of the standard of care by Respondent on the following grounds: (1) failing to make Patients A through G aware of the potential toxicities of drug combinations, (2) failing to provide adequate medical rationale for treatment of Patients A through G with ANP, PB, and/or the combined use of drugs, (3) failing to provide adequate medical rationale for the evaluation, diagnosis, and treatment of Patients A through G, or (4) providing inadequate medical documentation for Patients A through G. Therefore, the ALJs find that Staff failed to show that Respondent violated the standard of care in the treatment of Patients A, B, C, D, F, or G.

In regard to Patient E, the ALJs find that Staff did establish the following violations of the standard of care: (1) Respondent failed to document the risk factors related to Sutent in light of the prior problems Patient E had with the similar drug Votrient, in violation of 22 TAC § 165.1(a)(5), and (2) Respondent failed to explain the reason for the deviation from the purpose of treatment explained in the Afinitor informed consent form and failed to give Patient E the opportunity to give his informed consent to the simultaneous use of Afinitor and Sutent, in violation of the rule at 22 TAC § 190.8(1)(I).

V. INADEQUATE DELEGATION AND IMPROPER USE OF UNLICENSED PRACTITIONERS

Staff alleges that Respondent improperly delegated medical tasks to "individuals who were unqualified and . . . unauthorized to perform the task he delegated to them."[236] According to Staff, Respondent improperly delegated the treatment of cancer patients to licensed practitioners who lacked the necessary oncology training or expertise. Staff also alleged that Respondent aided and abetted foreign-trained physicians in the unlicensed practice of medicine in violation of Code §§ 157.001,[237] 164.052(a)(17), and 164.053(a)(8) and (9), and is subject to disciplinary action under Code § 164.051(a)(6). Respondent disputes these allegations and points out that they are inconsistent with Staff's allegation that he was the sole decision-maker at the Clinic. The ALJs will address the allegations regarding the licensed physicians first before proceeding to unlicensed practitioners.

A. Licensed Providers

Staff asserts that Respondent failed to adequately supervise the Clinic's licensed physicians who were allegedly unqualified or inadequately trained to practice oncology. In Dr. Wetmore's opinion, Dr. Gregory Burzynski, an internist, overstepped his training and qualifications by making oncology treatment decisions and prescribing anti-cancer drugs to Patient B.[238] She also accused Respondent of allowing Dr. Marquis to prescribe anti-cancer

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[236] Staff's Closing Argument at 46.

[237] Code § 157.001 states the following:

(a) A physician may delegate to a qualified and properly trained person acting under the physician's supervision any medical act that a reasonable and prudent physician would find within the scope of sound medical judgment to delegate if, in the opinion of the delegating physician:

(1) the act:

(A) can be properly and safely performed by the person to whom the medical act is delegated;

(B) is performed in its customary manner; and

(C) is not in violation of any other statute; and

(2) **the person to whom the delegation is made does not represent to the public that the person is authorized to practice medicine. . . .** (Emphasis added).

[238] Staff Ex. 68.03 at 25-26.

drugs and to treat patients with malignant cancer, when, in her opinion, Dr. Marquis was not qualified to do so.[239]

As a threshold legal issue, Respondent objects to Staff's claim that he is vicariously responsible for medical acts provided by other licensed physicians at the Clinic.[240] He argues that the Code does not impose a duty on one licensed physician to supervise another licensed physician who is exercising their own clinical judgment in the treatment of patients. Respondent agreed that he had input into patients' treatment plans, but stressed that the Clinic's oncologists evaluated, approved, and implemented the treatment plans.[241]

Respondent also argues that the Clinic's licensed physicians were medically qualified by training and experience to provide medical care to the Clinic's patients. As previously discussed, patients at the Clinic were assigned a team of health care providers that included an oncologist, an internist or family practitioner; and a research associate.[242] The licensed physicians, not the research associates, made treatment decisions and issued orders for patients,.

Dr. Gregory Burzynski is a board-certified internist who studied at the Jagiellonian University Medical School in Krakow, Poland, for four years. He completed his residency at Southwestern Seton Family in Austin, Texas. As part of his residency, Dr. Gregory Burzynski worked for a month at M.D. Anderson Cancer Center in an elective oncology rotation.[243] After his residency, Dr. Gregory Burzynski joined his father's practice at the Clinic in the summer of 2010. He was licensed by the Board in January 2011.[244] Dr. Gregory Burzynski has done his CMEs at the Society of Neuro-Oncology for the past four years.[245]

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[239] Staff Ex. 68.03 at 37.

[240] Respondent's Closing Arguments at 28.

[241] For example, Dr. Valladares signed Patient A's treatment plan. Staff Ex. 5.02.A at 845. Dr. Weaver signed Patient F's treatment plan. Staff Ex. 6.01.A at 2035.

[242] Tr. Vol. 7 at 81-82.

[243] Staff Ex. 66.GG at 4-5; Tr. Vol. 10 at 8-9.

[244] Tr. Vol. 10 at 46.

[245] Staff Ex. 66.GG at 5.

Dr. Gregory Burzynski testified that he was responsible for treating associated internal medical problems that arose during a patient's cancer treatments.[246] He explained that when evaluating a patient's treatment options, the team assigned to that patient discussed the patient's medical history and treatment options, but the oncologist on the team made the treatment decisions.

Dr. Gregory Burzynski agreed that he was involved in Patient B's care, but stressed that Dr. Valladares was the assigned oncologist. He pointed out that Patient B brought his personal physician from Germany, Dr. Brandt, to the Clinic.[247] Patient B's wife was also a physician. According to Dr. Gregory Burzynski, he participated in taking Patient B's history and in reviewing the informed consent forms with the patient and Dr. Brandt. During their conversations, Dr. Gregory Burzynski stated he paid attention to Patient B's language, behavior, and questions, as well as how he interacted with everyone, to evaluate the patient's mental state.[248] In Dr. Gregory Burzynski's opinion, Patient B and Dr. Brandt understood what he told them about the anti-cancer drugs recommended in the treatment plan.[249]

Dr. Marquis has an undergraduate degree from the College of Pharmacy at the University of Texas in Austin. He completed medical school at the University of Texas Medical Branch in Galveston, Texas, and did his residency at Central Texas Medical Foundation at Brackenridge Hospital in Austin.[250] He is a family physician and originally had his own practice in Austin. After his father-in-law developed prostate cancer, Dr. Marquis stated, he closed his practice and moved closer to the Dallas/Fort Worth area to help him. When his father-in-law improved, Dr. Marquis and his family moved to Houston, Texas, and he began working at the Clinic in 2006.[251] He continued to work there until 2014.[252]

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[246] Tr. Vol. 10 at 11.

[247] Tr. Vol. 10 at 33.

[248] Tr. Vol. 10 at 35.

[249] Tr. Vol. 10 at 35-36.

[250] Tr. Vol. 13 at 5.

[251] Tr. Vol. 13 at 5.

[252] Tr. Vol. 13 at 6.

According to Dr. Marquis, he received on-the-job training at the Clinic, but is not an oncologist and did not make oncology treatment decisions.[253] Dr. Marquis agreed that he was part of the team assigned to Patients C and D, but clarified that his role was to assist the oncologist in monitoring and communicating with the patients, to ensure the Clinic received the requested labs and scans in a timely manner, and in managing "toxicities."[254] As a family practitioner at the Clinic, Dr. Marquis said that he "had better and easier contact with the patients, more time on my hands to be able to communicate with them, and you know, speak to them as long as they needed me to . . . make sure everything was going well."[255]

Dr. Marquis testified that when he was assigned to a team to care for a patient he would attend the initial consultation. During this meeting, Dr. Marquis said, Respondent told the patient and their family, if present, that PB was not FDA-approved to treat their type of cancer.[256] Dr. Marquis confirmed that he conducted the patient's physical examination and documented his findings in the patient's medical records. Typically, Dr. Marquis said, the physical examination was done the day the patient arrived at the Clinic.[257]

The Clinic provided gene-targeted treatments using FDA-approved medications in a non-FDA approved manner, Dr. Marquis explained. The Clinic did not provide alternative cancer treatment, which in his experience involved treatment with herbs, creams, and vitamins, but did not include any anti-cancer medications.[258] Dr. Marquis said that when a patient who did not want to take anti-cancer drugs learned that the Clinic did not provide alternative treatment, they usually left the Clinic.[259]

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[253] Tr. Vol. 13 at 7.

[254] Tr. Vol. 13 at 9.

[255] Tr. Vol. 13 at 9.

[256] Tr. Vol. 13 at 13-14.

[257] Tr. Vol. 13 at 15.

[258] Tr. Vol. 13 at 12.

[259] Tr. Vol. 13 at 13.

Before Patient C arrived at the Clinic, his local oncologist in Indiana, Dr. Waits, diagnosed Patient C with mesothelioma. The diagnosis was confirmed in a pathology report.[260] Dr. Marquis confirmed that Patient C was informed that PB was not FDA-approved for his cancer and was informed about the potential side effects of the various anti-cancer agents that were being proposed for treatment.[261] When Patient C returned home, Dr. Marquis recalled, Dr. Waits continued the treatment regimen.[262] This indicated to Dr. Marquis that Dr. Waits had "looked at the logic behind the treatment plan that was put together" at the Clinic and found "it to be sound."[263]

Dr. Marquis emphasized that he was not Patient C's oncologist and did not make decisions concerning changes to the oncology treatments.[264] Once the oncologist made a decision about what medications to give the patient, Dr. Marquis explained, the oncologist told Dr. Marquis what mediations to order.[265] He would manage the side effects experienced by the patient, ensure that the "[l]ab and scan reports" were done, review the results, and share the information with Dr. Waits.[266]

Although some of Dr. Wait's communications with the Clinic were addressed to RA Acelar as "Dr. Acelar," Dr. Marquis confirmed that she passed on the information to Respondent and Dr. Joshi.[267] Dr. Marquis agreed that it would "not be right" if RA Acelar failed to inform Dr. Waits that she was not a licensed physician.[268]

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[260] Tr. Vol. 13 at 27-28.

[261] Tr. Vol. 13 at 34-35.

[262] Tr. Vol. 13 at 23-24.

[263] Tr. Vol. 13 at 24.

[264] Staff Ex. 66.II at 112.

[265] Staff Ex. 66.II at 112-113.

[266] According to Dr. Marquis, Dr. Valladares typically wrote his own prescriptions, but Dr. Joshi did not. Dr. Joshi had Dr. Marquis prepare and sign the prescriptions. Staff Ex. 66.II at 115.

[267] Staff Ex. 66.II at 109.

[268] Staff Ex. 66.II at 109.

Dr. Marquis did not remember Patient D because the patient elected not to be treated at the Clinic. After reviewing the patient's records, Dr. Marquis agreed that he prepared the June 7, 2011 consultation note in which he summarized the Caris genetic report and Respondent's treatment recommendations.[269] Dr. Marquis denied that he wrote any prescriptions for this patient.[270]

Dr. Marquis performed Patient G's August 31, 2012 physical examination and was responsible for the patient's history and physical report.[271] Dr. Marquis maintained that Patient G did not require a mental status examination because the patient was alert.[272] He reiterated that he did not make the oncology treatment decisions. Because Patient G's local oncologist treated Patient G's side effects, Dr. Marquis said that he just documented the information in the medical record.[273]

B. ALJs' Analysis Regarding Licensed Providers

Code § 157.001 allows a physician to delegate medical acts to a qualified and properly trained person acting under the physician's supervision if a reasonable and prudent physician would find such acts appropriate to delegate. The statute goes on to provide that this person may not "represent to the public that the person is authorized to practice medicine." The Clinic's licensed physicians, specifically Dr. Gregory Burzynski and Dr. Marquis, were and are licensed by the Board to practice medicine. Therefore, Respondent was not responsible for the medical acts performed by Drs. Gregory Burzynski and Marquis under Code § 157.001.

The issue then becomes whether Respondent violated Code §§ 164.051(a)(6) and 164.053(a)(8) and (9).[274] The credible evidence indicates that Dr. Gregory Burzynski and

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[269] Staff Ex. 66.II at 134, 139.

[270] Staff Ex. 66.II at 139.

[271] Staff Ex. 66.II at 139-140.

[272] Tr. Vol. 13 at 40.

[273] Staff Ex. 66.II at 148-149.

[274] Code § 164.051(a)(6) allows the Board to discipline a physician for failing to "practice medicine in an acceptable professional manner consistent with public health and welfare. Code § 164.053(a)(8) and (9) clarify that

Dr. Marquis had the training and expertise to participate in providing the medical services they provided to the Clinic's patients. Both physicians were assigned to work with an oncologist and a research associate in the treatment of specific patients, and assisted the oncologist at the Clinic in the treatment of these patients.

Dr. Gregory Burzynski and Dr. Marquis credibly testified that they did not make oncology treatment decisions, but deferred such decisions to the Clinic's oncologists and Respondent. Their contribution to the team of health care professionals assigned to specific patients was to conduct and document the patient's history and physical examination, write prescriptions, ensure laboratory results and scans were timely received and reviewed, and participate in discussions and conferences with the assigned oncologist regarding treatment options. In addition, they were responsible for treating side effects caused by the anti-cancer medications, such as diarrhea and increased blood pressure, and monitoring a patient's progress on treatment. Drs. Gregory Burzynski and Marquis also maintained weekly contact with the patients and the patients' local oncologists once the patients returned home and reported any side effects the patient experienced to the appropriate oncologist.

Based on the credible evidence, the ALJs find that Dr. Gregory Burzynski and Dr. Marquis were qualified by training, experience, and licensure to perform the medical acts they performed. Because Staff failed to prove by a preponderance of the evidence that Respondent improperly delegated to either physician medical responsibilities or acts that they were unqualified to perform, the ALJs find that in regards to the licensed physicians discussed above Respondent did not engage in unprofessional or dishonorable conduct as defined in Code § 164.053(a)(8) and (9).

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unprofessional conduct likely to deceive or defraud the public includes a physician's failure to adequately supervise those under the physician's supervision and delegating to a person professional responsibilities or acts that the physician knows or should have known the person is unqualified to perform by training, experience, or licensure.

C. Unlicensed Practitioners

The Clinic's research associates were often foreign-trained doctors unlicensed in the United States.[275] Respondent hired the research associates and supervised many of their activities. Staff alleges that Respondent misrepresented the qualifications of the following unlicensed foreign-trained physicians to the Clinic's patients, their families, and local oncologists, and improperly allowed them to practice medicine: Tolib Rakhmanov, Mohammed Khan, Larisa Tikhomirova, Sheryll Acelar, and Lourdes DeLeon.[276] Staff asserts that the medical records for Patients A through G reflect that these research associates practiced medicine by ordering medications, diagnostics tests, and laboratory tests without any documented input of a licensed physician; made treatment recommendations; and interacted with patients and other medical personnel without clarifying that they were not licensed to practice medicine in Texas. According to Staff, by allowing the research associates to represent that they were authorized to practice medicine and improperly delegating medical acts to them that they were unqualified to perform, Respondent violated Code §§ 157.001, 164.052(a)(17)[277] and 164.053(a)(8) and (9).

Patient F, Patient F's wife, Patient A's wife, and Dr. Lassiter (Patient A's local oncologist) testified that the Clinic's research associates were held out to be licensed medical physicians. However, Patient A's wife also agreed that the research associate assigned to her husband did not do anything without first talking to Dr. Valladares or Respondent.[278] Patient F testified that he did not think that the research associate assigned to his case, RA Tikhomirova, made treatment decisions.[279] However, he estimated that about 80% of the time, he met and discussed issues about his treatment with RA Tikhomirova.[280]

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[275] Tr. Vol. 7 at 81-82.

[276] To avoid confusion between the licensed physicians and the unlicensed foreign-trained physicians, the ALJs will use the abbreviation "RA" rather than "Dr." before their last names.

[277] According to Code § 164.052(a)(17), a physician is prohibited from directly or indirectly aiding and abetting the practice medicine by an unlicensed person.

[278] Tr. Vol. 5 at 74-75.

[279] Tr. Vol. 4 at 152-153.

[280] Staff Ex. 66.AA at 6.

Patient F acknowledged that he signed the informed consent forms that RA Tikhomirova discussed with him, but could not remember what RA Tikhomirova told him about the drugs because it was too long ago. He said that he thought he would remember if she told him about something that could damage his health.[281] Patient F acknowledged that he did not read the informed consent forms before signing them, but he should have.[282] If RA Tikhomirova was not a licensed doctor, he stated that he would feel "misled" because she was "the main one that doctored me,"[283] even though he assumed Respondent was treating him.[284]

Dr. Wetmore conceded that certain aspects of patient care, such as obtaining informed consent, may be properly delegated to someone other than a licensed physician.[285] However, because the research associates signed consent forms on the signatory line for the physician, she opined that the Clinic's patients were misled into believing that the research associates were licensed physicians.[286] This misrepresentation was reinforced, she noted, because the research associates were addressed as "doctor" and wore white lab coats with a name tags identifying them to be doctors. In Dr. Wetmore's opinion, Respondent did not tell the patients, the patients' families, or the patients' local oncologists that the research associates were unlicensed.[287] As a result, she concluded that Respondent failed to properly supervise the research associates, improperly delegated medical tasks to them, and aided and abetted them in the unlicensed practice of medicine.

Dr. Levin disagreed that the research associates were practicing medicine. He explained that a physician is the person who "synthesizes the data and makes a diagnosis, offers treatment,

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[281] Staff Ex. 66.AA at 39.

[282] Staff Ex. 66.AA at 37.

[283] Staff Ex. 66.AA at 54.

[284] Staff Ex. 66.AA at 86.

[285] Tr. Vol. 3 at 124.

[286] Staff Ex. 68.03 at 88, 94.

[287] In Staff's Reply Brief, Staff asserted that Respondent violated Code § 104.004, part of the Healing Art Identification Act. However, Staff did not include this allegation in its Second Amended Complaint. The Texas Government Code § 2001.052(a) requires that the notice of hearing include, among other things, a "reference to the particular sections of the statutes and rules involved." Therefore, allegations regarding the Healing Art Identification Act it will not be addressed further.

carries out treatment that's actually practicing medicine."[288] In his opinion, none of the Clinic's research associates participated in decision-making roles regarding patient care. Therefore, he opined, they were not practicing medicine.[289] Dr. Levin also pointed out that it is not uncommon for a person with a doctorate degree to be addressed as "Doctor."[290]

Dr. Burzynski testified that during the initial consultation patients were introduced to the oncologist, internist or family practitioner, and the research associate assigned as their health care team. He explained to patients that that the research associates were foreign-trained doctors who were unlicensed.[291] Dr. Burzynski emphasized that research associates had no independent decision-making authority regarding the diagnoses and treatment of Clinic patients and pointed out that even Dr. Wetmore agreed that the medical records do not prove that any unlicensed person made treatment decisions.[292]

Dr. Marquis confirmed that the Clinic's research associates stayed in contact with patients and acted as an intermediary between the physician and patient.[293] If there was an issue that required a physician's input, Dr. Marquis stated that the research associate took notes, consulted a physician and/or oncologist, and informed the patient about the physician's decision.[294] Dr. Marquis denied that the research associates practiced medicine.[295]

According to Dr. Gregory Burzynski, the research associates supported the Clinic's oncologists by serving as their scribes and communicating with patients.[296] As foreign medical

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[288] Tr. Vol. 11 at 169.

[289] Resp. Ex. 165 at 69.

[290] Resp. Ex. 165 at 69.

[291] Tr. Vol. 7 at 80-82, 214.

[292] Tr. Vol. 6 at 83.

[293] Tr. Vol. 13 at 37-39.

[294] Tr. Vol. 13 at 39-40.

[295] Tr. Vol. 13 at 38.

[296] Tr. Vol. 10 at 17.

doctors, he pointed out, they had a wealth of medical knowledge and were very competent.[297] In his opinion, the research associates freed up the oncologists' time so they could focus on medical issues.[298] While a physician was ultimately responsible for the patient, Dr. Gregory Burzynski maintained that non-physician medical professionals made valuable contributions and recommendations regarding a patient's treatment without engaging in the practice of medicine.[299]

In contrast to Patients A's and F's experience at the Clinic, Margaret Manning, a former Clinic patient, testified that the research associate assigned to her case told her that she was not a licensed physician and could not make treatment decisions or write prescriptions.[300] Mary Susan McGee, another Clinic patient, stated that that she knew the research associate, RA Rakhmanov, was not a licensed physician and served as a "communicator."[301] He received instructions from the licensed physicians. According to Ms. McGee, RA Rakhmanov did not provide medical treatment to her and did not prescribe any medications.[302]

Mary Michaels, the mother of a pediatric patient, testified that the research associates working on her son's team told her that they were licensed in Poland, but not in the United States.[303] Mary Jo Siegel, another Clinic patient, testified that when she arrived at the Clinic a research associate took her vitals and asked her how she had been doing.[304] She knew that they were foreign-trained physicians who were unlicensed in the United States. They did not diagnose or treat her cancer.

The background, allegations, and evidence regarding each research associate are separately addressed below.

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[297] Tr. Vol. 10 at 18.

[298] Tr. Vol. 10 at 19.

[299] Tr. Vol. 10 at 26-27.

[300] Tr. Vol. 13 at 95.

[301] Tr. Vol. 11 at 16-17.

[302] Tr. Vol. 11 at 16-17.

[303] Tr. Vol. 10 at 145.

[304] Tr. Vol. 10 at 155.

1. Tolib Rakhmanov

RA Rakhmanov attended medical school and practiced medicine in Tajikistan, but is unlicensed in the United States. He began working for the Clinic as a research associate in 2006 and left in July 2016.[305] His job duties included collecting the patient's medical history and obtaining the patient's prior medical records before the patient came to the Clinic. According to RA Rakhmanov, the Clinic divided the research associates among the licensed physicians and that he usually worked with Dr. Valladares.[306]

RA Rakhmanov insisted that he never performed the physical examination of a Clinic patient. If a patient decided to be treated at the Clinic after consulting with the licensed physicians, he gave the patient the informed consent forms for each prescribed treatment medication and then discussed with the patient information about the medications and what was on the informed consent form.[307]

Dr. Wetmore focused on the medical records that she said documented RA Rakhmanov's involvement in the evaluation and treatment of Patients A,[308] B,[309] and C.[310] She reported that the medical records reflect that RA Rakhmanov took patient histories, signed orders, reviewed laboratory results, oversaw the infusions, obtained informed consents from the patient, and corresponded with the patient's local oncologist. Such activities, she maintained, constitute the practice of medicine. Further perpetuating the misconception that RA Rakhmanov was a licensed physician, Dr. Wetmore pointed out, the Clinic referred to him as "Dr. Rakhmanov," and he was permitted to wear a white lab coat with a name tag identifying him as a doctor. In

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[305] Staff Ex. 66.H at 4.

[306] Staff Ex. 66.H at 24.

[307] Staff Ex. 66.H at 9.

[308] Staff Exs. 5.02; 33.5.

[309] Staff Exs. 5.03A; 33.1.

[310] Staff Exs. 5.04; 33.7.

her opinion, Respondent allowed RA Rakhmanov to engage in the unlicensed practice of medicine.[311]

RA Rakhmanov agreed that his colleagues at the Clinic referred to him as "Dr. Rakhmanov," but he explained they did so out of respect for his being a medical school graduate.[312] When a patient arrived at the Clinic, he said, he visited with the patient, but a licensed physician always saw the patient unless the patient came just to have their vital signs taken or the physician felt it was unnecessary.[313] When patients came for an infusion, RA Rakhmanov reported, they were directed to the infusion room where the infusions were done under the supervision of Clinic personnel who were "licensed to do infusions."[314] Although Patient A's wife and Dr. Lassiter believed he was a licensed physician, RA Rakhmanov denied that he mislead patients. He testified that when he introduced himself to patients he told them that he had graduated from medical school in Russia, but that he was not licensed in the United States.[315]

Patient A is deceased, but his wife was present with Patient A when RA Rakhmanov was introduced to her husband. Patient A's wife and his local oncologist, Dr. Lassiter, testified that they understood that RA Rakhmanov was Patient A's treating physician. Patient A's wife recalled that RA Rakhmanov told her and her husband that he was a "GI" doctor, so they assumed he was a specialist in gastrointestinal cancers.[316] After the initial consultation, Patient A's wife confirmed that the only doctor Patient A saw at the Clinic was RA Rakhmanov.

Patient A's October 7 and 13, 2010 laboratory test results identify both Dr. Marquis and RA Rakhmanov as Patient A's doctors.[317] The October 8 and 11, 2010 pathology reports

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[311] Staff Ex. 68.03 at 88, 92-94.

[312] Staff Ex. 66.H at 31.

[313] Staff Ex. 66.H at 48.

[314] Staff Ex. 66.H at 53.

[315] Staff Ex. 66.H at 12-13; 31-32.

[316] Patient A had colon cancer that had metastasized to his liver.

[317] Staff Ex. 5.02.A at 584-586.

indicate that the ordering physician was "Valladares/Rakhmanov."[318] RA Rakhmanov signed as the "Physician performing consent," on Patient A's October 11, 2010 Informed Consent Statement for PB.[319] In a letter dated October 15, 2010, Dr. Marquis notified Patient A that all of "Dr. Tolib Rakhmanov's" patients were being transferred to Dr. Valladares. The letter further instructed Patient A to direct all correspondence "including laboratory studies, scan results, questions, and concerns to both Dr. Rakhmanov and Dr. Valladares."[320] Additionally, the October 22, 2010 infusion nurse's note documented that "Dr. TR [RA Rakhmanov] notified of BP= 130/89, instructed to d/c IV and to home for today."[321] After Patient A returned home, RA Rakhmanov signed physician's orders to ship Patient A's treatment medication to the patient.[322]

Staff maintains that RA Rakhmanov engaged in similar conduct in the treatment of Patients B and C. Patient B's medical records show that Dr. Gregory Burzynski told Patient B's local physician, Dr. Brandt, that "Dr. Rakhmanov" could assist with any questions about Patient B.[323] RA Rakhmanov also communicated specific dosage instructions for the administration of ANP and Avastin to Dr. Brandt and signed the email as "Dr. Tolib."[324] When Patient B appeared to be dying from complications related to side effects from his treatment regime, Staff asserts, Dr. Gregory Burzynski deferred the treatment decision to RA Rakhmanov as indicated by the signature on the correspondence—"Dr. Tolib Rakhmanov."[325]

RA Rakhmanov remembered working on the team assigned to Patient A. He said that Dr. Valladares conducted Patient A's physical examination, and, together with Respondent,

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[318] Staff Ex. 5.02.A at 587-589.

[319] Staff Ex. 5.02.A at 837-838.

[320] Staff Ex. 5.02.A at 870.

[321] Staff Ex. 5.02.A at 803.

[322] Staff expert, Ms. Kloos, testified that the Clinic used RA Rakhmanov's orders as the basis for billing Patient A the monthly case management fee. This issue will be addressed in Section VIII regarding improper charges.

[323] Staff Ex. 5.03.A at 1165.

[324] Staff Ex. 5.03.A at 1159.

[325] Staff Ex. 5.03.A at 1142.

developed a treatment plan.[326] Although he signed Patient A's order for supplements, he said he did so at Respondent's direction.[327] RA Rakhmanov said that he signed the informed consent form for PB on October 11, 2010, but only after the licensed physician explained the benefits and side effects of the medication to Patient A in his presence.[328] Despite the infusion nurse's note, RA Rakhmanov stated that the nurse notified him about Patient A's blood pressure, but that he did not discharge the patient to go home; rather, the nurse did.[329] RA Rakhmanov could not explain why Dr. Lassiter thought he created the Patient A's treatment plan as reflected in Dr. Lassiter's letter.[330]

As for Patient B, RA Rakhmanov agreed that Patient B was not in a clinical trial event, though the patient received ANP. On July 5 through 7, 2011, RA Rakhmanov signed Patient B's informed consent as the physician performing the consents.[331]

2. ALJs' Analysis Regarding Unlicensed Practitioners

As noted before, a physician has the authority to delegate medical acts to an unlicensed person under Code § 157.001, but the unlicensed person may "not represent to the public that the person is authorized to practice medicine."[332] Code § 164.053(a)(8) further provides that a physician's failure to supervise adequately the activities of those acting under the physician's supervision constitutes unprofessional or dishonorable conduct likely to deceive or defraud the public.

Dr. Levin correctly noted that other professionals may be addressed as "Doctor." While the Code defines the word "physician," it does not define "doctor." Therefore, the context in

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[326] Staff Ex. 66.H at 26.

[327] Staff Exs. 66.H at 30; 5.02.A at 783.

[328] Staff Exs. 66.H at 39-40; 5.02.A at 836-838.

[329] Staff Exs. 66.H at 55; 5.02.A at 803.

[330] Staff Ex. 66.H at 60-64.

[331] Staff Ex. 5.03.A at 897-910.

[332] Code § 157.001(a)(2).

which the person is acting when called "doctor" is relevant. A person working in a medical setting, wearing a white lab coat with a name tag identifying the person as "doctor" and addressed by staff as "doctor," who signs informed consent forms and orders in the space designated for the physician's signature, and communicates with other health-care providers as though he were a licensed physician, is representing to the public that he is authorized to practice medicine. In a medical setting, RA Rakhmanov presented as a licensed physician, and Patient A, Patient A's wife, Dr. Lassiter, Patient F, and Patient F's wife reasonably trusted that RA Rakhmanov was a licensed physician.

Respondent was aware, or should have been aware, that patients such as Patients A and F and outside oncologists, such as Dr. Lassiter, believed RA Rakhmanov was a licensed physician because Respondent had access to correspondence and medical documents that evidenced this misrepresentation. Respondent had an obligation as a physician who supervised and delegated medical acts to RA Rakhmanov to ensure that RA Rakhmanov did not directly or indirectly represent to the public that he was authorized to practice medicine, and Respondent failed to do so. By failing to adequately supervise RA Rakhmanov to ensure that he did not misrepresent his licensure, either directly or indirectly, Respondent engaged in unprofessional conduct as described in Code § 164.053(a)(8).

Based on the credible evidence, the ALJs find that Respondent supervised RA Rakhmanov, delegated medical acts to RA Rakhmanov, and permitted him to be misrepresented as a person authorized to practice medicine in violation of Code § 157.001.[333] . By failing to adequately supervise RA Rakhmanov to ensure that he did not misrepresent his licensure, either directly or indirectly, Respondent engaged in unprofessional conduct as described in Code § 164.053(a)(8).

Although RA Rakhmanov represented himself to be a person authorized to practice medicine in violation of Code § 157.001, whether Respondent aided and abetted RA Rakhmanov

[333] Code § 151.002(a)(12) defines a physician to be "a person licensed to practice medicine in this state."

in the unlicensed practice of medicine is a different issue. Code § 151.002(a)(13) defines the term "practicing medicine" as:

> the diagnosis, treatment, or offer to treat a mental or physical disease or disorder . . . by any system or method, or the attempt to effect cures of those conditions, by a person who: (A) publicly professes to be a physician or surgeon; or (B) directly or indirectly charges money . . . for those services.

Patient A's wife agreed that although she believed that RA Rakhmanov was a physician, he would not do anything without instructions from Dr. Valladares or Respondent.[334] Ms. McGee, a former patient, confirmed that RA Rakhmanov did not make treatment decisions.[335]

RA Rakhmanov's testimony that he relied on the licensed oncologists and physicians to diagnose and treat the Clinic's patients was persuasive. The evidence does not support a finding that RA Rakhmanov was unqualified to perform the medical acts that were delegated to him by Respondent and the other Clinic physicians. Because RA Rakhmanov was performing medical acts under a physician's supervision that he was qualified to perform, he was not engaged in the practice of medicine. The ALJs find that the evidence is insufficient to establish that RA Rakhmanov engaged in the practice of medicine or that Respondent delegated to him medical acts that he was unqualified to perform. Therefore, Respondent did not aid and abet RA Rakhmanov in the unlicensed practice of medicine as defined in § 164.052(a)(17), and did not engage in unprofessional conduct as defined by Code § 164.053(a)(9).

3. Mohammed Khan

RA Kahn attended medical school and was licensed in Pakistan. He worked as a radiologist for 4 years before moving to the United States, but he is not licensed in the United States.[336] RA Khan has been employed by the Clinic as a clinical research associate since 1997,

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[334] Tr. Vol. 5 at 74-75.

[335] Tr. Vol. 13 at 95; Vol. 11 at 16-17.

[336] Staff Ex. 66.E at 16.

primarily working as the Clinic's radiology technician.[337] The Clinic does not perform its own radiology scans, but when radiology films arrived at the Clinic, RA Kahn collected them, downloaded them into the computer, and then showed them to the treating physicians.[338] RA Khan said that he has not worked directly with patients since 2000 through 2001, but he would see patients if they wanted to see their films.[339]

In Dr. Wetmore's opinion, Respondent knew that RA Khan was identified to patients, their families, and the patients' local physicians as a licensed radiologist.[340] Specifically, Staff asserts that RA Khan practiced medicine by reviewing diagnostic tests, writing radiology reports, and being involved in the evaluation and treatment of patients. Dr. Wetmore testified that "[t]he measurement of tumor size on radiographic imaging is the practice of radiology and the practice of medicine, even if [Respondent] also reviewed and measured after Mohammed Khan to check his work."[341]

According to Dr. Wetmore, Patients A through G's medical records contained conflicting radiological reports: some were performed by independent, unaffiliated radiologists and others performed by unidentified persons at the Clinic. The reports often contained different measurements and assessments than those contained in the independent reports.[342] Although she agreed that a radiology technician may measure tumors, particularly if the measurements are verified by a physician, Dr. Wetmore clarified that "the physician needs to remeasure the lesion and absolutely confirm that it is the correct position and orientation to make a valid measurement." She stressed that only the physician may determine if there has been a change in the tumor's size, and she saw no documentation to show that Respondent had remeasured the lesions.[343]

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[337] Staff Ex. 66.E at 5.

[338] Staff Ex. 66.E at 5.

[339] Staff Ex. 66. E at 16, 18.

[340] Staff Ex. 68.03 at 93-94.

[341] Staff Ex. 68.03 at 92-95.

[342] Staff Ex. 68.03, at 16, 22, 30-34, 41, 46-47, 52, 63-64.

[343] Tr. Vol. 3 at 137-138; Vol. 6 at 83-85.

RA Khan agreed that he measured tumors on the films and would share his measurements with the physicians when they viewed radiology films.[344] However, he testified that before making treatment decisions, Respondent always measured the lesions himself[345] and the physicians typically interpreted the films themselves and waited for the measurements from the outside report.[346]

Dr. Burzynski testified that he supervised RA Khan and had RA Khan retrieve the archived scans and current scans for the physicians for review. The physicians then instructed RA Khan as to which tumors to measure and where to place the cursors so the computer could calculate the tumor size. Later, Dr. Burzynski said, he would dictate the radiology notes to RA Khan so that RA Khan could write up the report for him.[347] According to Dr. Burzynski, when he was busy, RA Khan would "come up with the image; and then I came back and I checked this to make sure that the images were correct."[348]

Drs. Marquis and Weaver confirmed that RA Khan took cursory measurements of the lesion locations, and created reports that compared the patient's scans. According to Dr. Marquis, Respondent reviewed "every film, every measurement, and adjust [sic] them to his measurements."[349] Dr. Weaver also said that Respondent reviewed RA Khan's measurements.[350] RA Rakhmanov reported that:

> Dr. Khan will show them, I'm going to do from this side of the tumor to this side of the tumor. And then, you know, it's all computer, you know how tall the measurements are, that it right away gives you the measurements. And then doctors, they should tell their opinion, they agree with that or not. That's how it was done.[351]

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[344] Staff Ex. 66.E at 10.

[345] Staff Ex. 66.E at 11.

[346] Staff Ex. 66.E at 12-13, 23-24.

[347] Tr. Vol. 9 at 56; Staff Ex. 66.JJ at 11-12.

[348] Staff Ex. 66.JJ at 12-13.

[349] Tr. Vol. 13 at 19-20.

[350] Staff Ex. 66.Q at 25-27.

[351] Staff Ex. 66.H at 66.

What is "being accomplished, not what is being done," Dr. Levin stated, determines if the person preparing a radiology report is practicing medicine.[352] If the radiologist is a "scribe" who is taking dictation from the physician to prepare a radiology report, then the radiologist is not practicing medicine, according to Dr. Levin. He pointed out that radiology technicians are allowed to take the tumor measurements for a physician to use in the physician's radiology report without it constituting the practice of medicine.[353] But, if a person creates a radiology report that is to be used clinically or in a patient's ongoing care, not just to facilitate a physician's interpretation of a study, he agreed it is the practice of medicine and the person must have a medical license.[354]

4. ALJs' Analysis

RA Khan worked as a radiology technician and was not directly involved with the Clinic's patients. Because he had limited contact with patients, patients' families, or outside health-care providers, the ALJs find that the evidence is insufficient to show that RA Khan held himself out to the public to be a licensed physician. RA Khan admitted he took tumor measurements from scans he downloaded into the computer, but Respondent confirmed that he remeasured the tumors to verify the measurements. The other physicians relied on their own review of the radiologic imaging and the official radiology report to make treatment decisions. In addition, Respondent actively supervised RA Kahn while he measured the lesions and then adjusted these measurements to conform to his measurements. Although RA Khan prepared the radiology reports, Respondent dictated what he wanted in the report. Therefore, the ALJs find that Respondent did not fail to supervise RA Khan, did not improperly delegate medical acts to him, and did not aid and abet RA Khan in the unlicensed practice of medicine as set out in Code §§ 157.001, 164.052(a)(17), and 164.053(a)(8) and (9).

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[352] Tr. Vol. 11 at 91-92.

[353] Tr. Vol. 11 at 195.

[354] Tr. Vol. 11 at 92-93.

5. Larisa Tikhomirova

RA Tikhomirova worked at the Clinic as a research associate from July 2009 to May 2012.[355] She attended medical school outside the United States, but is not licensed in the United States.[356] While working at the Clinic, RA Tikhomirova's job duties included taking the patient histories, maintaining documentation, conducting follow-up visits, communicating with the patient and the patient's local physician, and issuing certain orders as Respondent directed.[357] According to RA Tikhomirova, when a new patient arrived, she took the patient's history and gathered all the medical information and documentation to deliver to the assigned physicians.

RA Tikhomirova agreed she was present during some of the initial consultations with patients, Respondent, and the physicians during which the patient's disease, diagnoses, and proposed treatments were discussed.[358] If the patient elected to start treatment, RA Tikhomirova said that she would issue the orders for lab tests, PET scans, and MRIs as instructed by the physicians. When the results were received, she gave them to the senior physician to review and sign. After the senior physician had signed off on the results, RA Tikhomirova stated, she then signed it.[359]

According to RA Tikhomirova, the Clinic had a mandatory policy that only a licensed physician could perform the patient's physical examination. Once treatment started, if a patient experienced any complications or symptoms arose, the research associates were required to call either the senior physician or the oncologist.[360] If the patient experienced no health problems, RA Tikhomirova said that she might not ask the physician to meet with the patient, but it was always the licensed physician's decision whether to see a patient.[361]

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[355] Staff Ex. 66.N at 4.

[356] Staff Ex. 66.N at 87-88.

[357] Staff Ex. 66.N at 5.

[358] Staff Ex. 66.N at 6-8.

[359] Staff Ex. 66.N at 11.

[360] Staff Ex. 66.N at 16.

[361] Staff Ex. 66.N at 17.

In Dr. Wetmore's opinion, Respondent aided and abetted RA Tikhomirova in the unlicensed practice of medicine for Patients B and F by: (1) permitting her to be addressed as "Dr. Tikhomirova"; (2) allowing her to wear a white lab coat with a name tag identifying her as a doctor; and (3) allowing her to take patient histories, sign orders, review laboratory results, oversee the infusion of prescribed drugs, review informed consent forms with patients, and communicate with other health care providers as though she were a treating physician.[362] According to Dr. Wetmore, Respondent knew and permitted RA Tikhomirova to engage in activities similar to those assigned to physician interns and residents.[363]

The medical records show that RA Tikhomirova signed the informed consent forms for Patient B as the "Physician performing consent" on February 7, 15, and 17, 2011.[364] She was identified on Patient B's laboratory results as a doctor, along with Dr. Marquis.[365] On February 7, 2011, she authorized giving supplements to Patient B and signed on the line designated for the physician's signature.[366] On February 7 and March 4, 2011, she signed radiology orders for an MRI of Patient B's brain on the line designated for "Physician Signature."[367]

RA Tikhomirova explained that while she reviewed and signed Patient B's informed consent forms, the team had already reviewed each treatment medication with Patient B and his local oncologist, Dr. Brandt.[368] Although Dr. Valladares was Patient B's oncologist, RA Tikhomirova signed documents in Patient B's medical records as "Dr. Tikhomirova."[369] This included signing the physician order for Aminocare Forte. RA Tikhomirova explained that

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[362] Staff Ex. 68.03 at 88, 92-93.

[363] Staff Ex. 68.03 at 88.

[364] Staff Ex. 5.03.A at 909-916; 918-919.

[365] Staff Ex. 5.03.A at 934-948, 959.

[366] Staff Ex. 5.03.A at 1086-1087.

[367] Staff Ex. 5.03.A at 1096, 1187.

[368] Staff Ex. 66.N at 25-26.

[369] Staff Exs. 66.N at 33; 5.03.A at 1056.

Respondent ordered this supplement for every patient.[370] As for the February 7, 2011 radiology order that she signed, RA Tikhomirova said that the physician ordered the MRI for Patient B and instructed her to prepare it. The entry regarding ANP on February 28, 2011, she explained, was to train Patient B on how to administer ANP even though it had not yet been prescribed.[371] RA Tikhomirova explained that this was an atypical situation because Patient B and Dr. Brandt were in a rush and wanted to be trained while waiting for the test results.[372]

RA Tikhomirova was also on the team assigned to Patient F. Patient F and Patient F's wife testified that they believed that RA Tikhomirova was a licensed physician.[373] Patient F's wife said that RA Tikhomirova saw her husband every day except for a ten-minute meeting that she and her husband had with Respondent and two other male doctors.[374] When she learned that RA Tikhomirova was not a licensed doctor, Patient F's wife said she felt "duped."[375] She acknowledged that the treatment decisions went through the chain of command. However, she said that she thought that RA Tikhomirova managed her husband's medication regimen because RA Tikhomirova told them how Patient F was going to take the medicine and when to start and stop each treatment series.[376] RA Tikhomirova was the only person at the Clinic who reviewed the informed consent forms with them and then signed where the physician's signature was indicated.[377]

RA Tikhomirova did not remember Patient F, but confirmed that she took his medical history and took dictation during the initial consultation with the patient.[378] Dr. Weaver testified that while RA Tikhomirova wrote the order for supplements, it was at Respondent's

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[370] Staff Ex. 66.N at 36.

[371] Staff Ex. 66.N at 56-57.

[372] Staff Ex. 66.N at 55-56.

[373] Tr. Vol. 4 at 111-112, 118-122, 217-219, 224-226.

[374] Tr. Vol. 4 at 220, 224-225; Staff Ex. 66.Z at 30-38.

[375] Tr. Vol. 4 at 224-225; Staff Ex. 66.Z at 31.

[376] Tr. Vol. 4 at 226.

[377] Tr. Vol. 4 at 272-273.

[378] Staff Ex. 66.N at 68.

directions.[379] Patient F's medical records reflect that on October 15, 2009, she signed Patient F's informed consents for Nexavar and Avastin as the "Physician performing consent." On October 13, 2009, she signed the informed consent for Xeloda, and on October 9, 2009, she signed the informed consents for Rapamune, PB, and Zolinza.[380] On each consent form, RA Tikhomirova signed as the "Physician performing consent" on the same page that documented that the "physician in charge of treatment is Dr. Stanislaw Burzynski."[381] The October 15, 2009 daily nursing report stated that "Dr. Tikhomirova" gave the order to proceed with Patient F's infusion, but explained that she only repeated to the nurse what the senior physician had instructed her to say.[382]

6. ALJs' Analysis

RA Tikhomirova was called "Dr. Tikhomirova," she wore a white lab coat with a name tag identifying her as "Dr. Tikhomirova," and she signed consent forms and orders in the space designated for the physician's signature. Because she worked at a medical facility, RA Tikhomirova presented to the public as a licensed physician. Respondent had access to patient records in which RA Tikhomirova routinely signed her name in the space reserved for the physician's signature. Respondent was aware, or should have been aware, that patients such as Patient F believed RA Tikhomirova was a licensed physician. As a supervising physician who delegated medical acts to RA Tikhomirova, Respondent had an obligation to ensure that she did not represent to the public that she was authorized to practice medicine, and he failed to do so.

Based on the credible evidence, the ALJs find that Respondent supervised RA Tikhomirova, delegated medical acts to RA Tikhomirova, and permitted her to be misrepresented as a person authorized to practice medicine in violation of Code § 157.001. By failing to adequately supervise RA Tikhomirova to ensure that he did not misrepresent his

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[379] Staff Ex. 66.Q at 41.

[380] Staff Ex. 6.01.A at 1966-1982.

[381] Staff. Ex. 6.01.A at 1966-1982.

[382] Staff Exs. 66.N at 78; 6.01.A at 2075.

licensure, either directly or indirectly, Respondent engaged in unprofessional conduct as described in Code § 164.053(a)(8).

It remains to be determined whether RA Tikhomirova practiced medicine and whether Respondent aided and abetted her to do so. In addition to the informed consents, RA Tikhomirova signed orders for lab work and supplements and communicated with Patient F and his wife as though she were a physician. But, Patient F and his wife agreed that RA Tikhomirova did not make treatment decisions. Respondent and Dr. Weaver confirmed that she acted under a physician's supervision when she performed medical acts. Staff presented insufficient evidence to show that Respondent delegated medical acts to RA Tikhomirova that she was unqualified to perform, or that she performed the medical acts without the supervision of a licensed physician.

The ALJs find that the evidence is insufficient to establish that RA Tikhomirova engaged in the practice of medicine or that Respondent delegated to her medical acts she was unqualified to perform. Therefore, Respondent did not aid and abet RA Tikhomirova in the unlicensed practice of medicine as defined in §§ 164.052(a)(17), and did not engage in unprofessional conduct as defined by Code § 164.053(a)(9).

7. Sheryll Acelar

RA Acelar graduated from St. Luke College of Medicine on August 26, 2005. Although she practiced medicine in the Philippines, she is not licensed in the United States.[383] Respondent hired RA Acelar in 2010 and frequently gave her instructions on what to do at work even though Dr. Marquis was her supervisor.[384] RA Acelar left the Clinic in 2014. In Dr. Joshi's opinion, RA Acelar was assigned activities that most interns and residents do, but she did not make treatment decisions—Respondent did.[385]

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[383] Tr. Vol. 12 at 18-19; Staff Ex. 66.C at 4-5.

[384] Staff Ex. 66.A at 29, 31.

[385] Staff Ex. 66.A at 30.

While working at the Clinic, RA Acelar said that she took the patient histories and reviewed the "systems with the patient for a new consultation for both targeted gene therapy and clinical trial."[386] She kept records for the physicians, monitored phone calls, and relayed messages about a patient's symptomatology in regards to the prescribed medications.[387] RA Acelar denied that she ever evaluated and diagnosed the Clinic patients.[388]

RA Acelar was on the team assigned to treat Patients C and G. According to Staff, she held herself out to these patients to be a licensed physician.[389] Dr. Wetmore testified that the Clinic referred to RA Acelar as "Dr. Acelar" and permitted her to wear a white lab coat with a name tag identifying her as a doctor.[390] According to Dr. Wetmore, if the research associates were not practicing medicine, then "they were certainly participating in the charade to patients and other health care providers that they were physicians."[391] Dr. Wetmore maintained that Respondent was responsible for, and aided and abetted RA Acelar in, the unlicensed practice of medicine.[392]

When Patient C first came to the Clinic, Dr. Joshi said RA Acelar took the patient's history, but Dr. Joshi denied that she or any research associate conducted the patients' physician examinations.[393] According to Dr. Joshi, RA Acelar was responsible for ensuring that the laboratory results were delivered to Respondent and Dr. Marquis so they could make treatment decisions,[394] but she did not participate in the patient's diagnosis or engage in the practice of

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[386] Staff Ex. 66.C at 6.

[387] Staff Ex. 66.C at 6

[388] Staff Ex. 66.C at 10.

[389] Staff Exs. 66.C at 63-64; 66.Q at 35, 56.

[390] Staff Exs. 66.C at 63-64, 77-80, 109-112; 66.Q at 37; 66.II at 108-110.

[391] Staff Ex. 68.03 at 88.

[392] Staff Ex. 68.03 at 94.

[393] Staff Ex. 66.A at 85.

[394] Staff Ex. 66.A at 31.

medicine. According to Dr. Joshi, RA Acelar "would never make decisions in regard to treating a patient, absolutely not."[395]

Dr. Weaver testified that RA Acelar was called "Dr. Acelar" because she had a medical degree but he agreed that she worked under the supervision of other licensed physicians.[396] According to RA Acelar, she reviewed the risks and benefits of Avastin with Patient C before initialing the Statement of Informed Consent in the space designated for the physician's signature as she was directed to do by the physicians.[397] Before Patient C signed the informed consents, RA Acelar informed him that he had the right to withdraw from treatment at any time.[398] RA Acelar put her initials on the Clinic's form entitled "Consent for Pretreatment Evaluation," where it called for the physician's signature.[399] She insisted that the licensed physicians made the treatment recommendations,[400] she only issued orders for radiology scans that the physician ordered.

According to RA Acelar, Dr. Marquis had her write his progress notes, but he told her what to write. After she had written the progress notes, Dr. Marquis reviewed and signed them.[401] Then, she initialed them. Although she also wrote the order for Patient C's infusion, RA Acelar said she did so because Dr. Marquis ordered it.[402]

The Clinic's billing supervisor, Leann Chiapetta, testified that RA Acelar handled many ANP patients and monitored their treatments, did office visits, evaluated the patients, and

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[395] Staff Ex. 66.A at 32.

[396] Staff Ex. 66.Q at 9-10.

[397] Staff Exs. 66.C at 50, 55; 5.01.A at 1222-1224.

[398] Staff Ex. 66.C at 50, 55.

[399] Staff Exs. 66.C at 13; 5.04.A at 1230.

[400] Staff Ex. 66.C at 20.

[401] Staff Ex. 66.C at 40.

[402] Staff Exs. 66.C at 43; 5.04.A at 1246.

performed the physical examinations. She clarified that RA Acelar did not make any decisions about the drugs a patient was being given.[403] Ms. Chiapetta testified that:

> [A] lot of time the R.A. was responsible for the patient. The R.A. would communicate to the oncologist. So the initial physical exam, yes, the oncologist would be there, review them; and then, of course, would get with Dr. Burzynski and they would come up with whatever treatment plan. After that the R.A. was responsible for that particular patient.
>
> So the R.A. would have been in the meeting. It is usually the oncologist, the R.A., Dr. Burzynski, they would all see the patient and discuss with the patient and then that was assigned to that particular R.A. from that point.[404]

Patient C's local oncologist, Dr. Waits, testified that he thought RA Acelar was a licensed physician because she identified herself as "Dr. Acelar."[405] It was his understanding that RA Acelar was the contact physician at the Clinic for Patient C. According to Dr. Waits, RA Acelar never told him that she was not a licensed doctor.[406] On December 9, 2010, an email was sent to RA Acelar at 9:39 a.m. requesting permission to reduce the dosage before the next infusion four days later. RA Acelar responded in two minutes at 9:41 a.m., directing Dr. Waits to make the following adjustment to the patient's treatment:

> Reduce it to 3 mg/kg and also I will await his [Dr. Waits's] email/call, thank you. Start him him [sic] on Medrol dose pack and maybe give him 40 mg of Solumedrol IV or IM. This may help with the rash. If he is still on antibiotics, please continue on with it.[407]

The same day, Dr. Waits responded in an email to "Dr. Acelar" indicating that "[a]s per your correspondence I will lower his dose to 3 mg/kg due on 12/13." RA Acelar responded, but did not tell Dr. Waits she was an unlicensed physician.[408] She explained that because he never asked

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[403] Staff Ex. 66.Y at 52-55.

[404] Staff Ex. 66.Y at 74-76.

[405] Staff Ex. 66.O at 46-50, 57-58, 63.

[406] Staff Ex. 66.C at 63.

[407] Staff Ex. 5.04.A at 1430.

[408] Staff Exs. 5.04.A at 1430; 66.C at 81.

RA Acelar if she was licensed, she did not volunteer this information.[409] According to RA Acelar, Respondent saw this communication and had her respond to Dr. Waits.[410]

According to Patient G's medical records, RA Acelar answered an email on October 30, 2012, in response to a question about whether Patient G could take various supplements. RA Acelar replied, "It is okay with me to let her have these supplements."[411] When Patient G's local oncologist notified RA Acelar that he had decreased the dosage of Decadron that Patient G received, RA Acelar wrote, "I want her back on ANP as soon as possible." RA Acelar said that the November 1, 2012 note regarding this patient was dictated to her by Dr. Marquis. After he reviewed and signed off on the note, she said that she initialed it. In that note, RA Acelar indicated that Patient G's scans were reviewed by Respondent, Dr. Marquis, and "Dr. Acelar" with the radiology department.[412]

8. ALJs' Analysis

The Clinic addressed RA Acelar as "Dr. Acelar," and she wore a white lab coat with a name tag identifying her as "Dr. Acelar." As in the previous discussions regarding the research associates, RA Acelar also signed consent forms and orders in the space designated for the physician's signature. Unlike the previous research associates, RA Acelar issued treatment orders regarding Patient C, as evidenced by her email communications with Dr. Waits. Patient C and Dr. Waits reasonably understood that RA Acelar was a licensed physician. Respondent and RA Acelar knew or should have known of this misconception and did nothing to correct it.

Respondent supervised RA Acelar, delegated medical acts to RA Acelar, and was aware, or should have been aware, that RA Acelar represented to the public that she was a licensed physician. Respondent had access to patient records in which RA Acelar routinely signed her

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[409] Staff Ex. 66.C at 63-64, 74.

[410] Staff Ex. 66.C at 74-75.

[411] Staff Ex. 5.01.A at 2839-40.

[412] Staff Ex. 66.C at 99 (RA Acelar's deposition).

name in the space reserved for the physician's signature and where she documented her treatment decisions regarding Patient C. Respondent had an obligation as a physician who supervised and delegated medical acts to ensure that RA Acelar did not practice medicine or misrepresent to the public that she was licensed to practice medicine, and he failed to do so in violation of Code § 157.001. Based on the credible evidence, the ALJs find that Respondent allowed RA Acelar to make treatment decisions regarding Patient C and permitted her to misrepresent that she was a person authorized to practice medicine. By doing so, Respondent failed to adequately supervise RA Acelar and aided and abetted RA Acelar in the unlicensed practice of medicine in violation of Code §§ 157.001, 164.052(a)(17), and 164.053(a)(8) and (9).

9. Lourdes DeLeon

RA DeLeon attended medical school in 1982, and worked for 10 years as a medical doctor in the Philippines.[413] She came to the United States in 1996 and began her pediatric residency at the University of Kansas Medical Center. RA DeLeon was unable to complete her residency because she had to care for her sick mother.[414] RA DeLeon has worked as a research associate at the Clinic since 2005.[415]

According to RA DeLeon, she did not see the patients on clinical trials or who were receiving ANP unless she was the only research assistant at the Clinic when the patient arrived. On those occasions, she would contact the patient's physician to find out what to do.[416] RA DeLeon emphasized that her function at the Clinic was to work with the oncologist as an assistant. Whatever the oncologist ordered, RA DeLeon said, she carried out because the oncologist made the diagnosis and determined the treatment.[417]

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[413] Tr. Vol. 12 at 6-7.

[414] Tr. Vol. 12 at 6-8, 18-19; Staff Ex. 66.D at 7.

[415] Tr. Vol. 12 at 8.

[416] Staff Ex. 66.D at 16, 21, 23.

[417] Staff Ex. 66.D at 10-11.

Staff accuses RA DeLeon of evaluating and treating Patient E. Staff reasons that because RA DeLeon took the patient's history, signed orders for tests and imaging, reviewed laboratory results, oversaw infusions, reviewed the informed consents with the patient, and communicated with Patient E's local oncologist as though she were a treating physician, she was practicing medicine without a license.[418] RA DeLeon admitted that she wore a white coat with a name tag identifying her as a doctor and was called "Dr." by the Clinic staff.[419] She also signed Patient E's informed consent documents on lines indicated for the physician's signature. For these reasons, Dr. Wetmore testified that Respondent improperly delegated medical acts to RA DeLeon and aided and abetted in RA DeLeon's unlicensed practice of medicine.[420]

RA DeLeon explained that she served as a liaison between a Clinic patient and the team of physicians assigned to treat that patient.[421] Although she is a licensed doctor in the Philippines, she testified that she understood that because she was unlicensed in the United States, she could not practice medicine. She maintained that she has not practiced medicine in the United States, and that she told Clinic patients that she was a graduate of a foreign medical school, but her function at the Clinic was as a research associate, not as a physician.[422]

RA DeLeon testified that she was present when Respondent explained to her patients that she was not a licensed physician.[423] During the initial consultation, she said, Respondent introduced her to the patients "as a research associate, as a foreign graduate medical, but it's [sic] not licensed to practice medicine here in . . . Texas or the United States."[424] She said that

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[418] Staff Ex. 66.A at 28-32, 70, 80-85.

[419] Tr. Vol. 12 at 31-36; Staff Ex. 66.D at 27-29, 60-63, 70-71.

[420] Staff Ex. 68.03 at 88, 93-94.

[421] Tr. Vol. 12 at 5, 11, 20.

[422] Staff Ex. 66.D at 28.

[423] Tr. Vol. 12 at 10-11.

[424] Tr. Vol. 12 at 11.

Respondent told patients that her role was as "a liaison between the patient and the physician and . . . as a contact – immediate contact with the patients and the physicians."[425]

RA DeLeon recalled that Patient E was a physician from New York.[426] Although the Clinic staff addressed her as Dr. DeLeon, she testified that she informed Patient E that she was "working as a research associate and this is my function. This is what I do here."[427] According to RA DeLeon, Respondent and Dr. Yi conferred and agreed on Patient E's cancer treatment and she documented their discussion. At the initial consultation, she said that Dr. Yi reviewed the treatment plan with Patient E and Respondent explained to Patient E the risks and benefits of taking the medications together.[428] Afterwards, RA DeLeon said she reviewed the informed consents with Patient E.

When Patient E's blood tests results arrived, RA DeLeon explained, she showed them to Dr. Yi and he told her if it was okay for the patient to start the infusion treatments. The first treatment, she said, was often PB. On September 8, 2011, she asked Respondent and Dr. Yi if Patient E could begin taking PB and both said to do so.[429] Before treatment, RA DeLeon said she discussed the risks and benefits of PB with Patient E, and then he reviewed and signed the informed consent form. She added that she had previously given Patient E the consent forms so he could read them. RA DeLeon said that she did not know why her name was on a September 7, 2011 radiology note because she was not involved in anything related to radiology.[430]

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[425] Tr. Vol. 12 at 11.

[426] Staff Ex. 66.D at 26.

[427] Staff Ex. 66.D at 28.

[428] Staff Ex. 66.D at 64.

[429] Staff Ex. 66.D at 55.

[430] Staff Ex. 66.D at 46.

10. ALJs' Analysis

The ALJs found RA DeLeon to be a credible witness. Although RA DeLeon wore a white lab coat with a name tag identifying her as "Dr. DeLeon," was called "Dr. DeLeon," and signed consent forms and lab and imaging orders in the space designated for the physician's signature, her testimony that she told patients she was unlicensed was persuasive. She clarified that she told Patient E that her function at the Clinic was to assist the Clinic's physicians and follow their instructions, and that appears to be what she did. The evidence presented was insufficient to show that RA DeLeon made treatment decisions.

Although RA DeLeon should have refrained from signing in areas designated for the physician's signature, she made certain that Patient E was aware that she was not authorized to practice medicine, and she acted only under the physician's supervision. Staff failed to provide sufficient evidence to establish that she was unqualified to perform the medical acts the physicians delegated to her. Therefore, the ALJs find that credible evidence shows that she performed the medical acts that she was qualified to perform under the direction of a licensed physician and did not misrepresent to Patient E that she was authorized to practice medicine.

11. Summary of ALJs' Analysis

The following is a summary of the ALJs' determinations:

1. Under Code § 157.001, Respondent was not responsible for the professional conduct of Dr. Gregory Burzynski and Dr. Marquis in diagnosing and treating patients at the Clinic. Both physicians were qualified by training, experience, and licensure to practice medicine. The evidence presented was insufficient to show that Respondent improperly delegated to either physician medical acts that they were unqualified to perform as set out in Code § 164.053(a)(8) and (9).

2. Respondent supervised and delegated medical acts to RAs Rakhmanov, Tikhomirova, and Acelar and permitted them to be misrepresented to the public as a person authorized to practice medicine in violation of Code § 157.001. By failing to adequately supervise these research associates so that they did not make

such misrepresentations, Respondent also engaged in unprofessional conduct as described in Code § 164.053(a)(8).

3. The evidence is insufficient to establish that RAs Rakhmanov, Kahn, Tikhomirova, and DeLeon engaged in the practice of medicine or that Respondent delegated medical acts to them that they were unqualified to perform. Therefore, Respondent did not aid and abet these research associates in the unlicensed practice of medicine as defined in §§ 164.052(a)(17), and did not engage in unprofessional conduct as defined by Code § 164.053(a)(9).

4. Respondent allowed RA Acelar to engage in the practice of medicine and therefore aided and abetted her in the unlicensed practice of medicine as defined in §§ 164.052(a)(17), and engaged in unprofessional conduct as defined by Code § 164.053(a)(9).

VI. INFORMED CONSENT[431]

Staff asserts that Respondent failed to meet the standard of care by inadequately informing Patients A through G about: (1) the efficacy and safety of combining various anti-cancer drugs; (2) the reasonably foreseeable side effects of such treatment; and (3) the off-label use of the drugs. In general, Staff argues that the Clinic's informed consent forms did not provide patients with enough information to clearly inform them about the potential dangers and the "untested, experimental" nature of Respondent's recommended treatments.[432]

Staff also alleges that Respondent failed to timely secure informed consents from patients and failed to comply with the requirements of Board Rule 200.3(2) and (7)(c). According to Staff, Respondent's failure to obtain valid informed consents from these patients constitutes a failure to practice medicine in an acceptable manner consistent with public health and welfare and subjects him to disciplinary action pursuant to Code § 164.051(a)(6). Staff further asserts that by failing to: (1) adequately disclose reasonably foreseeable side effects related to the combined used of drugs; (2) obtain informed consent before treatment; (3) disclose alternative treatments; and (4) appropriately delegate the responsibility of reviewing the informed consent

[431] Issues regarding Staff's allegations that Respondent failed to disclose to patients his ownership interest in other businesses that were associated with the Clinic are discussed in the next section of the proposal for decision and will not be discussed here.

[432] Staff's Closing Argument at 66. Although Staff accuses Respondent of giving Patient D inadequate informed consents, the ALJs are aware that Patient D elected not to be treated by the Clinic.

with Patients A through G to research associates, Respondent committed prohibited practices as described in Code §§ 164.052(a)(5) and 164.053(a)(8), and 22 TAC § 190.8(1)(A), (C), (G), (H), and (I).[433]

As discussed in the previous section, it is unnecessary for a physician to review the informed consent forms with a patient so long as a qualified person does so. Respondent had the research associates, unlicensed foreign-trained doctors, review the informed consent forms with the patients. Although Staff questions whether the research associates were qualified to do so, as discussed in the preceding section, Staff failed to show by a preponderance of the evidence that the Clinic's research associates were unqualified to review the informed consent forms with patients.

Similarly, the informed consent forms for Afinitor and Sutent signed by Patient E—that misrepresented that Afinitor would only be given if the treatment with Sutent failed—were previously discussed in Section IV(F)(3), and will not be further discussed here.

A. Concurrent Use of Medications

The Clinic gave each patient an informed consent statement for the patient's pretreatment evaluation as well as an informed consent statement for each prescribed drug.[434] The pretreatment evaluation informed consent form disclosed that before a specific treatment recommendation and plan could be developed, the patient had to undergo a physical examination, provide a blood and urine sample, and that additional x-rays and scans might be necessary. The form provided a signature line for the "Physician performing consent,"[435] and a paragraph entitled "Patient's Statement." This paragraph stated, among other things, the following:

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[433] Staff's Closing Argument at 22.

[434] For example, Staff Ex. 5.05.A at 1798-99.

[435] Staff Ex. 5.05.A at 1799.

> . . . any specific treatment plan proposed will be discussed with me further and that I [the patient] will be required to sign a more specific informed consent form for the specific treatment [sic] program that I might participate in. I understand that I may freely withdraw from being part of this regimen at any time. I have received a copy of this consent form to keep for myself.[436]

After a treatment plan was developed, the Clinic gave the patient a separate informed consent form for each drug being administered under the treatment plan. The informed consent form for each drug listed the potential side effects of that drug in a section entitled "POSSIBLE SIDE EFFECTS AND RISK OF THIS PROGRAM."[437] It did not address the effects of the concurrent use of the medications. The informed consent form also advised the patient that "all treatment for your malignancies, either conventional or experimental, have potential side effects, including those that may be life threatening; you should be aware that there are risks associated with this regimen," and that "this regimen might involve risks of which we are not currently aware."[438]

Patient F acknowledged that he signed the informed consent forms regarding the medications in his treatment plan, but said he did not understand what medications he was taking. Although RA Tikhomirova reviewed the informed consent information with Patient F, he admitted that he did not take the time to read the forms.[439] Patient F's wife explained that they felt hurried when they were going over the informed consent forms and did not understand what medications Patient F had been prescribed until they met with their local oncologist at home.[440] Patient F's wife agreed that there were lengthy discussions at the Clinic about the side effects of the medications, and that neither she nor her husband asked any questions to which they did not receive an answer.[441]

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[436] For example, Staff Exs. 5.03.A at 918-919; 5.01.A at 312-313; 5.05.A at 1798-1799.

[437] Staff Ex. 5.05A at 1787.

[438] Staff Ex. 5.05.A at 1787.

[439] Tr. Vol. 4 at 173-185; Staff Ex. 6.01.A at 1963-1982.

[440] Staff Ex. 66.Z at 36, 104; Tr. Vol. 4 (Confidential) at 239-240, 256.

[441] Tr. Vol. 4 (Confidential) at 258.

Staff maintains that Respondent failed to obtain adequate informed consents from these patients because he failed to disclose the risks associated with combining various anti-cancer drugs. Based on the information Staff provided to him, Staff's expert, Dr. Fost, testified that Respondent failed to meet his ethical and professional responsibility to candidly disclose to Patients A through F the known risks of the drugs being prescribed in their treatment regimen and the potential side effects from combining these drugs in an untested manner.[442]

Dr. Fost acknowledged that before his retirement, his medical practice focused on pediatrics and bioethics, that he is not an oncologist or a biochemist, and that he did not treat cancer patients. Although Dr. Fost has not been an IRB member for 10 years,[443] he stated that he frequently serves as a consultant in the care of cancer patients,"[444] and has served on two FDA committees. Dr. Fost agreed that he has never been a principal investigator in an FDA-approved clinical trial.[445]

Dr. Fost pointed out that the Clinic's pretreatment evaluation statement represented that the patient would "be asked to sign a treatment specific consent form indicating that [he] understands that particular treatment and that [he] wished to receive that treatment regimen."[446] However, Dr. Fost noted that after the treatment plan was established, Respondent did not give these patients a more specific informed consent regarding the treatment plan to review and sign. Instead, patients were given consent forms for individual drugs without disclosing the risks associated with the patients' particular treatment plan.

Respondent maintains that the Clinic's informed consent forms speak broadly to the treatment plan and regimen, including that the regimen may be life-threatening.[447] In addition, Respondent submits that the Board rules do not require that informed consent forms account for

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[442] Staff Ex. 68.01 at 24, 30.

[443] Tr. Vol. 1 at 100, 189.

[444] Tr. Vol. 1 at 100.

[445] Tr. Vol. 1 at 112.

[446] For example, Staff Exs. 5.03.A at 918-919; 5.01.A at 312-313; 5.04.A at 1229-1230.

[447] Staff Ex. 5.02.A at 823.

all possible combinations of drugs/agents that may be given a patient. Dr. Levin testified that, in private practice, physicians frequently prescribe medications concurrently without specific consent to the combinations, for instance, blood pressure and cholesterol medications.[448] In his opinion, the Clinic's informed consent forms were sufficient in a private practice setting to counsel the advanced cancer patients about the benefits of each medication, the possible side effects, and the rationale for the use of each drug.

In Dr. Levin's experience, a medical oncologist will tell the patient about the individual drugs, the side effects, benefits, and rationale for administering the drug, but not impart the side effects of the concurrent use of the drugs because they are unknown.[449] Dr. Levin explained:

> Personalized medicine is still a relatively new model although it is now completely accepted in the medical community . . . with advanced cancer patients a physician has to weigh carefully how much information should be provided to a patient. Moreover, in my experience, most patients who have chosen personalized multi-agent therapy know that their prognosis is very poor and have decided to employ a regimen that would probably not be given in an academic institution or in most general oncology practices. . . . To provide such information is simply not the standard of care used by private practitioners employing this treatment approach.[450]

When an adult cancer patient has no other curative treatment options, Dr. Levin explained, it is a physician's duty to consult with the patient and arrive at "the best possible treatment based, in part, on the physician's prior experience."[451] He noted that outside of clinical trials, it is more common than is evidenced by published articles that oncologists use multiple-target agents and anti-cancer drugs to treat advanced cancer patients where the use of the drugs is based primarily on the physician's prior experience.[452]

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[448] Resp. Ex. 165 at 56.

[449] Resp. Ex. 165 at 36.

[450] Resp. Ex. 165 at 36.

[451] Resp. Ex. 165 at 32.

[452] Resp. Ex. 165 at 34.

Dr. Levin emphasized that the Clinic's consent forms disclosed that the treatment regimen may be "life-threatening" and that it "might involve risks of which we are not currently aware."[453] The Clinic's medical records, Dr. Levin reported, showed that patients were given one drug and monitored for side effects before adding another drug.[454] Even Staff's expert, Dr. Wetmore, agreed that the Clinic provided every patient an informed consent form for each drug prescribed that advised the patient that the drug could have life-threatening side effects.[455]

Additionally, Dr. Levin pointed out that the toxicities and side effects of combined anti-cancer drugs are not widely published and are frequently unknown. In his opinion, a physician may explain the benefits and rationale for treatment with concurrent use of drugs, but it would be impossible for the physician to impart unknown side effects from this combination.[456] Because the risks of the concurrent use of anti-cancer drugs are unpredictable, he maintained that physicians are not required to provide a specific informed consent form to the patients about such risks.[457] Such a requirement, he insisted, is beyond the standard of care.[458]

The ALJs find that having represented to patients on the preevaluation informed consent that they would be asked later to sign a treatment-specific consent form for the specific treatment program, Respondent was obligated to ensure the Clinic provided such an informed consent to the patients. The record reflects that Respondent failed to do so for Patients A through G in violation of 22 TAC § 190.8(1)(I).

However, the credible evidence established that in a private practice setting, the informed consent statements given to the Clinic patients for each drug included in their treatment plan was sufficient to provide the patients with adequate information about the drug to give an informed consent for the drug. Dr. Levin's testimony that the concurrent use of various anti-cancer drugs

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[453] For example, Staff Ex. 5.2.A. at 822-823.

[454] Resp. Ex. 165 at 35-36.

[455] Tr. Vol. 3 at 121, 124, 125-126.

[456] Resp. Ex. 165 at 36.

[457] Resp. Ex. 165 at 35-37.

[458] Respondent's Brief at 33.

is frequently unknown and based in part on the physician's experience in using the drugs was compelling. The informed consent forms indicated that use of the drugs could be life-threatening and that the risks associated with the treatment regimen were unknown. Therefore, the ALJs find insufficient evidence to support Staff's allegation that Respondent was required to obtain an informed consent as to each combination of anti-cancer drugs used to treat an advanced cancer patient.

B. Timeliness of Obtaining Informed Consent

Staff asserts that Patients A, B, C, E, and F were treated with anti-cancer drugs before Respondent had the patients review and sign the informed consent forms in violation of Board Rule 190.8(1)(I).[459] Untimely consent, Staff submits, is inadequate because informed consent must be obtained "prior to the initiation of the treatment plan."[460] In addition, Staff contends that most of the informed consent forms for these patients did not identify the physician in charge or provide details on how the informed consent was obtained.

On August 30, 2011, Patient A signed the informed consent form for Afinitor and began taking this drug the same day.[461] On September 1, 2011, Patient A signed the informed consent form for Irinotecan[462] and began treatment with this drug the same day.[463] On September 2, 2011, Patient A signed the informed consent form for Votrient[464] and began treatment with this drug on September 6, 2011.[465] Patient A signed the informed consent for

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[459] 22 TAC § 190.8(1)(I) states that a physician's failure to obtain from a patient an informed consent before performing tests, treatment, or procedures, constitutes engaging in a practice inconsistent with public health and welfare.

[460] Staff Exs. 5.02.A at 814, 838 (Patient A); 5.03.A at 912, 1135 (Patient B); 5.05.A at 1618, 1797 (Patient E); 33 at 22637.

[461] Staff Ex. 5.02.A at 799, 829-831.

[462] Staff Ex. 5.02.A at 825-828.

[463] Staff Ex. 5.02.A at 799.

[464] Staff Ex. 5.02.A at 822-824.

[465] Staff Ex. 5.02.A at 796.

Avastin on October 14, 2010,[466] and began treatment on October 15, 2010.[467] Patient A signed the informed consent for PB[468] on October 11, 2010 and began PB treatments on October 11, 2010.[469] The ALJs find that the consent forms were reviewed and signed by Patient A before receiving treatment with the drugs.

On February 8, 2011, Patient B signed the informed consent form for PB and began treatment with it the same day. On February 9, 2011, Patient B was given Avastin, but the informed consent form for Avastin was not signed until February 17, 2011.[470] On February 15, 2011, Patient B signed an informed consent form for Votrient, the day the drug was first administered.[471] On July 5, 2011, Patient B signed an informed consent form for Tarceva, the day the drug was first administered.[472] On July 6, 2011, Patient B signed an informed consent form for Afinitor, the day the drug was first administered.[473] On July 7, 2011, Patient B signed informed consent forms for Sprycel and Nexavar, the day the drugs were first administered.[474] With the exception of the February 9, 2011 consent form for Avastin, the ALJs find that the informed consent forms were reviewed and signed by Patient B before receiving treatment with the drugs.

On May 14, 2010, Patient C signed the informed consent form and then began treatment with PB.[475] On May 17, 2010, Patient C signed the informed consent form and then began treatment with Avastin.[476] On May 18, 2010, Patient C signed the informed consent form and

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[466] Staff Ex. 5.02.A at 832-834.

[467] Staff Ex. 5.02.A at 808.

[468] Staff Ex. 5.02.A at 836-838.

[469] Staff Ex. 5.02.A at 836-838, 814.

[470] Staff Ex. 5.03.A at 909-911, 1020.

[471] Staff Ex. 5.03.A at 912-914, 1024.

[472] Staff Ex. 5.03.A at 906-908, 1049.

[473] Staff Ex. 5.03.A at 903-905, 1050.

[474] Staff Ex. 5.03.A at 897-902, 1051.

[475] Staff Ex. 5.04.A at 1226-1228, 1439.

[476] Staff Ex. 5.04.A at 1222-1224, 1438.

then began treatment with Tarceva.[477] On May 19, 2010, Patient C signed the informed consent form and then began treatment with Nexavar. Patient C signed the informed consent for each drug prior to receiving treatment with that drug.[478]

After Patient C was discharged from the Clinic and returned home to Indiana, he continued the cancer treatment under the care of his local oncologist, Dr. Waits. Respondent maintains that it was Dr. Waits's responsibility to secure informed consent for any new drugs administered to the patient while the patient was in Dr. Waits's care. Staff provided no authority to address such a situation. Because Dr. Waits was caring for the patient and administering the new drug, the ALJs find that once Patient C returned home and was being treated by Dr. Waits, any additional informed consent forms that the patient needed to review and sign were his responsibility. The ALJs find that the consent forms for drugs the Clinic administered were reviewed and signed by Patient C before receiving treatment with the drugs.

On September 8, 2011, Patient E signed the informed consent form for PB and then began treatment the same day.[479] On September 9, 2011, he signed the informed consent form and then began treatment with Xgeva (denosumab).[480] Patient E signed the informed consent for Afinitor on September 14, 2009, the same day he began treatment with this drug.[481] On September 13, 2011, Dr. Yi also prescribed Sutent to Patient E, indicating that it was to be started on September 15, 2011. Patient E signed the informed consent form for Sutent on September 14, 2011.[482] RA DeLeon signed these consent forms and represented that she reviewed them with the patient.[483] The ALJs find that the consent forms were reviewed and signed by Patient E before receiving treatment with the drugs.

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[477] Staff Ex. 5.04.A at 1219-1221, 1437.

[478] Staff Ex. 5.04.A at 1216-1218, 1436.

[479] Staff Ex. 5.05.A at 1648, 1795-1797.

[480] Staff Ex. 5.05.A at 1646, 1792-1794.

[481] Staff Ex. 5.05.A at 1645, 1789-1791.

[482] Staff Ex. 5.05.A at 1641, 1786-1788.

[483] Staff Ex. 5.05.A at 1632, 1786-1788.

Patient F began treatment with PB on October 9, 2009; Rapamune with grapefruit juice on October 10; Zolinza on October 11, 2009 and Xeloda on October 13, 2009. On October 14, 2009, he began receiving Avastin, with Nexavar scheduled to begin the next day. The informed consent forms for PB, Rapamune, and Zolinza were signed by Patient F on October 9, 2009, before he received treatment. The informed consent form for Xeloda was signed October 13, 2009, and the informed consent forms for Avastin and Nexavar were signed on October 15, 2009.[484] With the exception of the October 15, 2009 consent form for Avastin, the ALJs find that the consent forms were reviewed and signed by Patient F before receiving treatment with the drugs.

Based on the record, the ALJs find that Respondent did not timely obtain informed consent from Patients B and F before beginning treatment with Avastin, in violation of Board Rule 190.8(1)(I).

C. Off-label Use of FDA-Approved Drugs

Staff maintains that the informed consent forms signed by Patients A, B, C, E, and F failed to document that the drug was being prescribed off-label or that Respondent's treatment plan involved a drug treatment that could be "fatal." Instead, Respondent's informed consent forms advised the patient that the drug could be "life-threatening."[485] Dr. Levin testified that, in 2005, NCCN reported that approximately 50-75% of anti-cancer drugs used in treating cancer in the United States were used off-label.[486]

Drs. Burzynski and Levin disagree with Staff's allegation that Respondent was required to include on the informed consent form that the drugs being prescribed were being used "off-label," meaning that the FDA had not approved the medications for the use intended by Respondent. Dr. Burzynski pointed out that, although the Clinic's informed consent forms did

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[484] Staff Ex. 6.01.A at 2047-2049; 2066; 2071.

[485] Staff's Closing Argument at 54.

[486] Resp. Ex. 165 at 11.

not identify that the drugs were being prescribed "off-label," the forms did disclose for what uses the FDA had approved the medication. Dr. Burzynski also stressed that the patients were informed that the drugs were being prescribed "off-label."[487]

The ALJs find that Staff provided insufficient evidence to show that Respondent violated the Code or any Board rule by identifying in the informed consents what uses had FDA approval rather than stating that he was using the drug "off-label."

D. Alternative Therapy or Clinical Trials

According to Staff, Board Rule 200.3(2) and (7)(C) required Respondent to disclose to any patient receiving alternative therapy[488] the objectives of the treatment; the risks and benefits; the extent to which the proposed treatment could interfere with any ongoing or recommended medical care; the underlying therapeutic basis for the treatment; whether the FDA had approved it for human use; and that the treatment was under clinical investigation if it was. Staff acknowledged that the FDA had oversight of the informed consent forms the Clinic used for patients receiving ANP, but argued that the FDA's correspondence indicated that the Clinic's consent forms did not comply with federal regulations.[489]

Staff also asserts that Respondent failed to secure informed consent from Patient B for ANP. However, the evidence previously discussed showed that Dr. Brandt treated Patient B with ANP in Germany. Patient B did not receive ANP at the Clinic.[490] According to Staff, Patient G's informed consent was inadequate because it did not disclose the patient's financial

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[487] Tr. Vol. 7 at 152.

[488] Complementary and alternative medicine is defined in 22 TAC § 200.2(1) as "[t]hose health care methods of diagnosis, treatment, or interventions that are not acknowledged to be conventional but that may be offered by some licensed physicians in addition to, or as an alternative to, conventional medicine, and that provide a reasonable potential for therapeutic gain in a patient's medical condition and that are not reasonably outweighed by the risk of such methods." Conventional medicine is defined as "[t]hose health care methods of diagnosis, treatment, or interventions that are offered by most licensed physicians as generally accepted methods of routine practice, based upon medical training, experience and review of the peer reviewed scientific literature." 22 TAC § 200.2(2).

[489] Staff referred to its discussion in Section VII.1 of its reply brief regarding Dr. Burzynski's ethical responsibilities when conducting a clinical trial. Staff's Reply to Respondent's Closing Argument at 13.

[490] *See* Section IV.C.

responsibilities for all costs except for the ANP and did not disclose Respondent's interest in ownership in other businesses associated with the Clinic. These issues are addressed in subsequent sections and will not be addressed here.[491]

The ALJs find that the FDA and Respondent ultimately reached a resolution regarding the contents of the informed consent forms to be used in a clinical study. Therefore, the ALJs find that this issue was remedied through the proper process among Respondent, BRI, and the FDA. In addition, the FDA's correspondence regarding the consent forms does not establish a violation of the Code or the Board rules without further evidence of such a violation.

E. Summary of ALJs' Analysis

Board Rule 190.8(1)(I) provides that the failure to obtain informed consent from a patient "before performing tests, treatments, or procedures," is inconsistent with public health and welfare. Patients A through F were not involved in the Clinic's clinical trials, but because the treatments that were provided to them constituted "complementary and alternative medicine" as defined by Board Rule 200.3, this rule is also applicable to these patients.

1. Respondent allowed the Clinic to misrepresent in the patients' preevaluation informed consent form that the patient would be asked to sign a treatment specific consent form for the specific treatment program when no such informed consent was provided to patients. Such conduct violated 22 TAC § 190.8(1)(I).

2. Respondent failed to give Patients B and F the informed consent forms for Avastin before administering the drug to the patients in violation of 22 TAC §§ 190.8(1)(G), (H) and (I) and 200.3(2).

[491] The issue concerning Respondent's responsibility to disclose his financial interest in associated businesses is addressed in the next section of this PFD. The issue concerning Respondent's alleged failure to disclose Patient G's financial obligations while being treated with ANP is addressed in Section X.G.

VII. DISCLOSURE OF OWNERSHIP INTEREST IN PHARMACY AND LABORATORY

Staff alleged that the failure of Respondent to disclose his ownership interest in the pharmacies that dispensed the drugs prescribed to Clinic patients and his ownership interest in the laboratory that performed the tests ordered for Clinic patients constituted unprofessional conduct. Board Rule 190.8(2)(H) provides that a healthcare provider who refers a patient to a facility, laboratory, or pharmacy without disclosing the existence of the licensee's ownership interest in the entity to that patient has engaged in unprofessional conduct that is likely to deceive, defraud, or injure the public.

Respondent is the sole owner of Southern Family Pharmacy and SRB Pharmacy. Patients who received care from Respondent had their medication prescriptions, including PB and ANP, filled at Southern Family Pharmacy or SRB Pharmacy.[492] The SR Burzynski Lab, also owned by Respondent, conducted laboratory analysis of samples taken for patients treated by Respondent and Respondent's subordinates.[493]

Staff argues that Respondent and others at the Clinic did not disclose Respondent's ownership interests in the pharmacies or laboratory to patients. Dr. Burzynski testified that he had no understanding that he had a legal or ethical responsibility to disclose his ownership interest in the pharmacies to patients seen at the Clinic even though Southern Family Pharmacy was located within the Clinic building, but that he would explain his ownership if asked. He stated that he had relied on the legal advice of his long-time attorney in this assumption. He further stated that after the matter was brought up in the initial Staff Complaint, a notice was posted at the pharmacy that Respondent was the owner.[494] Patient F testified that the financial officer at the clinic told his wife and him that the pharmacy where they could get the prescriptions, and the only place they could get PB, was owned by Respondent.[495]

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[492] Tr. Vol. 9 at 127-129.

[493] Tr. Vol. 9 at 131-132.

[494] Tr. Vol. 8 at 111.

[495] Tr. Vol. 4 at 115-116.

In his deposition, Dr. Gregory Burzynski stated he was not sure if he disclosed Respondent's ownership interest in the pharmacy to Patients A through G, but he may have, and he thought the patients understood that his father was the owner.[496] In his deposition, Dr. Marquis stated that, for the patients he saw, he never disclosed Respondent's ownership interest in the pharmacy.[497]

Dr. Burzynski testified that he did not disclose his ownership interest in the lab because the name SR Burzynski Lab was on every lab report.[498] Staff asserts that this is not adequate to disclose his ownership interest because there is nothing in the records to indicate that patients knew the lab's name prior to the tests' being conducted. In addition, Staff argues that patients would not have seen the lab results bearing the name of the lab until after the tests were conducted and after they would have accrued charges for the laboratory tests.

In regard to the pharmacies, even though Southern Family Pharmacy was located in the same building as the Clinic, it is apparent that no specific disclosure of Respondent's ownership in it or in SRB Pharmacy was made to the Clinic patients. Respondent's failure to disclose his ownership interest in the only pharmacies where the patients could get PB or ANP was a violation of 22 TAC § 190.8(2)(H).

In regard to the laboratory, it is clear from the name SR Burzynski Lab that Respondent had some ownership interest in it. In addition, Staff has pointed to no evidence that patients were directed to have laboratory tests prior to being informed that the tests were to be performed by SR Burzynski Lab. As a result, Staff has failed to establish that Respondent failed to disclose his ownership interest in the laboratory, in violation of 22 TAC § 190.8(2)(H).[499]

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[496] Staff Ex. 66.GG at 8-9.

[497] Staff Ex. 66.II at 6.

[498] Tr. Vol. 9 at 132-133.

[499] In its Briefs, Staff also argued that Respondent failed to disclose his ownership interest in Ampolgen, a company owned by Respondent that markets and distributes a generic version of PB tablets, and in BRI. However these issues were not included in the pleading and therefore cannot be addressed in this proposal for decision.

VIII. IMPROPER CHARGES AND RETAINER DEMANDS

Staff alleges that Respondent and other persons under Respondent's direction, supervision, and control participated in misleading patients into paying retainers prior to receiving evaluation and treatment, billing patients for exorbitant charges for drugs, medical supplies and medical services, and charging for drugs, medical supplies and medical services that were not medically necessary and that Dr. Wetmore testified were often several times the national average and the recommended cap for services.[500] According to Staff, these improper charges to Patients A through G, as listed on Appendix B of the Complaint, constituted violations of Code § 164.053(a) that authorizes the Board to take disciplinary action against Respondent based on (1) 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;[501] and/or (2) in violation of § 311.0025(7) of the Texas Health and Safety Code[502] that prohibits a hospital, treatment facility, mental health facility, or health-care professional from submitting to a patient or a third party payor, a bill for a treatment that the hospital, facility, or professional knows was not provided or knows was improper, unreasonable, or medically or clinically unnecessary.[503] In addition, Staff alleges that these actions constituted violations under Code § 164.052(a)(5) and 22 TAC § 190.8(2)(J), which states that providing medically unnecessary services to a patient constitutes unprofessional and dishonorable conduct.

Staff's expert Elaine Kloos, maintained that Respondent, as the president and owner of the Clinic, was responsible for the Clinic's billings.[504] In her opinion, Respondent improperly charged Patients A through G and third-party payors for:

> medically unnecessary diagnostic testing, drugs, treatments other than drugs, medical supplies, and medical services; [505]

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[500] Staff Exs. 61.A.01 at 45074, 45079, 45081, 45085, 45088, 45091, 45094; 68.03 at 22-23, 31-32, 36, 46, 49-50, 56, 61-62, 67, 69-70, 90.

[501] Code § 164.053(a)(1).

[502] Code § 164.053(a)(7).

[503] Tex. Health & Safety Code § 311.0025(a).

[504] Staff Ex. 68.02 at 7, 9, 14, 16-17, 75-76, 80-102.

> prolonged services, after-hours visits, diagnostic testing, drugs, treatments other than drugs, medical supplies and medical services that were inadequately supported by documentation in the medical record;
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> office visits, education, and telephone contacts as though a physician's services were provided when the services were rendered by non-licensed foreign medical graduates or nursing staff;
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> "monthly case management fees," as though the patients were under the care of a home health agency when they were not; and
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> six weeks of near-daily infusions of ANP to Patient G as though the drugs were being administered by clinic staff when ANP was administered the drugs at home by the patient or her caregivers.

Additionally, Ms. Kloos pointed out that Respondent opted out of Medicare, but failed to provide adequate opt-out notices to the Clinic patients.[506]

Respondent disputes that the Clinic improperly charged any patient. Respondent argues that the following charges were reasonable and medically appropriate: (1) patient treatment with PB based on Dr. Burzynski's experience and knowledge; (2) the monthly case management fees based on the ongoing management by Clinic staff of patients who returned home and were under the primary care of their local physicians; (3) medical testing and other services; and (4) visits or consultations with the Clinic's physicians and other medical staff. Respondent further maintains that charging a retainer before providing services is not prohibited by statute or Board rules, and the patients who paid for services actually received them.

Respondent argues that Staff's allegations concerning "fraudulent" billing and inaccurate coding overlooked that Patients A through F were private pay patients and were not covered by insurance or Medicare. (Patient's G's treatment was partially covered by insurance.) After their initial visit to the Clinic, Respondent asserts, these patients (except Patient D) paid a flat rate for services. Such private pay patients, as the Clinic's billing manager Leann Chiapetta explained,

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[505] Ms. Kloos admitted that she was not qualified to give an opinion on the standard of care. Tr. Vol. 2 at 17.

[506] Staff Exs. 61.C.01 at 45201-45202; 68.02 at 14-18, 98-99, 103.

were often billed "flat . . . instead of billing all the codes out," while for some insurance companies, the bills are broken down into codes for supplies, monitoring, etc.[507]

Danuta Wojciechowski, the Clinic's coder, explained that, although it was the financial counselor's job to explain the monthly management fee, the services covered by the fee included, in addition to supplying PB, "face to face [visits], monitoring, [and] follow up visit[s]."[508] Sadie Ratliff, a Clinic financial counselor, testified that the monthly management fee, as described in the Treatment Billing Agreement signed by each patient,[509] covered a variety of services, including:

> follow-up visits, intensive patient monitoring, physician supervision and management of patient care. Telephone conferences with the patient, family, and/or other healthcare providers, analysis of data, integration of new information into the revised treatment programs, per patient tolerance, compilation of dictated medical report, laboratory findings, progress notes, and other data in order to maintain maximum patient care and medical supplies for the pump and catheter care.[510]

Respondent points out that Ms. Kloos agreed that, due to the growing complexity of CPT coding and medical billing, there is a movement in a part of the medical industry to move away from fee-for-service towards flat fee rates, but that this movement is slow-moving in the practice of oncology.[511] In addition, Respondent pointed out that the private Clinic patients agreed from the beginning that they would be responsible if insurance did not cover their treatment.[512]

Ms. Kloos conceded that Patients A, E, and F's billing agreements were examples of flat fee billing for certain services.[513] Respondent argues that, because coding was not a basis for

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[507] Staff Ex. 66.Y at 27-28.

[508] Staff Ex. 66.S at 24-25.

[509] See *e.g.*, Staff Ex. 7.06.M at 3522.

[510] Staff Ex. 66.I at 18.

[511] Tr. Vol. 2 at 30-33.

[512] See *e.g.*, Staff Ex. 7.06.M at 3524.

[513] Tr. Vol. 2 at 34-40.

charging these patients and, as testified to by Ms. Chiapetta, was not used in billing some insurance payors, any inaccurate coding was immaterial.

Ms. Kloos acknowledged that of the approximately 80 oncology practices she has audited in her career, only one was correctly billing.[514] She explained that billing and coding had increased in complexity in the past 10 to 15 years, and the use of the wrong code was a common mistake.[515] She acknowledged that there was an extreme shortage of people who were capable of what she believed to be proper coding and billing in the oncology setting.[516]

Ms. Kloos stated that the Clinic's director of finance administration "should be responsible for the integrity of proper coding and billing," and that Ms. Chiapetta, as the billing supervisor, would be the person responsible for making sure the coders and the billers were properly performing their duties.[517] Dr. Burzynski testified that neither he nor any of the physicians at the Clinic was involved in billing, and that he only reviewed a bill if there was a complaint.[518] Ms. Kloos acknowledged that at one hospital she worked for, the COO did not make any effort to get involved in billing because doing so was "a little bit beneath his pay grade."[519]

Respondent argues that although Ms. Kloos opined that if something is not documented in the medical records, it cannot be billed,[520] she did not investigate in this case beyond what medical records were provided to her. She never spoke with a patient, any of the physicians, or anyone working at the Clinic.[521] Ms. Kloos stated that, in general, the oncologists at the Clinic were required to properly keep their medical records; that Respondent, as the owner of the

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[514] Tr. Vol. 2 at 13-14.

[515] Tr. Vol. 2 at 21; Staff Ex. 66.FF at 26.

[516] Staff Ex. 66.FF at 39-40.

[517] Staff Ex. 68.03 at 10.

[518] Staff Ex. 7 at 78.

[519] Tr. Vol. 2 at 21-22.

[520] Tr. Vol. 2 at 65, 68-69.

[521] Tr. Vol. 2 at 17-18.

Clinic, was responsible for the accuracy of the medical records; and that, according to the federal Office of the Inspector General, the CEO is responsible for the integrity of his practice

In reply, Staff asserts that the billing records for Patients C, F, and G were sent to third party payors and that the Board Rule 190.8(2)(J) requires that proper billing statements be submitted to patients and/or third party payors, meaning that the billing statement must not be false, fraudulent, misrepresenting the services provided, or otherwise failing to meet professional standards. As for the argument that Respondent billed flat fees, Staff points to the testimony of Jasmine Spotswood, the backup biller at the Clinic, that the charges were initially broken down into a predetermined set of codes derived from a super bill (a piece of paper with services and codes set forth) and then compared with the notes dictated by the physician into the medical records for each patient.[522]

A. Patient A

1. Billings

In Appendix B to its Complaint, Staff asserts that the charges to Patient A for PB and monthly case management; a Lipid Panel test; a measurement of blood oxygen level; a CA 19-9 Cancer Antigen test; and an office visit on August 29, 2011, with Dr. Marquis were improper, unreasonable, or medically or clinically unnecessary. Of these charges, only the August 30, 2011 charge for measurement of blood oxygen level is cited by Ms. Kloos in her expert report as not being supported by documentation in the medical records. It should be noted that Ms. Kloos stated in her report that she did not include bills as being improper for which the CPT code was properly documented in the medical records. [523]

In her expert report, Ms. Kloos noted that Patient A presented to the Clinic without a pathologically confirmed cancer diagnosis, which apparently was the basis for her opinion that

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[522] Staff Ex. 66.P at 10-14; Staff Ex. 5.02.A at 712-716.

[523] Staff Ex. 61.03.C at 45185-45187.

none of the Clinic charges for his treatment were reasonable.[524] Patient A's wife testified that Patient A had cancer when he presented at the Clinic.[525] Patient A filled out a client information sheet indicating he had been diagnosed with colon cancer.[526] Records from the Clinic show the physicians recommended that the patient have a biopsy.[527] Patient A's wife testified that Patient A had already had one biopsy and was not interested in another, and that his doctors in North Carolina did not want him to have to go through that again.[528]

The record establishes that there was sufficient documentation in the medical records to support the Clinic's treatment of Patient A for cancer.

As for the charges for PB, Ms. Kloos stated in her expert report that the administration plan for PB dated October 11, 2010, was not signed by a physician.[529] Ms. Kloos also testified that the Clinic had no documentation in Patient A's medical records explaining the rationale and medical necessity for the prescribing of PB.[530] This opinion is apparently the basis for Staff's allegation that the charges to Patient A for PB were not supported by the medical records.

The notes from the October 10, 2011 oncology assessment signed by Dr. Valladares indicate that, based on Respondent's recommendation, Patient A would start receiving PB.[531] Patient A's treatment plan lists the amount, frequency, number of refills, and dosage of PB, which Respondent argues is all that is required by the rule.[532] In addition, Respondent points to the informed consent form for PB signed by Patient A on October 11, 2010. That form states that its purpose was to "alleviate the symptoms and decrease the size of your tumor and to

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[524] Staff Ex. 61.03.C at 45176.

[525] Tr. Vol. 5 at 79.

[526] Staff Ex. 5.02.A at 816.

[527] Staff Ex. 5.02.A at 729.

[528] Tr. Vol. 5 at 82-84.

[529] Staff Ex. 61.03.C at 45176. Staff also cites in its Closing Argument to Ms. Kloos's prefiled testimony regarding billings for physician consultations and Medicare opt-out that are not included in Staff's pleadings.

[530] Staff Ex. 68.02 at 30.

[531] Staff Ex. 5.02.A at 791-792.

[532] 22 TAC § 165.1(a(6)(A).

improve your nutritional status." It acknowledged that PB was "not yet standard," but had "demonstrated anticancer activity in both laboratory and clinical studies." In addition, the informed consent advised Patient A that "tests have revealed anti-tumor activity of sodium phenylbutrate . . . [there is] evidence that phenylbutrate induces death in cancer cells . . . [and that PB] may be of benefit to advanced cancer patients."[533]

The record establishes that there was sufficient rationale in the medical records for the prescribing of PB to Patient A.

Ms. Kloos also testified that Patient A's medical records did not indicate that he actually received PB on October 11 through 14, 2010.[534] Respondent points out that the Clinic's nursing notes listed PB as a medication given to Patient A on October 11 through 14, 2010,[535] and a patient checklist, signed and dated October 11, 2010, showed that Patient A had "completed test dose of PB tablet," and was "given instruction and understands the dosage regimen ordered by the physician."[536] The Clinic's nursing records for October 12 through 15, 2010, also cited the PB dosage given to Patient A on the previous day, which matched the amount the Clinic billed to the patient.[537] This dosage comports with the October 11, 2010 treatment plan to start PB at 0.5 grams four times a day and increase until reaching a three-gram dosage given four times per day.[538]

The record establishes that Patient A actually received PB on October 11 through 14, 2010.

In regard to the allegation that the amount of the charges for PB and monthly case management were improper or unreasonable, Respondent argues that, as the billing statements

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[533] Staff Ex. 5.2.A at 836-838.

[534] Staff Ex. 68.02 at 22-23.

[535] Staff Ex. 5.2.A at 809-812.

[536] Staff Ex. 5.2.A at 813.

[537] Staff Ex. 5.2.A at 809-812, 880.

[538] Staff Ex. 5.2.A at 718.

show, by the time Patient A achieved the recommended dosage of PB, the cost would have been $240 per day, or $7,200 per month.[539] However, after Patient A reached the treatment plan's recommended dosage, the Clinic stopped charging separately for PB and rolled the cost into the monthly case management fee that started at $4,500 per month.[540] According to Patient A's billing records, by December of 2010, two months after Patient A began treatment, the Clinic cut the case management fee in half.[541]

Patient A's wife acknowledged that she understood the case management fee covered the cost of PB,[542] and testified that, at their request, the Clinic reduced the case management fee to make the treatment more affordable for her husband.[543]

The record establishes that charges for PB and the monthly case management fee to Patient A were reasonable.

As for the charge on August 29, 2011, for a $200 office visit with Dr. Marquis, Respondent argues that this was actually a visit with Dr. Valladares and was simply an entry error.[544] Although Patient A's wife initially testified that RA Rakhmanov conducted the physical on her husband on August 29, 2011, she later agreed that it could have been performed by Dr. Valladares.[545]

The office visit charge of August 29, 2011, was supported by the evidence despite the erroneous entry as to which physician was seen. In addition, the rationale for the Lipid Panel test, measurements of blood oxygen level, and CA 19-9 Cancer Antigen test are fully discussed in Section IV(B)(2) and (3) above.

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[539] Staff Ex. 5.2.A at 880.

[540] Staff Ex. 5.2.A at 883-890.

[541] Staff Ex. 5.2.A at 890-892.

[542] Staff Ex. 66.T at 56-57.

[543] Tr. Vol. 5 at 75.

[544] Staff Ex. 5.02.A at 770-71, 892.

[545] Tr. Vol. 5 at 44; 47-48.

2. Summary of ALJ's Analysis

The ALJs find no violations as alleged regarding the billings to Patient A.

B. Patient B

1. Billings

In Appendix B to its Complaint, Staff asserts that the charges to Patient B were improper, unreasonable, or medically or clinically unnecessary. Specifically, Staff cited the charges from February 7through March 4, 2011, for genetic testing, physician services, office consultations, drugs, office/outpatient visits, blood oxygen level measurements, Lipid Panel tests, medical equipment, health education, nutritional therapy, and the monthly management fees for March through September, 2011.

Ms. Kloos testified that the coding for Patient B's initial office visit on February 7, 2011, was inaccurate and unsupported by the medical records because it reflected that Dr. Valladares personally spent 2½ hours with Patient B when his dictated notes were barely a page long.[546] However, the medical records show that other physicians, including Respondent, were involved in Patient B's treatment that day. Respondent argues that even though he participated in the initial consultation and recommended the treatment plan that Patient B decided to follow rather than the standard radiation treatment recommended by Dr. Valladares, only Dr. Valladares billed the patient for that meeting.[547] Respondent points out that Respondent did not bill Patient B for the time spent reviewing the medical records Patient B sent to the Clinic before the meeting.[548]

The charges for a 2½ hours initial consultation between two Clinic physicians and Patient B were reasonable.

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[546] Staff Ex. 68.02 at 52:20.

[547] Staff Ex. 5.03.A at 1060-61.

[548] Staff Ex. 5.03.A at 1125-26.

The office visits with a physician were billed at $125 for each outpatient visit. On February 8, 2011, Patient B reported to the Clinic and "the team," including Respondent, reviewed the patient's MRIs.[549] Patient B was started on PB. Dr. Gregory Burzynski reviewed and executed the informed consent form for PB with the patient.[550] On that day, Patient B was only charged $125 for a visit with Dr. Valladares.[551] On February 9, 2011, the records showed that Patient B reported to the Clinic, where his vitals were taken, and he was started on Avastin and Decadron. All side effects of these two drugs were discussed with the patient,[552] and he was given a complete history and physical by Dr. Valladares.[553] For this he was charged $125 for a visit with Dr. Marquis, which was a clerical error.[554]

On February 10, 2011, Patient B was charged $125 for a visit with Dr. Gregory Burzynski for which there is no medical record.[555] On February 11, 2011, Patient B presented at the Clinic and had his vitals taken. The results of his blood (genetic) tests were reviewed and, based on the results, a profile 1 iron saturation was ordered. It was also noted that he would be considered for participation in an ANP clinical trial.[556] Patient B was charged $125 for this visit with Dr. Valladares.[557] On February 14, 2011, Patient B presented at the Clinic and had his vitals taken. Dr. Marquis directed that his dressing for the Hickman catheter be changed.[558] Patient B was charged $125 for this visit with Dr. Valladares, which again was a clerical error.[559] On February 15, 2011, Patient B presented at the Clinic and had his vitals taken. Dr. Marquis

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[549] Staff Ex. 5.03.A at 1019.

[550] Staff Ex. 5.03.A at 915-917.

[551] Staff Ex. 5.03.A at1201.

[552] Staff Ex. 5.03.A at 1020.

[553] Staff Ex. 5.03.A at 1063-1064.

[554] Staff Ex. 5.03.A at 1201.

[555] Staff Ex. 5.03.A at 1202.

[556] Staff Ex. 5.03.A at 1021.

[557] Staff Ex. 5.03.A at 1202.

[558] Staff Ex. 5.03.A at 1022.

[559] Staff Ex. 5.03.A at 1203.

directed that the administration of Votrient be started.[560] Patient B was charged $125 for this visit with Dr. Valladares, which again was a clerical error.[561]

On February 16, 2011, Patient B presented at the Clinic and had his vitals taken. Dr. Valladares directed that the administration of Avastin be started.[562] Patient B was charged $125 for this visit with Dr. Valladares.[563] On February 17, 2011, Patient B presented at the Clinic and had his vitals taken. Dr. Valladares again directed that the administration of Avastin be started.[564] Patient B was charged $125 for this visit with Dr. Valladares.[565] On February 18, 2011, Patient B presented at the Clinic and had his vitals taken. Dr. Marquis directed that he continue the treatments.[566] Patient B was charged $125 for this visit with Dr. Weaver, which was a clerical error.[567] On February 21, 2011, Patient B presented at the Clinic and had his vitals taken. Dr. Valladares directed that the Avastin dosage be increased.[568] Patient B was charged $125 for this visit with Dr. Weaver, which again was a clerical error.[569] On February 22, 2011, Patient B presented at the Clinic and had his vitals taken, at which visit Dr. Valladares discussed the beginning of the administration of ANP in Germany.[570] Patient B was charged $125 for this visit with Dr. Valladares.[571]

On February 23, 2011, Patient B presented at the Clinic and had his vitals taken, and Dr. Valladares directed that the regimen be continued.[572] Patient B was charged $125 for this

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[560] Staff Ex. 5.03.A at 1024.

[561] Staff Ex. 5.03.A at 1203.

[562] Staff Ex. 5.03.A at 1025.

[563] Staff Ex. 5.03.A at 1204.

[564] Staff Ex. 5.03.A at 1026.

[565] Staff Ex. 5.03.A at 1205.

[566] Staff Ex. 5.03.A at 1029.

[567] Staff Ex. 5.03.A at 1207.

[568] Staff Ex. 5.03.A at 1030.

[569] Staff Ex. 5.03.A at 1207.

[570] Staff Ex. 5.03.A at 1031.

[571] Staff Ex. 5.03.A at 1209.

[572] Staff Ex. 5.03.A at 1032.

visit with Dr. Valladares.[573] On February 24, 2011, Patient B presented at the Clinic and had his vitals taken, and Dr. Valladares directed that the dosage of Votrient be increased.[574] Patient B was charged $125 for this visit with Dr. Valladares.[575] On February 25 and 28, 2011, Patient B presented at the Clinic and had his vitals taken, and Dr. Valladares directed that the regimen be continued.[576] Patient B was charged $125 for these visits with Dr. Valladares.[577]

On March 1, 2011, Patient B presented at the Clinic and had his vitals taken, and Dr. Valladares directed that the dosage of Votrient be decreased.[578] Patient B was charged $125 for this visit with Dr. Valladares.[579] On March 2, 2011, Patient B presented at the Clinic and had his vitals taken, and Dr. Valladares directed that the regimen be continued.[580] Patient B was charged $125 for this visit with Dr. Valladares.[581] On March 4, 2011, Patient B presented at the Clinic and had his vitals taken, and Dr. Valladares discussed his future treatment preparatory to his initial discharge from the Clinic.[582] Patient B was charged $200 for this visit with Dr. Valladares.[583]

With the exception of the undocumented office visit with Dr. Gregory Burzynski on February 10, 2011, the charges for the office visits of Patient B were reasonable, and the erroneous designation of the physician who actually met with the patient did not establish otherwise.

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[573] Staff Ex. 5.03.A at 1210.

[574] Staff Ex. 5.03.A at 1033.

[575] Staff Ex. 5.03.A at 1210.

[576] Staff Ex. 5.03.A at 1034-1035.

[577] Staff Ex. 5.03.A at 1211.

[578] Staff Ex. 5.03.A at 1036.

[579] Staff Ex. 5.03.A at 1212.

[580] Staff Ex. 5.03.A at 1037.

[581] Staff Ex. 5.03.A at 1213.

[582] Staff Ex. 5.03.A at 1037.

[583] Staff Ex. 5.03.A at 1213.

Ms. Kloos testified that she assumed that the monthly management fee being charged to Patient B was "to take care of him on antineoplastons while he's in Germany," because she was of the opinion that was all the care that he was getting.[584] Ms. Kloos also asserted that the documented telephone calls were insufficient to support Patient B's monthly case management fee billed under CPT Code 99499, because that code should only be used for patients receiving home health care.[585] However, she later agreed that Code 99499 is a code for "unlisted evaluation and management service," not for home health care services.[586]

Once Patient B was discharged from the Clinic, beginning in March 2011, the Clinic charged him a monthly case management fee of $3,511 per month through September of 2011.[587] Respondent argues that the services that justified this case management fee included, among other things, the following:

> March 21, 2011- Respondent reviewed Patient B's MRI and gave "further recommendations" to Dr. Brandt.[588]
>
> May 24, 2011- Dr. Marquis spoke to Dr. Brandt and discussed the patient's progress.[589]
>
> June 16, 2011- the Clinic physicians evaluated a recent MRI of Patient B's brain showing a significant increase in tumor size, and recommended that the patient return to Houston for a follow-up.[590]
>
> July 1, 2011- Patient B returned to Houston where Dr. Marquis updated his history and conducted a physical.[591]
>
> July 5 through 7, 2011- Patient B returned to the Clinic where his treatment plan was reassessed and modified.[592]

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[584] Staff Ex. 68.02 at 67.

[585] Staff Ex. 68.02 at 62.

[586] Tr. Vol. 2 at 63.

[587] Staff Ex. 33 at 22482-22489.

[588] Staff Ex. 5.03.A at 1041.

[589] Staff Ex. 5.03.A at 1043.

[590] Staff Ex. 5.03.A at 1044.

[591] Staff Ex. 5.03.A at 1057-59.

> August 19, 2011- Clinic staff held a conference call with Patient B and his family during which Patient B decided to resume the treatment plan after overcoming the side effects.[593]
>
> September 9, 2011- Clinic staff spoke with Patient B's family regarding his hospitalization.[594]

Respondent asserts that all these services, together with the cost of the prescription drugs, were covered by the monthly management fee, and points out that Patient B never received ANP treatment from the Clinic, only from Dr. Brandt while he was in Germany.

The record establishes that the monthly case management fees charged to Patient B were reasonable.

Ms. Kloos testified that Respondent improperly charged for prolonged service without contact and prolonged physician services because the times of the face-to-face contacts with licensed physicians were not documented in the medical records, nor did the records identify what services were being provided without physician contact. In addition, she stated that there was no documentation that licensed physicians performed the physical examinations or provided group health education as required by the CPT code used in the billings. [595]

On February 7, 2011, Respondent charged Patient B $350 for prolonged physician services and $500 for prolonged service without contact.[596] On February 28 and March 2, 2011, Respondent charged Patient B $60 each for group health education.[597]

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[592] Staff Ex. 5.03.A at 1049-51.

[593] Staff Ex. 5.03.A at 1052.

[594] Staff Ex. 5.03.A. at 1053.

[595] Staff Ex. 68.02 at 67.

[596] Staff Ex. 33 at 22376.

[597] Staff Ex. 5.03.A. at 1212-1213.

In his briefs, Respondent does not point to any documentation or testimony to explain the charges for prolonged service without contact and prolonged physician services other than the office visit charges discussed above, or for the group health education charges. Accordingly, Staff has established that these charges are not sufficiently documented.

From February 17 to March 4, 2011, the Clinic charged for the intravenous administration of medication to Patient B. Patient B started intravenous administration of Avastin at the Clinic on February 17, 2011. The same day, he signed the Avastin informed consent form that explained the purpose of the treatment and how it inhibited cancer growth by blocking receptors on the surface of endothelial cells.[598] The consent forms for PB, Votrient, and Avastin explained their purpose to the patient, be it targeted gene therapy to block receptors on certain cancerous cell receptors or, for PB, to cause death in cancer cells and increase the activity of common chemotherapeutic agents.[599] The records also established that with each drug the side effects were discussed with the patient, handouts were provided, and all questions were answered.[600]

The record establishes that the charges for the intravenous administration of medications to Patient B were reasonable.

Staff also maintained that Respondent ran various tests such as blood and urine, lipid panel, and genetic testing that were medically unnecessary. Dr. Levin opined that these tests, including the EGFR, HER2, plasma, and VEGF testing from Caris Life Sciences, were medically necessary and fully appropriate.[601] These tests were part of the treatment plan for targeted therapy. In the June 17, 2011 "Treatment Summary," the patient wanted to follow Dr. Burzynski's recommendations for a "Profile III, genetic markers x 4 and an MRI of the head

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[598] Tr. Vol. 2 at 63; Staff Ex. 5.3.A at 1088, 909-911.

[599] Staff Ex. 5.3.A at 909, 912, 915.

[600] Staff Ex. 5.3.A at 1024 (Votrient), 1026 (Avastin).

[601] Res. Ex. 165 at 51-53, 60-61.

without contrast."[602] The "Treatment Summary" further explains that, based on the results of the Caris Target Summary, both Tarceva and Iressa were recommended.

The pretreatment evaluation signed by Patient B explained that x-rays, CT scans, MRIs, nuclear medicine tests, blood studies, and urine studies were a series of tests that might be required before a full treatment plan was developed.[603] Patient B also signed the informed consent form for Avastin that explained that tests such as x-rays, CT scans, MRI scans, nuclear medicine tests, and blood and urine lab studies were needed before the patient could start Avastin or any target therapy agents.[604]

The record establishes that the x-rays, CT scans, MRIs, nuclear medicine tests, and blood and urine lab studies charged to Patient B were reasonable. The reasonable basis for the charges for the Lipid Panel test, measurement of blood oxygen level, and genetic testing are fully discussed in Section IV(B)(2) and (3).

2. Summary of ALJs' Analysis

The ALJs find that the charge for the office visit with Dr. Gregory Burzynski on February 10, 2011, the charges for the February 7, 2011 prolonged physician services and prolonged service without contact, and the charges for group health education are not supported by the medical records, in violation of Code § 164.051(a)(3) and 22 TAC § 165.1.

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[602] Staff Ex. 5.3.A at 1061-62.

[603] Staff Ex. 5.3.A at 918.

[604] Staff Ex. 5.3.A at 909, 897 (Nexavar), 900 (Sprycel), 903 (Afinitor), 906 (Tarceva), 912 (Votrient), 915 (PB).

C. Patient C

1. Billings

In Appendix B to its Complaint, Staff asserts that the charges to Patient C were improper, unreasonable, or medically or clinically unnecessary. Specifically, Staff cited the charges from May 11, 2010, through August 31, 2011, for office consultations, prolonged service without contact, genetic testing, physician services, drugs, office/outpatient visits, blood oxygen level measurements, medical supplies, phone calls, and the monthly management fees (including unidentified fees).

Ms. Kloos testified that Patient C presented to the Clinic without a pathologically confirmed cancer diagnosis; this belief again apparently affected her opinion that none of the Clinic charges for his treatment were reasonable.[605] Patient C's medical records contain a cytology report dated April 5, 2010, showing a diagnosis of mesothelium cells.[606] This report was reviewed by the Clinic's doctors when Patient C reported to the Clinic on May 11, 2010. In addition, Patient C's oncologist in Indiana, Dr. Waits, previously recommended that the patient start chemotherapy drugs and undergo a surgical evaluation because he had cancer.[607] Dr. Waits's records from April 29, 2010, which were received by the Clinic in early June 2010, showed that Dr. Waits had diagnosed Patient C with "advanced mesothelioma caused by prior radiation therapy."[608]

The record establishes that there was sufficient documentation in the medical records to support the Clinic's treatment of Patient C for cancer.

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[605] Staff Ex. 68.02 at 74.

[606] Staff Ex. 5.04.A at 1351.

[607] Staff Ex. 5.04.A at1353.

[608] Staff Ex. 5.04.A at 1573.

In her expert report, Ms. Kloos took issue with the charges for office consultation and prolonged service without contact on May 11, 2011, the office outpatient visit on May 14, 2011, and the management fee on August 31, 2011, primarily because the wrong codes were used.[609]

The "Oncology Consultation" note dated May 11, 2010, signed by Dr. Joshi, a Clinic oncologist, identified those who participated in the consultation, and documented that Patient C's tests and history were presented to the staff.[610] On May 11, 2010, Respondent charged Patient C $1,000 for the office consultation and $350 for prolonged service without contact.[611] On May 14, 2010, the records show that Patient C presented at the Clinic and had his vitals taken, and Dr. Marquis directed that the administration of PB be started.[612] Patient C was charged $125 for this visit with Dr. Marquis.[613]

On May 17, 2010, the records show that Patient C presented at the Clinic and had his vitals taken, and Dr. Marquis directed that the dosage of PB be increased and the administration of Avastin be started.[614] He was charged $125 for the visit with Dr. Marquis.[615] On May 18, 2010, the records show that Patient C presented at the Clinic and had his vitals taken, and Dr. Marquis directed that the dosage of PB be increased and the administration of Tarceva be started.[616] He was charged $125 for the visit with Dr. Marquis and a prolonged visit charge of $410 that was adjusted to $66.63.[617] On May 19, 2010, the records show that Patient C presented at the Clinic and had his vitals taken, and Dr. Marquis directed that the administration of Nexavar be started.[618] He was charged $125 for the visit with Dr. Marquis.[619] On

[609] Staff Ex. 61.C.01 at 45190-45191.

[610] Staff Ex. 5.04.A at 1420.

[611] Staff Ex. 5.04.A at 1582.

[612] Staff Ex. 33 at 22891.

[613] Staff Ex. 5.04.A at 1585.

[614] Staff Ex. 33 at 22891.

[615] Staff Ex. 5.04.A at 1585.

[616] Staff Ex. 33 at 22906-22907.

[617] Staff Ex. 5.04.A at 1587.

[618] Staff Ex. 33 at 22914.

[619] Staff Ex. 5.04.A at 1587.

May 20, 2010, the records show that Patient C presented at the Clinic and had his vitals taken, and Dr. Marquis directed that Patient C start receiving Lisinopril for high blood pressure.[620] He was charged $200 for a visit with Dr. Marquis. [621]

The records establish that the charges for the initial consultation and the visits of Patient C with Dr. Marquis were reasonable.

Ms. Kloos claimed that the Clinic had insufficient documentation to support the monthly case management fee for August, 31, 2011.[622] The management fees contested by Staff in its Complaint included undefined fees that, based on the amount charged, were clearly monthly management fees. Respondent pointed to numerous progress notes evidencing that the Clinic actively monitored and participated in Patient C's treatment in coordination with his local physician.[623] Dr. Waits confirmed that he had several conference calls with doctors and staff at the Clinic.[624]

The record establishes that the monthly case management fees charged to Patient C were reasonable.

From May 14, 2010, to July 30, 2011, the Clinic charged for the intravenous administration of medications to Patient C. On May 14, 2010, the Clinic charged for the intravenous administration of PB. The same day, Patient C signed the PB informed consent form that explained the purpose of the treatment and how it caused death in cancer cells and increased the activity of common chemotherapeutic agents. [625] Patient C started intravenous administration of Avastin at the Clinic on May 17, 2010. The same day, he signed the Avastin informed consent form that explained the purpose of the treatment and how it inhibits cancer growth by

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[620] Staff Ex. 33 at 22918.

[621] Staff Ex. 5.04.A at 1588.

[622] Staff Ex. Vol. 68.02 at 78.

[623] Staff Ex. 5.04.A at 1356-1409; 1418-1436.

[624] Staff Ex. 66.O at 31-32; 60- 62.

[625] Staff Ex. Vol. 5.04.A at 1226-1228.

blocking receptors on the surface of endothelial cells. The initial charges for Tarceva and Nexavar were both adjusted downward by almost $3,000 each.[626] The records also established that with each drug the side effects were discussed with the patient, handouts were provided, and all questions were answered.[627]

The record establishes that the charges for the intravenous administration of medications and for medication prescriptions to Patient C were reasonable.

Staff asserts that Respondent ran various genetic tests that were improperly billed and medically unnecessary. According to Dr. Burzynski as well as Dr. Waits, these tests were medically necessary to create a personalized treatment plan.[628] Staff also maintained that the measurement of blood oxygen was medically unnecessary.

The reasonable nature of the charges for the measurement of blood oxygen level and genetic testing are fully discussed in Section IV(B)(2) and (3).

Staff asserts that the phone evaluation/maintenance charges of $125 each from June 23, 2010, through March 1, 2011, are improper. Ms. Kloos cited the phone calls with Dr. Marquis as having been coded incorrectly, while she pointed out that the call on November 23, 2010, was conducted by Ms. Acelar, an unlicensed physician.

In his briefs, Respondent does not point to any documentation or testimony to support the telephone consultation charges for June 23, July 2, July 13, July 27, August 10, August 17, August 23, September 27, December 14, 2010, and August 31, 2011. Accordingly, Staff has established that these charges are not sufficiently documented.

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[626] Staff Ex. 5.04.B at 1583-1584.

[627] Staff Ex. 33 at 22906, 22914.

[628] Staff Ex. 66.O at 24.

2. Summary of ALJs' Analysis

The ALJs find that the charges to Patient C for the telephone consultations for June 23, July 2, July 13, July 27, August 10, August 17, August 23, September 27, and December 14, 2010, and August 31, 2011, are not supported by the medical records, in violation of Code § 164.051(a)(3) and 22 TAC § 165.1(a).

D. Patient D

1. Billings

In Appendix B to its Complaint, Staff asserts that the charges to Patient D were improper, unreasonable, or medically or clinically unnecessary. Specifically, Staff cited the charges from June 7, 2011, for office consultation, prolonged service without contact, and genetic testing. Staff also alleged that unspecified charges from June 8 through July 1, 2011, were unreasonable even though Patient D received no treatment or billings for those dates.

Ms. Kloos opined that the billing for the office visits on June 7, 2011, specifically the prolonged initial consult, were not supported by the records.[629] Respondent points out that Patient D's medical record contained 76 pages of reports from Patient D's other providers that the Clinic's physicians reviewed before the initial meeting, as well as Dr. Marquis's detailed summary of Patient D's history and the initial consultation.[630] Respondent argues that the tests were justified because Patient D came to the Clinic for a second evaluation and treatment recommendation and that part of that evaluation included undergoing the genetic profile testing.[631] Patient D signed the Pre-treatment Evaluation form agreeing to undergo the various

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[629] Staff Ex. 61 C.01 at 17.

[630] Staff Ex. 5.01.A at 388-463.

[631] Staff Ex. 5.01.A at 373.

tests including blood, urine, nuclear medicine tests, scans, and x-rays that the Clinic routinely administered in order for the physicians to create a treatment plan.[632]

The medical records support the reasonableness of the charges to Patient D for the initial consultation and prolonged services without contact, as well as the genetic testing.

2. Summary of ALJs' Analysis

The ALJs find no violations as alleged regarding the billings to Patient D.

E. Patient E

1. Billings

In Appendix B to its Complaint, Staff asserts that the charges to Patient E were improper, unreasonable, or medically or clinically unnecessary. Specifically, Staff cited the charges from September 7 through 16, 2011, for office consultations, prolonged service without contact, genetic testing, medical services after hours, drugs, office/outpatient visits, blood oxygen level measurements, Lipid Panel, and the monthly management fees.

Ms. Kloos testified that Patient E was improperly charged for office visits using CPT Codes 99358, 99359, and 99212.[633] The September 7, 2011 initial consultation fee of $1,000 was agreed to by Patient E in writing,[634] and included review by the Clinic physicians of nearly 100 pages of records from Patient E's prior providers, Weill Cornell Medical Center and New York Presbyterian.[635] Dr. Yi's Initial Oncology Assessment and History and Physical report provided an extensive summary of Patient E's medical history regarding his previous CT

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[632] Staff Ex. 5.01.A. at 312.

[633] Staff Ex. 68.02 at 83-86.

[634] Staff Ex. 5.05.A at 1802.

[635] Staff Ex. 5.05.A at 1747-1785 (records from Weill Cornell Medical Center); 1696-1,744 (records from New York Presbyterian).

scans, biopsies, surgical history, and prior treatment. The note for the initial consultation also showed that Dr. Yi and Respondent reviewed prior laboratory findings and radiology films. These services were reflected in the prolonged service without contact charges of $500.[636]

On September 8, 2011, the records show that Patient E presented at the Clinic and had his vitals taken, and Dr. Yi directed that he do a 24-hour urine protein test and that the administration of PB be started. Patient E was charged $100 for this visit.[637] On September 9, 2011, the records show that Patient E presented at the Clinic, had his vitals taken, and discussed his symptoms and the blood test results, and Dr. Yi directed that that the administration of Xgeva be started. Patient E was charged $100 for this visit.[638] Respondent pointed out that CPT Code 99212 is used for a patient office visit of approximately 10 minutes addressing "minor" issues.

On September 10, 2011, the records show that Patient E presented at the Clinic and had his vitals taken, and Dr. Yi directed that the dosage of PB be increased. Patient E was charged $75 for this visit. [639] On September 11, 2011, the records show that Patient E presented at the Clinic, had his vitals taken, and Dr. Yi directed he continue the regimen. Patient E was charged $75 for this visit. [640] On September 14, 2011, the records show that Patient E presented at the Clinic and had his vitals taken, and Dr. Yi directed that the administration of Afinitor (everolimus) be started. Patient E was charged $100 for this visit.[641] On September 15, 2011, the records show that Patient E presented at the Clinic and had his vitals taken, and Dr. Yi directed that the administration of Sutent be started and the patient be prepared for discharge. Patient E was charged $200 for this visit.[642] On September 16, 2011, Patient E was charged $100 for an office visit, for which there is no documentation.

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[636] Staff Ex. 5.05.A at 1615-1625.

[637] Staff Ex. 33 at 22648-22649.

[638] Staff Ex. 33 at 22651-22652.

[639] Staff Ex. 33 at 22654-22655.

[640] Staff Ex. 33 at 22657-22658.

[641] Staff Ex. 33 at 22672-22673.

[642] Staff Ex. 33 at 22674-22675.

The medical records establish, with the exception of the September 16, 2011 charge, the reasonableness of the charges to Patient E for the initial consultation, prolonged services without contact, and office visits.

On September 10 and 11, 2011, Patient E was charged $95 each day for after-hours medical services.

Respondent has not referenced any notes to indicate after-hours medical services being provided on September 10 or 11, 2011. Accordingly, those charges are not supported by the medical records.

Staff asserts that Respondent ran various genetic tests that were improperly billed and medically unnecessary. Staff also maintained that the Lipid Panel and the measurement of blood oxygen were medically unnecessary.

The reasonable nature of the charges for the genetic testing, measurement of blood oxygen, and Lipid Panel is discussed in Section IV(B)(2) and (3).

From September 7 through 15, 2011, the Clinic charged for the intravenous administration and prescription of medications to Patient E. On September 8, 2011, the Clinic began the intravenous administration of PB. The same day Patient E signed the PB informed consent form that explained the purpose of the treatment and how it caused death in cancer cells and increased the activity of common chemotherapeutic agents.[643] On September 13, 2011, Patient E began receiving Xgeva. On September 14, 2011, Patient E began receiving Afinitor, the informed consent form for which was signed on September 13, 2011. The "purpose of the treatment" section in the form describes Afinitor as a kinase inhibitor indicated for the treatment of patients with advanced renal cell carcinoma after failure of treatment with Sutent or

[643] Staff Ex. Vol. 5.05A at 1795-1797.

Nexavar.[644] (The discussion regarding the simultaneous administration of Afinitor and Sutent is set forth in Section IVF1, 2, and 3 above.) The records establish that with each drug, the side effects were discussed with the patient. [645]

Staff cited to no evidence explaining why the drug charges were unreasonable. The record establishes that the intravenous administration of PB and the prescribed medications and their costs charged to Patient E were reasonable.

On September 8, 2011, Patient E had a nutritional consultation with Madhavi Raju that was reviewed by Dr. Gregory Burzynski and for which Patient E was charged an adjusted amount of $255.[646]

Staff has provided no evidence as to why this charge was not medically necessary.

Staff alleges that Respondent improperly charged Patient E a $4,500 monthly case management fee on September 15, 2011. Patient E agreed to pay this monthly case management in writing on the first day he visited the Clinic.[647] Respondent points out that the Clinic only charged one monthly case management fee even though the Clinic monitored Patient E through October and November 2011.[648]

The record establishes that the single monthly case management fee charged to Patient E was reasonable.

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[644] Staff Ex. 5.05.A at 1789-1791.

[645] Staff Ex. 33 at 22667.

[646] Staff Exs. 5.05.A at a 1613-1614; 33 at 22640.

[647] Staff Ex. 5.05.A at 1802.

[648] Staff Ex. 5.05.A at 1626-1631.

2. Summary of ALJs' Analysis

The ALJs find that the office visit charge for September 16, 2011, and the after-hours medical services charges for September 10 or 11, 2011, to Patient E are not supported by the medical records, in violation of Code § 164.051(a)(3) and 22 TAC § 165.1(a).

F. Patient F

1. Billings

In Appendix B to its Complaint, Staff asserts that the charges to Patient F were improper, unreasonable, or medically or clinically unnecessary. Specifically, Staff cited the charges from October 8 through November 11, 2009, for office consultations, prolonged evaluation, genetic testing, drugs, office/outpatient visits, blood oxygen level measurements, and the Lipid Panel.

Ms. Kloos testified that Patient F's medical records do not support billing Patient F for his initial consultation on October 8, 2009.[649] Patient F signed a billing agreement to pay the $1,000 for the initial consultation and the $500 charged for evaluation of his medical records.[650] Dr. Weaver's "History and Physical" concerning Patient F documented that he: (1) reviewed extensive medical documents pertaining to the consultation, including the patient's biopsy results, ultrasounds, CT scans, prior doctors' recommendations, lab reports, and other past medical and surgical history; (2) thoroughly examined the patient; and (3) developed a plan of treatment from that examination.[651]

On October 9, 2009, the records show that Patient F presented at the Clinic, had his vitals taken, and Dr. Weaver directed that the administration of PB and Rapamune be started, that Zolinza be started on October 11, that Xeloda be started on October 13, and that his existing

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[649] Staff Ex. 68.02 at 87- 88.

[650] Staff Ex. 6.01.A at 1960.

[651] Staff Ex. 6.01.A at 2032-2035.

dosage of Valtrex be increased.[652] (The issue of the Valtrex dosage is discussed in Section IVG1). Patient F was charged $125 for this visit.[653] On October 12-16, 2009, the records show that Patient F presented at the Clinic and had his vitals taken, and met with Dr. Weaver. [654] Patient F was charged $125 for each visit.[655] On October 19, 2009, the records show that Patient F presented at the Clinic, had his vitals taken, and met with Dr. Weaver prior to being prepared for discharge. [656] Patient F was charged $200 for this visit. [657]

The medical records support the charges to Patient F for the reasonableness of the initial consultation, prolonged evaluation, and office visits.

Staff asserts that Respondent ran various genetic tests that were improperly billed and medically unnecessary. Staff also maintained that the Lipid Panel and the measurement of blood oxygen were medically unnecessary.

The reasonable nature of the charges for the genetic testing, measurement of blood oxygen, and Lipid Panel are discussed in Section IV(B)(2) and (3).

From October 9 through November 11, 2009, the Clinic charged for the intravenous administration and prescription of medications to Patient F. On October 9, 2009, the Clinic began the intravenous administration of PB and the oral administration of Rapamune. The same day, Patient F signed the PB informed consent form that explained the purpose of the treatment and how it caused death in cancer cells and increased the activity of common chemotherapeutic agents.[658] That same day, Patient F signed the Rapamune informed consent form that explained

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[652] Staff Ex. 6.01.A at 2049.

[653] Staff Ex. 33 at 22683.

[654] Staff Ex. 6.01.A at 2045-2048.

[655] Staff Ex. 33 at 22684-22687.

[656] Staff Ex. 6.01.A at 2044.

[657] Staff Ex. 33 at 22688.

[658] Staff Ex. Vol. 6.01.A at 1980-1982.

that the purpose of the treatment was to suppress the body's immune system.[659] On October 11, 2009, Patient F began receiving Zolinza, the informed consent form for which was signed on October 9, 2009.[660] On October 13, 2009, Patient F began receiving Xeloda, the informed consent form for which was signed on that same date.[661] The records established that with each drug, the side effects were discussed with the patient.[662]

Staff presented insufficient evidence as to why the drug charges were unreasonable. The record establishes that the intravenous administration of PB and the prescribed medications and their costs charged to Patient F were reasonable.

2. Summary of ALJs' Analysis

The ALJs find no violations as alleged regarding the billings to Patient F.

G. Patient G

1. Billings

In Appendix B to its Complaint, Staff asserts that the charges to Patient G were improper, unreasonable, or medically or clinically unnecessary. Specifically, Staff cited the charges from August 31 through November 14, 2012, for office consultations, group health education, testing, medical equipment, intravenous infusions, drugs, office/outpatient visits, blood oxygen level measurements, Lipid Panels, nutritional therapy, and after-hours medical services.

Patient G was entered into a single patient protocol to receive ANP treatment. On August 31, 2012, Patient G agreed in the Billing Agreement to pay $1,250 for the initial

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[659] Staff Ex. Vol. 6.01.A at 1973-1976.

[660] Staff Ex. Vol. 6.01.A at 1977-1979.

[661] Staff Ex. 6.01.A at 1970-1972.

[662] Staff Ex. 6.01.A at 2049.

consultation.[663] The History and Physical notes by Dr. Marquis indicate that the Clinic physicians conducted a comprehensive review of the patient's medical history and a physical examination, and began formulating a treatment plan.[664]

On September 13, 2012, Dr. Marquis's progress note reported that he examined Patient G, analyzed the lab reports, and modified Patient G's treatment plan to increase ANP.[665] Patient F was charged $125 for this visit.[666] On September 14, 2012, Dr. Marquis reported that he examined Patient G, analyzed the lab reports, and again increased ANP.[667] Patient G was charged $125 for a visit with Dr. Valladares, a clerical error.[668] On September 15 and 16, 2012, Dr. Marquis reported that Patient G's vitals were checked, and that he observed her bipedal edema, and again increased ANP.[669] Patient G was charged $75 for each visit.[670] From September 17 through 21, 2012, Patient G met with Drs. Marquis or Yi and each time her ANP was increased.[671] Patient G was charged $125 for each visit. (The September 18, 2012 charge was erroneously shown as being for Dr. Gregory Burzynski.)[672] On September 22 and 23, 2012, Dr. Yi reported that Patient G's vitals were checked and he held the ANP dosage steady.[673] Patient G was charged $75 for each visit. (The charges were erroneously showed as being for Dr. Gregory Burzynski or Dr. Marquis, respectively.)[674] On September 24, 2012, Dr. Yi

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[663] Staff Ex. 7.06.M at 3522.

[664] Staff Ex. 7.01 at 2434-2438.

[665] Staff Ex. 7.01 at 2533.

[666] Staff Ex. 33 at 22605.

[667] Staff Ex. 7.01 at 2532.

[668] Staff Ex. 33 at 22607.

[669] Staff Ex. 7.01 at 2530-2531.

[670] Staff Ex. 33 at 22609, 22611.

[671] Staff Ex. 7.01 at 2525-2529.

[672] Staff Ex. 33 at 22609, 22611.

[673] Staff Ex. 7.01 at 2523-2524.

[674] Staff Ex. 33 at 22624, 22626.

reported that Patient G's vitals were checked and he stopped the ANP dosage.[675] Patient G was charged $125 for this visit, again erroneously shown with Dr. Marquis.[676]

On September 25, 2012, Dr. Marquis's progress note recorded that he met with Patient G about her recent issues with edema and that Respondent recommended that she stay off ANP and remain in Houston for an additional week so the Clinic could monitor her condition.[677] Patient G was charged $200 for this visit, erroneously shown with Dr. Gregory Burzynski.[678]

The record establishes that the charges for the initial consultation and office visits of Patient G were reasonable, and the erroneous designations of the physician who actually met with the patient do not establish otherwise.

On September 15, 16, and 23, 2012, Patient G was charged $95 each for after-hours medical services. Progress notes for September 15, 2012, signed by Dr. Marquis indicate that Patient G called the Clinic at 8:30 p.m. regarding a malfunctioning pump, which was then reprogrammed.

The records support the charge for September 15, 2012. However, Respondent has not referenced any notes to indicate after-hours medical services being provided on September 16 or September 23, 2012. Accordingly, those charges are not supported by the medical records.

On September 12, 2012, the medical records document that Patient G received two ANP infusions. The first infusion was Atengena (one type of ANP). After Patient G was observed to see how she tolerated the infusion, she was given the prolonged infusion of "Astugenal"—a

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[675] Staff Ex. 7.01 at 2522.

[676] Staff Ex. 33 at 22628.

[677] Staff Ex. 7.01 at 2521-2522.

[678] Staff Ex. 33 at 22630.

different ANP.[679] Patient G was charged $170 for the first infusion and $395 for the second infusion.[680]

Ms. Kloos testified that Respondent improperly billed Patient G for the September 12 IV push and prolonged chemotherapy infusion because there was no time recorded or documentation of who performed the infusions.[681] Respondent replied that the progress notes satisfy the coding requirements because they indicated that Patient G was being monitored during the infusions by a healthcare professional.

Although the record establishes that the September 12, 2012 infusions of Patient G took place, nothing in the progress notes cited by Respondent identify a health professional who was present during the infusion. Accordingly, these two billings are not supported by the medical records.

From September 13 through 22, 2012, Patient G received infusions of ANP at the Clinic for which she was charged $395 each. On September 29 through October 19, October 23 through 27, November 1, and November 5 through 14, 2012, Patient G self-administered the infusions of ANP at her home. She was charged $395 for each of these infusions as well. All the infusions were coded as CPT Code No. 96416.

Ms. Kloos testified that Code 96416 is the proper code to use when ANP is given through a pump continuously by a nurse or other licensed health provider.[682] Respondent argues that the billing for daily administration of ANP (not ANP itself) was an issue for which the Clinic sought clarification, and was not an effort to overcharge the patient or her insurance. Respondent points to a letter from the Clinic's former Account Receivables Manager to the American Medical Association's Department of Coding requesting clarification on how to bill for administration of

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[679] Staff Ex. 7.01 at 2487, 2534.

[680] Staff Ex. 33 at 22504.

[681] Staff Ex. 68.02 at 67-68.

[682] Staff Ex. 68.02 at 67-68.

ANP but did not receive a determination other than that the CPT Code Manual does not designate the specific ANP agents that are to be administered. [683]

Although the record establishes that the infusions of Patient G took place, nothing in the progress notes cited by Respondent identify a health professional who was present during the infusions in the Clinic. Accordingly, those billings are not supported by the medical records. As for the charges for the self-administered infusions, although the record establishes that the self-infusions by Patient G took place, the coding used by the Clinic indicated they were administered by the Clinic. Since Respondent argues that these charges were for the administration of ANP and not the costs of the medication itself, there should have been no billings for Patient G's self-infusion. In addition, there is nothing in the records to indicate that these charges were for the shipment of ANP to Patient G, as elsewhere asserted by Respondent. Accordingly, those billings are not supported by the medical records.

Ms. Kloos testified that billings for "group education" under CPT Code 99078 for September 12, 13, 14, 17, 18, 19, 20, and 21, 2012, were improper because the medical records do not document that Patient G received education from a physician in a group setting.[684] According to Respondent, all of the group education codes were supported by the medical record. Respondent argues that, because Patient G qualified to receive ANP treatment, she had to be trained on how to administer it when she returned home. The consent form for treatment of Patient G with ANP includes the requirement that she and her family members remain in Houston for two weeks for training in monitoring the infusion pump and replacing the bag containing the ANP as the bag's contents are used.[685] Dr. Marquis noted in the medical record that he explained to Patient G that the training would last a few weeks during which they would be taught how to prepare IV ANP bags, calculate the appropriate dosages, draw blood, calculate and inject IV steroids, and care for the central line.[686]

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[683] Staff Ex. 64.B4 at 45892-45893.

[684] Staff Ex. 68.02 at 93-94.

[685] Staff Ex. 7.1 at 2449-2455.

[686] Staff Ex. 7.1 at 2438.

On September 12, 2012, Patient G was counseled by someone about birth control and appropriate diet while on ANP treatment, for which she was charged $60.[687] Patient G's Daily Worksheets document that she attended the ANP training from September 13 through 21, 2012, for which she was charged $60 for each day of training.[688]

The problem with Respondent's argument is that, while the records indicate that Patient G did receive the training in a group, albeit small, the medical records do not establish that the training was provided by a physician. Accordingly, the billings are not adequately supported by the medical records.

Dr. Wetmore opined that Respondent frequently overcharged Patient G for tests like the comprehensive metabolic panel and lipid panel.[689] Respondent noted that Patient G was advised in the Billing Agreement that lab testing after the initial consultation could cost $3,500 or more.[690] During her history and physical, Dr. Marquis documented that he explained to Patient G that blood tests were required as part of the FDA approval process for the single patient protocol.[691]

Staff presented no expert testimony to support its allegations that Respondent charged Patient G unnecessarily for various medical supplies. As for the lab testing and the tests for blood oxygen levels, these issues are discussed in Section IVB2 and 3.

On September 18, 2012, Patient G had a nutritional consultation with Debbie Bertland, a certified nutritionist, and was provided additional educational materials concerning a healthy diet and lifestyle.[692] She was charged $300 for this consultation.[693]

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[687] Staff Ex. 7.1 at 2534.

[688] Staff Ex. 7.1 at 2710-2714; 2717-2718.

[689] Staff Ex. 68.03 at 69-70.

[690] Staff Ex. 7.6.M at 3522.

[691] Staff Ex. 7.1 at 2438.

[692] Staff Ex. 7.1 at 2528.

[693] Staff Ex 33 at 22528.

Staff has provided no evidence as to why this charge was not medically necessary.

2. Summary of ALJs' Analysis

The ALJs find that the charges for after-hours medical services on September 16 or 23, 2012, the charges for the September 12 through 22, 2012 infusions of ANP at the Clinic, the charges for the self-administered infusions of ANP on September 29 through October 19, October 23 through 27, November 1, and November 5 through 14, 2012, and the charges for group health education are not supported by the medical records, in violation of Code § 164.051(a)(3) and 22 TAC § 165.1(a).

IX. DECEPTIVE MARKETING AND ADVERTISING

Patient F initially sought treatment by the Clinic with ANPs in part due to reading or viewing statements referenced on the website of the Clinic, but he and his wife were informed at the initial consultation that he did not qualify for ANP treatment.[694]

The Clinic's and BRI's websites during the period covered by the Complaint regarding Patients A through G (October 8, 2009 through November 26, 2012) contained several statements that were objected to by the FDA. In a letter dated October 18, 2012, Thomas N. Moreno, Acting Office Director of the Office of Scientific Investigations of the Office of Compliance of the Center for Drug Evaluation and Research of the FDA notified Respondent that certain claims on the Clinic website suggested that ANPs were safe and effective for the treatment of various types of brain tumors when they had not been approved for those uses. Mr. Moreno requested that the Clinic and BRI discontinue use of those promotional materials.[695] In a follow-up letter dated January 10, 2013, Kendra Y. Jones, Regulatory Review Officer of the Division of Consumer Drug Promotion of the Office of Prescription Drug Promotion of the FDA notified Respondent that even though changes had been made to the websites, there were continued claims and presentations that promoted the use and efficacy of

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[694] Tr. Vol. 9 at 140-146.

[695] Staff Ex. 4.02 at 283-291.

ANPs, and requested that those claims and presentations be discontinued.[696] In a letter dated April 17, 2013, Ms. Jones stated that all of the objectionable materials had been removed from the websites and the matter was now closed.[697]

As of October 2012, the Clinic website stated in several places that ANP therapy was the subject of FDA supervised clinical trials and that only patients eligible to enroll in such trials could receive ANP treatments. It further stated that patients not eligible for a clinical trial may receive the approval of FDA to enroll for ANP treatment on an individual basis.[698]

In its Brief, Staff merely restates the allegation in its Complaint with cites to the websites and the FDA correspondence regarding them, but makes no argument as how those cites support its allegation. However, as discussed below, FDA concerns about possible violations of non-criminal federal regulations that were resolved to the satisfaction of the FDA are not the basis for determining that violations of the Texas statutes or rules have occurred.

Staff also cites to deposition testimony of Clinic employees to support its allegation. Those statements merely established that patients had learned about the Clinic and ANP from the websites and other sources and that they were interested in pursuing alternative therapy because conventional therapy had not worked. However, there is no evidence that Respondent's websites misled prospective patients into thinking that because ANP had been successfully used to treat certain patients, it could or would be used in their individual treatments. Accordingly, Staff has failed to establish that Respondent used advertising statements that were false, misleading, or deceptive, in violation of Code § 164.052(a)(6).

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[696] Staff Ex. 12 at 7004-7009.

[697] Staff Ex. 12 at 7031-7033.

[698] Staff Ex. 1.04 at 30, 35.

X. ETHICAL AND PROFESSIONAL RESPONSIBILITIES[699]

As discussed above in Section I, in Order No. 7 the ALJs partially granted Respondent's motion for summary disposition disposing of certain allegations raised by Staff in regards to Respondent's ethical and professional responsibilities as the principal investigator of clinical studies. § 164.053(a)(1) of the Code defines "unprofessional or dishonorable conduct that is likely to deceive, defraud, or injure the public" as including the commission of an act that "violates state or federal law if the act is connected with the physician's practice of medicine." The Board has interpreted that section of the statute in its rules. Board Rule 190.8(2)(R) expressly identifies the violations of "federal and state laws whether or not there is a complaint, indictment, or conviction" that constitute unprofessional and dishonorable conduct. This subsection clarifies that the violations of federal law that the Board has determined constitute unprofessional or dishonorable conduct are criminal in nature. This subsection of the rule does not expressly state that this is a nonexclusive list, as do other subsections.

The ALJs concluded in Order No. 7 that, based on the specific language of 22 TAC § 190.8(2)(R), the Board has interpreted Code § 164.053(a)(1)'s reference to federal laws to apply to those related to criminal violations of federal law. Accordingly, the alleged violations of non-criminal FDA regulations regarding promotional statements and the violation of FDA regulations regarding Phase 2 clinical studies do not constitute violations of 22 TAC § 190.8(2)(R), and, therefore, do not violate Code § 164.053(a)(1).

Staff accused Respondent of having a conflict of interest serving as both principal clinical investigator and sponsor. BRI is the sponsor; however, Respondent owns 80% of BRI's stock. The documentary evidence indicates that the FDA is aware of the relationship between Respondent and BRI and has approved the applications listing Respondent as the principal investigator and BRI as the sponsor. Notably, the FDA regulations define not only the terms "investigator" and "sponsor," it also defines a "sponsor-investigator" to mean "a person who

[699] Pursuant to Order No. 34, the ALJs will consider only those patients discussed in the parties' closing arguments. Claims about other patients are deemed waived.

both initiates and actually conducts, alone or with others, a clinical investigation."[700] This in an apparent acknowledgement by the FDA that there is no conflict of interest for Respondent to serve as both principal clinical investigator and sponsor.

A. Failure to Protect Patients G and I through BB in Clinical Trials

As a clinical investigator,[701] Respondent was responsible for complying with statutes and rules applicable to clinical investigations,[702] including Board Rule 200.3(7).[703] According to Staff, 21 Code of Federal Regulations (C.F.R.) §§ 312.3(b), 312.50, and 312.60 are the primary federal regulations governing the ethical and professional responsibilities of clinical investigators. An investigator is responsible for "protecting the rights, safety, and welfare of subjects under the investigator's care; and for the control of drugs under investigation" by ensuring that the investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulations.[704]

BRI was the sponsor of the Clinic's clinical studies. As the sponsor, BRI was responsible for the following:

> selecting qualified investigators, providing them with the information they need to conduct an investigation properly, ensuring proper monitoring of the investigation(s), ensuring that the investigation(s) is conducted in accordance with the general investigational plan and protocols contained in the IND, maintaining an effective IND with respect to the investigations, and ensuring that FDA and all

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[700] 21 Code of Federal Regulations (C.F.R.) § 50.3(f).

[701] According to 21 C.F.R. § 312.3, an "investigator" is "an individual who actually conducts a clinical investigation (*i.e.*, under whose immediate direction the drug is administered or dispensed to a subject). In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. 'Subinvestigator' includes any other individual member of that team."

[702] 21 C.F.R. § 312.03(b) defines "clinical investigation" to mean "any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice."

[703] 22 TAC § 200.3(7) requires clinical investigators to ensure that the clinical studies are part of a systematic program, have the same concern and caution for the welfare of the patient as in a non-clinical investigation, and have patients signed informed consent forms compliant with federal regulations.

[704] 21 C.F.R. § 312.60.

> participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug. Additional specific responsibilities of sponsors are described elsewhere in this part.[705]

Staff asserts that Respondent violated his ethical and professional responsibilities as a clinical investigator towards patients in clinical studies in violation of Board Rule 200.3[706] by: (1) failing to adhere to established standards of scientific research; (2) failing to adequately protect Patient G and Patients I through BB, who were being treated with ANP in either a clinical trial or as an expanded access patient; (3) destroying imaging measurements or failing to maintain the patients' underlying imaging as part of the medical records; and (4) overprescribing corticosteroids.[707] Staff also maintains that Respondent misrepresented the tumor responses that Patients Q, R, V, W, X, Y, Z, AA, and BB had to ANP treatment and that these patients experienced serious adverse events that Respondent did not report to BRI, and ultimately to the FDA.[708]

Dr. Fost explained that it is the physician's duty when treating adult cancer patients to learn whether the patient wants treatment, "whether it's experimental or just standard clinical practice."[709] To do so, he said, the patient must be informed about the risks and benefits of

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[705] 21 C.F.R. § 312.50. IND is the acronym for "investigational new drug."

[706] 22 TAC § 200.3(7)(A) and (B) state:

(7) Clinical Investigations. Physicians using conventional medical practices or providing complementary and alternative medicine treatment while engaged in the clinical investigation of new drugs and procedures (a.k.a. medical research, research studies) are obligated to maintain their ethical and professional responsibilities. Physicians shall be expected to conform to the following ethical standards:

> (A) Clinical investigations, medical research, or clinical studies should be part of a systematic program competently designed, under accepted standards of scientific research, to produce data that are scientifically valid and significant;
>
> (B) A clinical investigator should demonstrate the same concern and caution for the welfare, safety and comfort of the patient involved as is required of a physician who is furnishing medical care to a patient independent of any clinical investigation;

[707] Staff Ex. 65, Vol. 14.09.L at 46162.

[708] Staff's Closing Argument at 63. Although Staff asserts that Respondent misclassified Patients Q, R, V, W, Y, Z, AA, and BB and failed to report their adverse events, Staff only discussed these allegations in reference to Patients H, I, J, N, O, P, S, T, and U. The issue regarding informed consent Staff asserts pertained to Patients I, J, N, Q, R, S, T, V, Z, AA and BB.

[709] Staff Ex. 68.01 at 17.

proposed treatment and any alternative treatments. According to Dr. Fost, a physician must respect the adult patient's "autonomous preferences" even if the adult patient makes "decisions that may violate their own interests"[710] However, when treating pediatric cancer patients, Dr. Fost maintained, the physician has a different duty. The physician must honestly and candidly discuss with the child's legally authorized representative the types of treatments available and the associated risks and benefits, and must also do what is in the child's "best interest."[711]

Respondent disagrees with Staff's allegations and adamantly asserts that he met both the federal and state requirements in treating these patients in a clinical trial. As a threshold issue, however, Respondent objected to Staff's addition of "failure to protect" allegations regarding Patients H and CC in its closing argument because Staff did not plead these allegations in the Complaint.[712] Consequently, Respondent requested that the ALJs disregard these allegations. The ALJs agree. Therefore, Staff's allegations that Respondent failed to protect Patients H and CC in a clinical trial will not be considered, in accordance with Texas Government Code § 2001.052. However, Patients H and CC were cited in the Complaint for other ethical violations and will be addressed in the appropriate section.

Respondent questioned Dr. Fost's expert opinions because Dr. Fost admittedly did not interview the patients or the patients' families; did not review most of the medical records;[713] and could not recall what records he reviewed regarding Patients H through BB.[714] Although Dr. Fost acknowledged that Respondent's cancer patients had poor prognoses, he could not remember if most of these patients had terminal cancer or had already tried conventional cancer treatment without success.[715] Instead, Dr. Fost based his opinions on the assumption that the

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[710] Tr. Vol. 1 at 160; Staff Ex. 68.01 at 18.

[711] Staff Ex. 68.01 at 17-18.

[712] Regarding the failure to protect allegations, Staff only cited to Patients A through G and I through BB in its Complaint.

[713] Tr. Vol. 1 at 163-164.

[714] Tr. Vol. 1 at 184.

[715] Tr. Vol 1 at 172-173.

preliminary FDA findings referenced in the 2013 warning letter were true even though he agreed that a warning letter "in and of itself does not mean that there's been an ethical violation."[716] Respondent points out that Dr. Fost could not identify whether the Board's allegations concerning Patients I through BB dealt with any FDA issues.[717]

Respondent emphasizes that Patients G and I through BB were previously diagnosed with terminal cancer and had either rejected convention treatment or had conventional treatments fail. Staff's expert, Dr. Fost, agreed that traditional cancer treatments, such as radiation and chemotherapy, had already failed many of Respondent's patients.[718] According to Respondent, Board Rule 200.3(7) does not require a physician to ensure to a patient that the risk associated with the proposed treatment is reasonable in relationship to the anticipated benefits because even traditional cancer treatments have deadly side effects.

Dr. Levin, who has oncology experience in both academic and private practice settings, emphasized that the FDA heavily monitors and scrutinizes clinical studies. He noted that the layers of federal oversight that apply in a clinical trial setting, including record keeping, do not usually apply to an oncologist in private practice.[719]

Dr. Burzynski represented that it was only necessary to report adverse events that were "serious, unexpected, and causatively related to the investigation of the agent."[720] Expected and known side effects, he clarified, did not need to be reported. Dr. Burzynski explained that at the Clinic, the subinvestigators (other physicians) reported all adverse events to him because he was the principal investigator in the FDA-approved clinical trials. He then reported those adverse events that were serious, unexpected, and causatively related to ANP to the sponsor, BRI. Ultimately, BRI reported the adverse events to the FDA.[721]

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[716] Tr. Vol. 1 at 194-195.

[717] Tr. Vol. 1 at 184.

[718] Tr. Vol. 1 at 166.

[719] Resp. Ex. 165 at 6.

[720] Tr. Vol. 8 at 68.

[721] Tr. Vol. 8 at 82-83.

According to Protocol BT-10[722], the investigator had to report any adverse reactions that were "unexpected and fatal or life threatening" or are "unexpected and serious."[723] According to Protocol BT-10, the known side effects of ANP included the following:

> Central nervous system toxicity including blurred vision, ringing in ears, hearing loss, headache, dizziness, slurred speech, hallucinations, depressions, tiredness, mood changes, sleepiness, polyneuropathy (numbness and tingling) and thickening of the skin, arrhythmia (changes in your heart rate), nausea, vomiting, diarrhea, anemia, increase of blood pressure, swelling, fluid retention or fluid loss (both of which may be serious), weakness, electrolyte imbalance including: decrease of calcium, sodium, potassium, magnesium, and or increase in sodium concentration in blood (forgetfulness, confusion, cramps) which in extreme cases may become life-threatening. Other side effects include: Decreased white blood cell count which can result in an increased chance of infection, a decrease in platelet count, (increase[d] chance of bleeding), blood in the urine, an elevated bilirubin which can result in jaundice (yellowing of the skin and whites of the eye), fever chills, skin rash, muscle aches, joint pain, abdominal pain. There is a possibility of liver toxicity, increased urination, increased thirst. You many also experience a metallic taste or shortness of breath while on therapy. AS2-1 also has a distinct chemical smell. Because the Antineoplaston treatment will require prolonged administration by way of a central venous line, there is some likelihood of infection of that line and of phlebitis of the infused blood vessel.[724]

1. Patient G

As noted above, after the first ANP infusion on September 12, 2012, Patient G reported experiencing dizziness, discomfort, and fatigue. Two days later she reported having fatigue, headaches, and pressure. Blood tests showed she had abnormally low potassium levels. The next day, Patient G reported having edema in both feet and increased blurred vision. Two days later, Patient G reported that her vision was getting worse, as were her headaches. The edema was still present and worsened at night and with activities. The next day, Patient G reported that her vision was getting worse and that her eye pain and headaches remained unchanged. In

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[722] The FDA approves the protocols to be used in each type of clinical trial.

[723] Staff Ex. 31 at 20960.

[724] Staff Ex. 31 at 20959-20960. Protocol BT-09 appears to identify the same side effects from ANP treatment. Staff Ex. 30 at 20174.

response, Dr. Marquis increased her dosage of potassium and ANP. On September 19, 2012, she had no eye pain but said that she still had blurred vision in her right eye together with agitation and increased anxiety. Dr. Marquis recommended that one type of ANP and the potassium be increased. Several days later Patient G was admitted to a hospital in her home city after waking up in the night with extreme leg pain. Subsequently, Patient G restarted ANP and her lower extremity pain returned. The edema increased as Patient G increased the ANP dosage over the next few days. Patient G discontinued treatment with ANP due to persistent edema.

Dr. Wetmore testified Patient G experienced "significant side effects" from Respondent's treatment that included edema, electrolyte disturbances, fungal growth in the mouth and on the skin, and extremity pain. Despite these side effects as well as a central venous line infection, Dr. Wetmore noted, Respondent did not report the adverse events, as required. However, as set forth above, the protocol included in its list of known side effects blurred vision, headache, dizziness, tiredness, swelling, fluid retention, electrolyte imbalance including decreased potassium, skin rash, and infection of the central venous line.

Based on the evidence, the ALJs find that Protocol BT-10 only required Respondent to report serious, unknown side effects causally related to ANP treatment. Consequently, the ALJs find insufficient evidence that Respondent failed to report adverse events from Patient G's treatment with ANP as required by Protocol BT-10, and that Respondent violated 22 TAC § 200.3(7).

2. Patients I and J

According to Dr. Wetmore, Respondent misrepresented that Patients I and J experienced no adverse events attributable to the ANP treatments because she noted that both patients experienced serious side effects. Respondent disagrees with Dr. Wetmore and stated that only unknown and unexpected side effects constituted adverse events that had to be reported.

Patient I was a 5-year-old boy from New York. A November 2011 MRI revealed that he had a brainstem lesion, although a biopsy was not taken because of the lesion's location.

Patient I was treated at a New York hospital with radiation concomitant with Zolinza (vorinostat) from November 4 until December 16, 2011. When the February 16, 2012 MRI showed that the tumor's size had increased, Patient I was treated with chemotherapy that included the concurrent use of Temodar (temozolomide) and Zolinza from March 6 to April 1, 2012. The tumor continued to grow.[725]

Patient I's parents elected to discontinue traditional treatment and arrived at the Clinic on April 30, 2012.[726] According to the history and physical, when Patient I arrived at the Clinic, he was wheelchair-bound and somnolent. Although the child could open his eyes, "his response could not be assessed" and he had "cushingoid features secondary to the steroids."[727] Patient I began ANP treatment on May 7, 2012.[728] On May 11, 2012, Patient I was admitted into Texas Children's Hospital and no further ANP treatments were given to him. On May 14, 2012, Patient I died of an intracranial hemorrhage located within the tumor.[729] The Clinic only had the April 20, 2012 MRI taken to establish the baseline as required by the clinical study.[730] That MRI was taken at the Long Island Jewish Medical Center.

Patient J was a 4-year-old girl from South Africa whose August 2011 MRI revealed a brainstem glioma.[731] From August 31 to October 10, 2011, Patient J received radiation therapy in South Africa. The therapy appeared to have stabilized the disease, but two weeks before visiting the Clinic, the parents reported that Patient J's condition had deteriorated. According to the medical records, Patient J was offered no further treatment options. The April 13, 2012 MRI taken shortly before Patient J arrived at the Clinic showed that the mass had grown—measuring

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[725] Staff Ex. 54 at 41468. Respondent's records indicate that the November 2011 MRI records were unavailable. The April 20, 2012 MRI of the tumor was reported as 3.7 cm x 2.4 cm x 3.4 cm; on the February 16, 2012 MRI it was 3.6 cm x 2.2 cm x 2.3 cm. Staff Ex. 54 at 41556.

[726] Staff Ex. 54 at 41469.

[727] Staff Ex. 54 at 41469.

[728] Staff Ex. 54 at 41498.

[729] Staff Ex. 54 at 41474.

[730] Staff Ex. 54 at 41551, 41554.

[731] Staff Ex. 56.A at 41731.

5.8 cm x 4.7 cm.[732] Patient J's parents brought their child to the Clinic on May 1, 2012.[733] Patient J was provisionally approved to receive ANP according to Protocol BT-10 and began treatment on May 7, 2012. The child died on October 16, 2012.

After the patients began ANP treatment, Dr. Wetmore noted, Patient I suffered the following adverse effects: somnolence, Grade 2 hypokalemia requiring hospitalization, vomiting, hypernatremia, and an ANP overdose.[734] She also noted that Patient J experienced fever, somnolence, loss of appetite, CVC infection and hospitalization, Grade 2 anemia, lower extremity swelling, vomiting, diarrhea, Grade 2 hypernatremia, and Grade 2 hypokalemia.[735]

Contrary to Dr. Wetmore's claim that Patients I and J experienced adverse events that Respondent failed to properly report, Respondent stressed the distinction between known and expected side effects and adverse events as defined in the FDA-approved protocol. He explained that, according to the protocol for the clinical study, an adverse event had to be serious, unexpected, and an unknown side effect causally related to the ANP treatment.[736] The side effects Patients I and J experienced, Respondent pointed out, were not adverse events because they were either unrelated to ANP treatment or were not unexpected.[737]

Patient I's and J's respective medical records documented the side effects each patient experienced. These side effects were known side effects of ANP treatment. Therefore, the ALJs find that Staff failed to prove that Respondent inaccurately reported to BRI the adverse events Patients I and J experienced while receiving ANP treatments.

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[732] Staff Ex. 56.A at 41731.

[733] Staff Ex. 56.A at 41731.

[734] Staff Ex. 68.03 at 127.

[735] Staff Ex. 68.03 at 127.

[736] 21 C.F.R. § 312.32(c)(1).

[737] Staff Exs. 53 at 41, 650-51; 31 at 21071.

In addition, Dr. Wetmore opined that the imaging reports for Patient I had numerous inconsistencies and misrepresentations that were caused by Respondent's failure to measure the lesion consistently from the same location and with the same type scan.[738] She stated that:

> Dr. Burzynski did not measure the lesion consistently from the same location and type of scan; he did not consistently and accurately report in the medical record or to the family when the lesion was larger in size. Dr. Burzynski several times over-reported the initial size of the lesion. The lesion was clearly getting larger from January to April 2012 [and] while on antineoplastons, and yet Dr. Burzynski did not document this in the medical record or tell the family. Dr. Burzynski does not consistently compare enhancing and non-enhancing parts of the tumor, which represent very different parts of the tumor.[739]

According to Patient I's medical records, Respondent received Patient I's April 20, 2012 MRI, but ordered no other scans before Patient I died. The April 20, 2012 radiology report from Long Island Jewish Medical Center reported that Patient I had a history of brainstem glioma and that the soft tissue mass had increased in size when compared to a prior exam. According to Barry Shpizner, M.D., attending radiologist, Patient I's tumor mass had increased from 3.5 cm x 2.3 cm x 3.4 cm to 3.7 cm x 2.4 cm x 4.1 cm and was "strongly suspicious for tumor progression . . ."[740] Based on the April 20, 2012 radiology films from Long Island Jewish Medical Center, the Clinic's baseline radiology report indicated that the brainstem enhancing mass was 3.7 cm x 2.4 cm.[741]

BRI-IRB provisionally approved Patient I to receive ANP as a special exception on May 2, 2012.[742] Patient I started ANP treatment on May 7, 2012,[743] discontinued ANP treatment on May 10, 2012,[744] and was admitted into Texas Children's Hospital on May 11, 2012. The

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[738] Staff Ex. 68.03 at 97-98.

[739] Staff Ex. 68.03 at 97. At the hearing, Dr. Wetmore testified that the word "and" needed to be inserted into the sentence.

[740] Staff Ex. 54 at 41554-41555.

[741] Staff Ex. 54 at 41551.

[742] Staff Ex. 54 at 41633-41634.

[743] Staff Ex. 54 at 41484.

[744] Staff Ex. 54 at 41477.

child died on May 14, 2012, when the tumor hemorrhaged.[745] The only radiology scan taken during this time was the baseline scan taken on April 20, 2012, in New York.[746] Respondent maintains that he properly reported that Patient I's tumor measurement was not evaluable.[747]

Dr. Wetmore faulted Respondent for not documenting in the medical record that Patient I's tumor was "clearly getting larger from January to April 2012," and for withholding this information from Patient I's family. At that time, Patient I was under another oncologist's care. Patient I's parents knew the lesion had grown and that traditional cancer treatment had failed their child. Patient I did not become Respondent's patient until April 30, 2012. Dr. Wetmore also claimed that the tumor was getting larger while Patient I was on ANP; however, the medical record reflects that the child only received ANP for three days and no other MRIs were taken. It is unclear how Dr. Wetmore concluded that Respondent should have documented and informed the child's parents that the tumor had gotten larger over the three days that Patient I was on ANP.

The ALJs find persuasive Respondent's testimony that no other radiologic scans were taken while Patient I was treated with ANP because the child was only on ANP for a couple of days before he was admitted to the hospital and died. Contrary to Dr. Wetmore's testimony, the medical records do not reflect that Respondent inaccurately or inconsistently measured the lesion because Patient I only had a baseline radiology report. As for Dr. Wetmore's direct testimony that Respondent "several times over-reported the initial size of the lesion," the records reflect that Respondent's measurements were consistent with those reported by Dr. Shpizner, the attending radiologist at Long Island Jewish Medical Center. While Dr. Wetmore correctly opined that the lesion grew from January to April 2012, this was before Patient I even began treatment with ANP. Therefore, Staff incorrectly accused Respondent of failing to accurately record this in Patient I's medical records. The preponderance of evidence does not support Staff's allegations that Respondent failed to protect Patient I in the clinical trial.

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[745] Staff Ex. 54 at 41474.

[746] Staff Ex. 54 at 41551.

[747] Staff Ex. 54 at 41550.

Regarding Patient J, Dr. Wetmore accused Respondent of over-reporting the size of the initial tumor and improperly comparing MRI scans to CT images. Because Patient J died on October 30, 2012, due to the malignancy, Dr. Wetmore found it improper for Respondent to report that Patient J had a stable disease that showed a decrease in tumor size.[748]

The Clinic's measurements of Patient J's tumor are dated from May to August 2012. The last measurement Respondent took was on August 24, 2012, and he reported in the Radiology Notes that the tumor was 4.5 cm x 4.4 cm. An outside radiologist's findings taken on November 10, 2011, measured the tumor as "65 mm x 51 mm x 50 mm" (6.5 cm x. 5.1 cm x 5.0 cm).[749]

Respondent disputed Staff's claim that Respondent misclassified Patient J's response to the ANP treatment as "stable disease" with a decrease in tumor size. Respondent pointed out that the most recent outside report before Patient J began treatment at the Clinic was from April 13, 2012.[750] At that time, the tumor measured 5 cm x 5cm x 4.7 cm.[751] The final outside radiology report taken while Patient J was still under the Clinic's care measured the tumor at 4.9 cm x 3.3 cm.[752] Based on this outside radiology report, Respondent asserted, the tumor had decreased in size while the child was on ANP and his classification of "stable disease" was in compliance with the applicable protocol.

According to Protocol BT-10, if the patient's tumor response does not meet the definition of a complete response, partial response, or progressive disease, then it is considered a stable disease (SD). A complete response is defined as "the disappearance of all enhancing tumor on neuroimaging studies such as MRI or ancillary radiologic studies of at least 4 weeks . . . ."[753] A

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[748] Staff Ex. Vol. at 99-101.

[749] Staff Ex. 56 at 42130.

[750] Staff Ex. 56 at 42136.

[751] Staff Ex. 56 at 42136-42137.

[752] Staff Ex. 56 at 42132.

[753] Staff Ex. 31 at 20952.

partial response is defined as a greater than or equal to 50% reduction in the lesion and a progression disease is a greater than or equal to 25% increase in the lesion.[754] Respondent asserts that the patient did not have a 50% reduction in the lesion and was properly reported as a "SD."[755]

Although Dr. Fost discussed Patient J's medical condition and treatment in his direct testimony,[756] when asked at the hearing about the type of cancer Patient J had, Dr. Fost said he could not recall.[757] Dr. Fost initially testified that Respondent had misclassified Patient J as "stable," but when Dr. Fost reviewed the Response Assessment of Neuro-Oncology (RANO) criteria and the protocol definition of "stable," he conceded that Respondent had properly classified Patient J's tumor.[758]

Based on the credible evidence, the ALJs find that Respondent did not misclassify Patient's J as "stable," but evaluated the tumor in compliance with Protocol BT-10. The evidence presented was insufficient to establish that Respondent measured the lesions inaccurately.

3. Patient N

On October 15, 2010, Patient N, a 4-year-old boy from Prague, Czech Republic, was taken to "Children Clinic Ke Karlova" where an MRI revealed "an expansile lesion in the brainstem, partially enhanced with IV contrast, necrotic and cystic and compressing the fourth ventricle."[759] A biopsy was not taken due to the risk to the child. Patient N was diagnosed as having a diffuse intrinsic pontine glioma (DIPG).[760] Patient N was transferred to the neurology clinic at University Hospital in

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[754] Staff Ex. 31 at 20952.

[755] Staff Ex. 56 at 42128.

[756] Staff Ex. 68.01.

[757] Tr. Vol. 1 at 238-239.

[758] Staff Ex. 68.01 at 66; Tr. Vol. 1 at 247.

[759] Staff Ex. 48 at 38883.

[760] Staff Ex. 48 at 38883.

Motol, Prague, and began radiation therapy on November 2, 2010. He completed the radiation treatments on December 6, 2010. The post-radiation MRI showed a decrease in the tumor size. Between February 12 and June 2011, Patient N was treated with Temodar (chemotherapy). An MRI taken on May 6, 2011, revealed that the tumor had progressed. The child's parents discontinued Patient N's treatment with chemotherapy and brought Patient N to the Clinic on July 25, 2011.

Patient N was provisionally approved to receive ANP therapy as an expanded access patient under Protocol BT-10. According to the Patient N's medical records, he began ANP treatments on July 29, 2011, and experienced frequent fevers, fatigue, night sweats, and diarrhea.[761] Patient N continued taking ANP until October 7, 2011, when his mother discontinued the treatment. Dr. Gregory Burzynski noted in the progress notes that Patient N had an MRI taken on July 26, 2011, that revealed a brainstem glioma measuring 4.2 cm x 3.23 cm x 3.9 cm with a borderline prominent ventricular system.[762] Patient N died on October 25, 2011. Respondent reported that the tumor was "non evaluable."

According to Dr. Wetmore, Patient N suffered from numerous side effects that Respondent failed to report to the FDA. According to the medical records, she noted that while being treated with ANP, Patient N experienced somnolence, headaches, fever, slurred speech, gait dysfunction, hypokalemia, lower extremity swelling, lethargy, and vomiting.[763] Patient N's condition required hospitalization on September 28, 2011. She also opined that Respondent's imaging reports for Patient N had numerous inconsistencies, misrepresentations, and were missing documents. In Dr. Wetmore's opinion, Respondent misdiagnosed Patient N as having DIPG. She opined that the tumor was actually a "pilocytic astrocytoma."[764]

Respondent noted that the side effects Patient N experienced were not reportable adverse events because none were unexpected.[765] As for alleged misrepresentations in the radiology

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[761] Staff Ex. 48 at 48883-48884.

[762] Staff Ex. 48 at 38887, 39036.

[763] Staff Ex. 68.03 at 128-129.

[764] Staff Ex. 68.03 at 101; Staff Ex. 48 at 39031-39039.

[765] Staff Ex. 31 at 21071.

reports, Respondent asserted that Dr. Wetmore assigned the wrong baseline to this patient because Patient N was only treated at the Clinic from August to September of 2011. During this time, Patient N had two MRIs, one dated July 27, 2011 and the other August 31, 2011.[766] According to Respondent, the Clinic's measurements taken on July 27 and August 31, 2011, were consistent with the outside radiology reports.[767] Although the Clinic's second radiology report showed a marked decrease in the tumor size of 16%,[768] the Clinic still classified Patient N's response as "non-evaluable," rather than the more favorable "stable disease."[769]

Dr. Wetmore testified that the "tumor enhancement, along with the cystic regions and septae within the tumor suggest that it is a pilocytic astrocytoma and NOT a DIPG."[770] Respondent disagreed that Patient N was misdiagnosed, as Dr. Wetmore alleged. He emphasized that before Patient N came to the Clinic, Patient N's diagnosis was confirmed at two separate health care institutes, one of which was a neurology clinic. Dr. Wetmore provided little support to show how she arrived at her medical opinion that this patient had pilocytic astrocytoma and not DIPG. Patient N had been diagnosed by several physicians who treated the child before he came to the Clinic and all diagnosed him with DIPG.[771] Based on the evidence in the record, the ALJs find that Staff presented insufficient evidence to establish that Respondent misdiagnosed Patient N's condition or that Respondent inaccurately reported the results of Patient N's imaging studies.

4. Patient O

According to Staff, Patient O, a 63-year-old female, was an expanded access patient who received ANP under Protocol BT-09. Dr. Wetmore stated that Respondent "did not measure the lesion consistently from the same location and type of scan; he did not consistently and

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[766] Staff Ex. 48 at 39031.

[767] Staff Ex. 48 at 39031 (clinic report), 39036 (outside report).

[768] Staff Ex. 48 at 39032.

[769] Staff Ex. 48 at 39031.

[770] Staff Ex. 68.03 at 101.

[771] *See* Staff Ex. 48 at 39039.

accurately report in the medical record or to the family when the lesion was larger in size. Dr. Burzynski several times over-reported the initial size of the lesion."[772]

Contrary to Dr. Wetmore's testimony that Patient O was "involved in a clinical investigation,"[773] or alternatively, in expanded access,[774] Respondent stated that Patient O was not in a clinical trial or an expanded access patient, and did not receive ANP therapy at the Clinic. Instead she had an "Orphan Drug designation for the treatment of adrenocortical carcinoma,"[775] and was treated with PB and targeted therapy. Under Respondent's direction, one radiology measurement was made before Patient O arrived for treatment at the Clinic, on May 29, 2012. This measurement, Respondent pointed out, was similar to the outside radiologist's findings.[776]

The Clinic's medical records for Patient O indicate that she began PB treatments on February 13, 2012. She was also started on Gemzar (gemcitabine) with Xeloda (capecitabine) with the last infusion of Gemzar given on April 3, 2012. On June 6, 2012, Respondent applied a second time to have Patient O approved to participate in an ANP clinical trial (Protocol AD-2) because standard cancer treatments had failed her. Patient O had an extensive cancer history that began in 2006. She came to the Clinic "seeking active treatment for her advancing metastatic adrenocortical carcinoma."[777] Although Respondent requested permission to treat Patient O with ANP under expanded access for single patient use,[778] there is no documentary evidence that this request was approved.

In reaching her opinion that Respondent did not measure the lesion accurately, Dr. Wetmore appeared to be referring to the Clinic's June 1, 2012 Radiology Note regarding the

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[772] Staff Ex. 68.03 at 102-103.

[773] Staff Ex. 68.03 at 102.

[774] Staff's Closing Argument at 65.

[775] Staff Ex. 47 at 38753.

[776] Staff Ex. 68.03 at 103.

[777] Staff Ex. 47 at 38754.

[778] Staff Ex. 47 at 38753, 38786.

CT scan taken of Patient O's chest, abdomen, and pelvis and the May 29, 2012 M.D. Anderson's CT scan report.[779] The May 29, 2012 CT scan report from MD Anderson Cancer Center measured the lesion on the right lobe of liver at 3.8 x 3.5 cm, and the one on the left at 6.9 x 5.8 cm.[780] The Clinic's Radiology notes indicated that on June 1, 2012, the right lesion measured at 3.8 x 3.6 cm, and the left at 6.5 cm x 6.0 cm.[781] The measurements were similar.

Based on the credible evidence, the ALJs find that Staff presented insufficient evidence to establish that Patient O participated in a clinical study or that she received ANP. Because Patient O was not in a clinical trial, tumor measurements would not be subject to FDA protocol. Even if Patient O had been in a clinical trial, the evidentiary records does not support that Respondent inaccurately measured Patient O's lesion.

5. Patient P

Patient P, a 57-year-old male, was diagnosed with multiple myeloma and compromised bones. He came to the Clinic for treatment on April 30, 2012. This patient also had a herpes infection secondary to Revlimid.[782] According to Dr. Wetmore, Respondent's imaging reports for Patient P did not measure the lesion consistently from the same location or utilize the same type of scan for comparison.[783]

According to Patient P's medical records, Patient P was not an expanded access patient who was treated with ANP and was not in a clinical study. Although Respondent requested that Patient P be approved for treatment under expanded access for single-patient use of intravenous ANPs, the documentary evidence does not show that this request was approved or that Patient P received ANP treatment. What was approved was the Clinic's Statement of Informed Consent

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[779] Staff Ex. 68.03 at 103.

[780] Staff Ex. 47 at 38830.

[781] Staff Ex. 47 at 38825-38826.

[782] Staff Ex. 52 at 40630, 40634.

[783] Staff Ex. 68.03 at 104; Staff Ex. 52 at 40636.

for Investigation Clinical Study for this patient.[784] The credible evidence presented does not show that Patient P participated in a clinical study or that he received ANP. Therefore, the ALJs find the evidence insufficient to show that Respondent failed to protect Patient P in the clinical study. Because Patient P was not in a clinical trial, Staff's charge that Respondent's failed to protect this patient in a clinical trial is misplaced.

6. Patient S

Patient S, a 9-year-old boy, was diagnosed with pilocytic astrocytoma, WHO grade I[785] and enrolled in the Protocol BT-10 clinical trial. This patient was treated at the Clinic from July 19, 2002, to September 15, 2014.[786] On September 30, 2014, Respondent initially reported that Patient S's disease was SD, but changed his classification to PR (partial response) on December 20, 2014.

Staff asserts that Respondent improperly changed Patient S's tumor response to the ANP treatment because Patient S's disease had spread to his spine.[787] Staff relied, in part, on the FDA's 2013 inspection report and subsequent warning letter which represented that Patient S was in the Protocol BT-09 clinical study, which prohibited corticosteroid use in a patient with a PR classification. But, Respondent's records reflect that Patient S was in the Protocol BT-10 clinical trial which did not have the same prohibition. Based on the evidentiary records, the ALJs are unclear for which clinical study Patient S was approved.[788]

Dr. Wetmore opined that Respondent did not accurately and consistently document changes in the tumor size, but instead "skewed the results to make it appear that there was a tumor response to his investigation therapy when there was not."[789] She also found that

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[784] Staff Ex. 52 at 40621.

[785] Staff Ex. 58.A at 42361.

[786] Staff Ex. 68.03 at 133.

[787] Staff Exs. 58 at 43373, 43375, 43377-43379, 43392-43393, 43408; 31 at 20926.

[788] Staff Exs. 58 at 42323; 65 Vol. 14. L.09 at 46158-46159.

[789] Staff Ex. 68.03 at 109-111.

Respondent failed to report the severe side effects that Patient S experienced while being treated with ANP, including two ANP overdoses, vomiting, diarrhea, persistent headaches, and fatigue.[790]

Respondent again pointed out that the side effects these patients experienced were known side effects listed in Protocol BT-10 and did not need to be reported.[791] Respondent also maintained that Patient S's imaging reports were consistent and did not contain misrepresentations. For example, the slight increase of tumor size on the in-house report of October 30, 2012, (1.2 cm x 1.1 cm) was consistent with outside report (1.2 cm x 1.5 cm x 1.3 cm); both reports indicated that there was a slight increase in the size of the mass.[792] The decreased size of the tumor measured on the January 23, 2013 in-house radiology note (1.2 cm x 1.1 cm) was also consistent with the outside radiology report (1.2 cm x .7 cm).[793] The in-house radiology note of July 24, 2013, showed a stable tumor size, but the outside radiology report actually showed that the tumor size had decreased.[794]

Dr. Burzynski explained that over the years the criteria for measuring tumor response has changed three times, and is about to change again.[795] In the 1990s, the Clinic used the McDonald criteria which required measuring the two largest perpendicular diameters of the tumor and then multiplying the measurements to make a product.[796] Currently, the RANO criteria is used to determine how to classify the disease. Each time the FDA changed the criteria, Dr. Burzynski said, it affected the tumor measurements.[797]

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[790] Staff Exs. 68.03 at 133-134.

[791] Staff Ex. 31 at 20937, 20959-20960.

[792] Staff Ex. 58 at 43403, 43406.

[793] Staff Ex. 58 at 43397, 43400.

[794] Staff Ex. 58 at 43390, 43392.

[795] Staff Ex. 66.JJ at 187-189.

[796] Staff Ex. 66.JJ at 186.

[797] Staff Ex. 66.JJ at 187-188.

Based on the evidentiary record, the ALJs could not find that Respondent failed to report side effects that were reportable as adverse events under either Protocol BT-09 or Protocol BT-10. As for the ANP overdoses, it is unclear that they were to be reported as an adverse event attributable to ANP. Respondent documented on the "Antineoplaston Overdose Report" for each time a patient reported an ANP overdose and noted it in the progress notes.[798] The ALJs find that Staff presented insufficient evidence to establish that Respondent failed to properly report the adverse events, engaged in misrepresenting Patient S's response to ANP, or skewed the results of the tumor measurements.

7. Patient T

Patient T, a 4-year-old boy, was enrolled in Protocol BT-10 and was treated at the Clinic from February 11, 2011 to March 26, 2014.[799] Prior to coming to the clinic, the child was diagnosed at UCSF Medical Center with a Grade III anaplastic astrocytoma.[800] While being treated with ANP, the patient had four separate ANP overdoses.[801] These overdoses, Dr. Wetmore opined, should have been reported as adverse events along with all the following side effects this patient experienced: somnolence, vomiting, extreme dehydration, hypernatremia, diarrhea.[802] Staff also asserts that Respondent improperly characterized Patient T's treatment response as SD.[803] According to Dr. Wetmore, Respondent did not consistently measure Patient T's tumors, did not accurately report when the tumors had increased in size, created reports that were based on missing MRI imaging, and created reports that were contrary to outside radiology reports.[804]

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[798] Staff Ex. 58 at 42323, 42446.

[799] Staff Ex. 68.03 at 135.

[800] Staff Ex. 46 at 36256.

[801] Staff Ex. 65, V. 14.L.09 at 46158-46159.

[802] Staff Ex. 68.03 at 135-137.

[803] Staff Ex. 68.03 at 133.

[804] Staff Ex. 68.03 at 111-113.

In addition, Staff maintains that Respondent failed to protect the safety and welfare of Patient T, because he did not provide adequate support and training to Patient T's parents on how to properly operate the infusion pump. Patient T's parents had difficulty in operating Patient T's pump, and as a result Patient T experienced four ANP overdoses.[805] Respondent pointed out that Patient T experienced no serious adverse events as a result of the ANP overdoses and that the overdoses were not side effects of ANP. They were caused by operator error.[806]

In support of its allegation, Staff referenced the 2013 FDA inspection report and warning letter. According to the report, despite widespread ANP overdoses, Respondent had not taken corrective action since 2003, had not trained the Clinic's staff on how to address this issue, and had not reevaluated the in-house training program provided to patients.[807] The inspection dealt with Protocols BT-09, BT-10, BT-21, and BT 22, dealing with the study of ANP on brain tumors.[808]

Notably, this report also states that the inspection did not reveal any evidence to support a lack of appropriate medical supervision; "did not reveal a failure of this clinical investigator to protect the right, safety, and welfare of subjects enrolled in a clinical study or receiving ANP treatment under an SPP/SPE;" and found "[n]o objectionable conditions or practices" regarding the delegation of study tasks to unlicensed or inappropriately trained physicians.[809] Yet, Staff alleged that Respondent improperly delegated tasks to physicians and nonphysicians.

As noted in the documentary evidence, the Clinic had an opportunity to respond to the findings in this report and to any subsequent FDA warning letters. The FDA is authorized to take further action, including terminating the clinical study or disqualifying the clinical

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[805] Staff Exs. 46 at 36453, 65, Vol. 14.L.09 at 46159.

[806] Staff Ex. 46 at 36217.

[807] Staff Ex. 65, Vol. 14.L.09 at 46161-46162.

[808] Staff Exs. 48 at 45917; 12 at 7149-7164.

[809] Staff Ex. 65, Vol. 14.L.09 at 46092-46093.

investigator, but there is no evidence that the FDA has done so.[810] It is unclear in the evidentiary record what final action, if any, was taken by the FDA. Moreover, the FDA investigator did not testify and was not subject to cross-examination. Without further evidence, the ALJs find that the report and warning letter do not prove by a preponderance of the evidence that the Clinic failed to properly train Patient T's parents on how to use the pump.

Again Respondent noted that the side effects that Patient T experienced were known and not unexpected under Protocol BT-10, and were not adverse events that required reporting.[811] Respondent documented any ANP overdoses on the "Antineoplaston Overdose Report," and the action taken.[812] Although Dr. Wetmore claimed that Respondent had no measurements from an outside radiologist, the outside radiology report is in the patient's medical records and contains measurements that are very similar to the Clinic's measurements.[813] Respondent agreed that the comparison of the Clinic's baseline measurement of Patient T's tumor in February to that referenced in the March report was done in error. The wrong baseline measurements were used—5.8 cm x 4.4 cm rather than 6.7cm x 3.7 cm. Had the baseline been accurately reported in the March report,[814] the tumor would have been documented as stable, rather than slightly increased, which was a less favorable result.

The ALJs find that Staff presented insufficient evidence to establish that Respondent misrepresented Patient T's response to ANP or skewed the results of the tumor measurements. A mistake that inured to Respondent's detriment does not constitute an intentional misrepresentation.

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[810] 21 C.F.R. § 312.70. The regulation affords the clinical investigator and the sponsor an opportunity for a regulatory hearing under part 16 of this chapter if there is a dispute with the FDA.

[811] Staff Ex. 31 at 20937, 20959-60.

[812] Staff Exs. 46 at 36200, 36217, 36218, 36220 and 36453.

[813] Staff Ex. 46 at 38408.

[814] Staff Ex. 46 at 38394.

8. Patient U

Patient U had stage IV adrenal cortical carcinoma and was enrolled in Protocol AD-02.[815] According to Dr. Wetmore, Respondent treated Patient U from November 26, 2002, to August 8, 2009, during which time Patient U suffered side effects that Respondent under-reported to BRI-IRB and the FDA.[816] These side effects, Dr. Wetmore opined, included hypertension, fatigue, dry mouth, nausea, vomiting, somnolence, headache, edema, joint pain, fever, chills, muscular pain, ANP overdose, CVC infections, hypernatremia, and grade 2 hypokalemia.[817] Respondent argues that ANP overdoses did not have to be reported because they were not caused by the ANP, but by the patient mixing up the lines and giving himself too much ANP.[818] The CVC infection that Patient U experienced, Respondent pointed out, was not "caused" by ANP and therefore did not need to be reported.

The ALJs find that Staff presented insufficient evidence to establish that Respondent failed to report adverse events as required by the clinical study. It is unclear from the record that Respondent was required to report overdoses caused by operator errors as adverse events; therefore Staff failed to prove this allegation.

9. Consent Forms

Staff alleges that the informed consent forms that the Clinic gave Patients I, J, N, Q, R, S, T, V, Z, AA, and BB (in the Protocol BT-10 and BT-21 clinical trials)[819] did not comply with federal regulations because they failed to disclose the additional costs the patients were responsible for paying, as required by 21 C.F.R. § 50.25(b)(3).[820] According to Staff, these

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[815] Staff Ex. 29.B.

[816] Staff Ex. 68.03 at 137:22-139:3.

[817] Staff. Ex. 68.03 at 137.

[818] Staff Ex. 39 at 27034, 27086.

[819] Protocol BT-10 is Staff Ex. 31. Protocol BT-21 is in Staff Ex. 32.

[820] 21 C.F.R. § 50.25(b)(3) provides:

patients only learned of these additional charges when they were presented with a billing agreement laying out their obligations after they had consented to participate in Respondent's clinical trials.[821] Staff presented no testimony from any of these patients or their families to verify that Respondent did not provide this information to them until they agreed to participate in Respondent's clinical trial. Staff argues that because Respondent received the December 13, 2003 warning letter from the FDA about this issue, his failure to comply with federal regulations is a violation of Respondent's ethical and professional responsibilities under the Code.[822]

Respondent pointed out that there is a signed informed consent form for Patients H,[823] I,[824] J,[825] N, [826] Q,[827] R,[828] S,[829] T,[830] V,[831] Z,[832] AA,[833] BB,[834] and Patient CC.[835] These patients participating in a clinical trial or as expanded access patients signed the informed consent forms that the FDA had approved. Respondent stressed that Staff's expert, Dr. Fost, candidly admitted

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(b) *Additional elements of informed consent.* When appropriate, one or more of the following elements of information shall also be provided to each subject.

...

(3) Any additional costs to the subject that may result from participation in the research.

[821] Staff Ex. 12 at 7157.

[822] Staff Exs. 12 at 7157; 16 at 10139 (Warning Letter Item 3); 65, Vol. 14.L.09 at 46165. This issue was effectively decided in Respondent's favor in Order No. 7.

[823] Staff Ex. 53 at 41296, 41302.

[824] Staff Ex. 54 at 41659.

[825] Staff Ex. 56 at 42165, 42171.

[826] Staff Ex. 48 at 39052-39057.

[827] Staff Ex. 42 at 33687.

[828] Staff Ex. 45 at 36076.

[829] Staff Ex. 58 at 43494.

[830] Staff Ex. 46 at 38492.

[831] Staff Ex. 36 at 24729.

[832] Staff Ex. 43 at 34308.

[833] Staff Ex. 44 at 34948.

[834] Staff Ex. 41 at 32821.

[835] Staff Ex. 49 at 40132.

he did not read Respondent's informed consent form used in the ANP studies,[836] and had not read all of the protocols that he alleged Respondent violated.[837]

The FDA warning letter also gave Respondent 15 working days to file a letter advising the FDA what Respondent intended to do to correct the informed consent or the FDA could take further regulatory action. As previously discussed, it is unclear from the evidentiary record whether the FDA imposed any sanctions.

Moreover, 21 C.F.R. § 50.25(b) indicates that where appropriate the information regarding additional costs must be included as an "additional" element of the informed consent. The evidence presented indicates that the informed consent statement provided to patients under a clinical study was submitted to the FDA and approved as part of the application process. The evidence presented is insufficient to establish that Respondent failed to protect the patients in a clinical trial or engaged in unprofessional conduct by failing to disclose all the additional costs associated with the clinical trial in the informed consent, particularly given that patients were given a written billing agreement before receiving treatment that explained the additional costs.[838]

Dr. Fost agreed that he does not believe "perfect compliance with human subjects' is possible, or necessarily desirable."[839] He added that non-compliance with federal regulations can be found "in almost any large clinical research center."[840] As discussed in Section XI, five patients testified on Respondent's behalf. They all agreed that they were aware of the additional costs associated with being in a clinical trial. The Board imposes no specific regulations on what must be included in the informed consent.

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[836] Staff Ex. 61.B.1 at 45136.

[837] Tr. Vol. 1 at 135:10-11.

[838] Staff Ex. 12 at 7157.

[839] Staff Ex. 61.B.1 at 45133.

[840] Staff Ex. 61.B.1 at 45133.

Based on the credible evidence, the Clinic's patients knew before they received treatment in a clinical trial that the Clinic would charge additional costs. This information was provided in a treatment billing agreement given to Clinic patients before treatment began. Therefore, the ALJs find that the credible evidence does not establish that Respondent failed to protect these patients in a clinical trial such that he engaged in unprofessional and unethical conduct by failing to disclose additional costs related to a clinical trial in the informed consent process. Instead, the evidence showed that Respondent had this information provided to the patient or patient's family in the treatment billing agreement before treatment was provided.

B. Unethical Treatment of Patients A Through F

Dr. Wetmore testified that Respondent did not meet his ethical and professional responsibilities for Patients A through F because he did not ensure that these patients fully understood the risks and benefits of the proposed treatments, that the risks were reasonable in relation to the anticipated benefits, and that he had obtained adequate informed consent from the patients.[841] She opined that Respondent's over-reading of radiological imaging was a violation of his ethical and professional responsibilities because he is "not a trained and licensed radiologist, he's not even a trained oncologist, and he doesn't have the training or experience to make an objective assessment of the lesion. He also has a conflict of interest because he gets financial reward from treating his patients and having that treatment be perceived as successful. So there's (six) significant conflicts."[842]

Dr. Fost testified that Respondent did not meet his ethical and professional responsibilities for Patients A through F because (1) he had a responsibility to do innovative therapy research in a way that he and others could have learned from what they were doing, (2) he had the responsibility to be extremely candid with the patients about the known benefits and risks of the drugs and combinations of drugs and to go to special efforts to make sure that the patients were making informed choices about whether to be involved, and (3) he had a duty to

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[841] Staff Ex. 68.03 at 89-90.

[842] Tr. Vol. 6 at 98-99.

practice medicine in a way that involved honesty and disclosure and in which the personnel who were working with him were qualified and could be trusted to carry out the patients' treatment in a responsible way.[843]

As noted above in the discussions of the individual patients, the records indicate that they were all, with the exception of Patient D who was never treated, being monitored for, and their medications adjusted due to, side effects.

To agree with Staff's allegation, the ALJs first have to accept Staff's proposition that Patients A-F were human subjects in non-FDA approved clinical trials. As pointed out by Respondent, these patients were private practice patients treated with targeted agents to which they consented. Respondent argues that the rules of clinical trials do not apply to these patients. Both the opinions of Dr. Wetmore and Dr. Fost are based on the assumption that Patients A through F were subjects of clinical investigations. However, the record is clear that these patients were seeking alternative treatment and Respondent was monitoring the effects of and making adjustments to the alternative treatments of each patient, not performing clinical trials on them. Accordingly, Staff has failed to establish that Patients A through F were in fact human subjects in non-FDA approved clinical trials or that Respondent was performing in the role of a clinical investigator when treating them. As a result, Staff has failed to establish the Respondent was in violation of 22 TAC § 200.3(7).

C. Treating Patients H-P Without Proper BRI-IRB Approval

Staff asserts that Respondent failed to obtain IRB approval before initiating treatment with ANP for Patients H,[844] I, J,[845] K,[846] L,[847] M,[848] N, O, and P,[849] as required by "22 TAC

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[843] Staff Ex. 68.01 at 23-24.

[844] Staff Ex. 53 at 41263, 41265.

[845] Staff Exs. 56 at 42150, 41252, 42165; 68.01 at 62-66.

[846] Staff Ex. 50 at 40166.

[847] Staff Ex. 55 at 41685.

[848] Staff Ex. 57 at 42273.

§ 200.3(B)."[850] According to Staff, these patients were "provisionally approved" by one BRI-IRB member, Gary Harvey, who was not a physician, and therefore his approval was meaningless. As a result, Respondent failed to get a meaningful safety review for these patients prior to initiating ANP treatment. By failing to do so, Staff contends, Respondent committed a serious breach of his ethical and professional responsibilities under 22 TAC § 201.3(7)(B) to protect the expanded access patients' welfare, safety, and comfort.

Respondent stressed that Dr. Fost only offered testimony concerning the Clinic's treatment of Patient J on this issue.[851] Therefore, without any expert testimony or proof concerning the other patients, Respondent contends that the allegations regarding Patients H, I, K, L, M, N, O, and P should be disregarded. Respondent also pointed out that Patients K, L, M, O, and P did not receive ANP and were not enrolled in a clinical trial or approved as a special exception. Instead, as reflected in the medical record, these were private practice patients who received PB and targeted therapy or no treatment at all from the Clinic. Because these patients did not receive ANP, their treatment did not have to be approved by BRI-IRB. Therefore, Staff's allegations regarding these patients are unsubstantiated.[852]

Respondent argues that because BRI-IRB does not engage in the practice of medicine,[853] BRI-IRB's actions are outside the Board's jurisdiction, which is limited to regulating the practice of medicine.[854] In addition, Respondent is not a member of BRI-IRB and, therefore, BRI-IRB's decisions to allow him to treat these patients under a clinical study were made independently.

The ALJs agree that neither Patient O nor Patient P received treatment with ANP, as discussed in Section X(A). Regarding Patients K, L, and M, the ALJs find that, although

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[849] Staff Ex. 52 at 40621.

[850] 22 TAC § 200.3(B) is not a proper citation. The ALJs believe Staff was referring to 22 TAC § 200.3(7)(B).

[851] Staff Closing Argument at 68.

[852] Respondent's Final Reply Brief at 21.

[853] Tr. Vol. 1 at 114.

[854] 22 TAC § 161.1(a) states that the Board is "statutorily empowered to regulate the practice of medicine in Texas." See also *Texas Bd. of Chiropractic Examiners v. Texas Med. Ass'n*, 375 S.W.3d 464, 466 (Tex. App.—Austin, 2012).

Respondent requested that these patients be approved for treatment under a special exception or expanded access for single patient use of intravenous ANP, the documentary evidence does not show that this request was approved or that the patients received ANP treatment.[855] What was approved was the Clinic's Statement of Informed Consent for Investigation Clinical Study for these patients, none of which were signed by the patients.[856] The credible evidence presented failed to show that Patients K, L, M, O and P participated in a clinical study or that they received ANP.

In regards to Patients H, I, J, and N, Staff's argument that Respondent failed to obtain IRB approval before initiating treatment with ANP centers on federal requirements regarding the IRB approval process. Patients I and N received provisional approval from IRB to receive ANP treatments. IRB gave Patient I provisional (expedited) approval on May 2, 2012, but Patient I died on May 14, 2012. The IRB board did not grant full board approval to Patient I until August 3, 2012.[857] Patient N received provisional approval from BRI-IRB on June 28, 2011, and he died on October 25, 2011. The IRB board did not grant Patient N final approval until January 27, 2012. Respondent pointed out that he is not a member of the IRB board. Staff presented insufficient evidence to show that Respondent directed or coerced the IRB board's representative to grant the provisional approvals.

These patients were seriously ill when they arrived at the Clinic. Staff's reasoning that because Respondent only received provisional approval from BRI-IRB to treat Patients H-J and N, he ethically breached his responsibilities under Board Rule 200.3 is too far-reaching. With the exception of Patient N, the FDA also approved Respondent's request for a special exception to treat Patients H, I, and J. All these patients received detailed explanations of the treatment they would receive in the clinical study and signed an informed consent for the treatment.

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[855] Staff Exs. 50, 55, 57.

[856] Staff Exs. 50 at 40167-40174; 52 at 40621-40629; 57 at 42274-42281.

[857] Staff Exs, 54 at 41633-41634, 41657-41658, 41694; 27 at 17802; 12 at 7520.

Notably, even Staff's expert Dr. Fost has criticized the FDA regulatory system as being "dysfunctional."[858]

The ALJs find that Staff failed to present sufficient evidence to establish that Respondent had control over the IRB approval process or was responsible for the board's activities. Therefore, the ALJs find that Staff presented insufficient evidence to establish that Respondent violated 22 TAC § 200.3.

D. Inadequate/Inaccurate Reports of Therapeutic Response[859]

As a threshold issue, Respondent objects to any of Staff's arguments concerning Patients H and J regarding this issue because Staff did not include these allegations in its Complaint. The Complaint alleged that Respondent incorrectly reported the therapeutic response for Patients Q, R, V, W, X, Y, Z, AA, and BB, but Patient H and J were not included as part of this allegation.[860] Therefore, the ALJs will not consider this allegation as it pertains to Patients H and J because Staff failed to provide proper notice of these claims as required by the Texas Government Code § 2001.052.

Staff asserts that Respondent had a duty to utilize accepted standards of research as part of a competently designed program, to produce data that was scientifically valid and significant, and to protect the welfare of clinical trial participants in the same manner as patients receiving care in private practice.[861] Staff maintained that Respondent failed to meet these ethical and professional responsibilities by misrepresenting tumor responses to ANP and failing to report

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[858] Tr. Vol. 1 at 148, 152, 153-154. In this article, Dr. Fost wrote:

> Over the past decade, the oversight of IRBs has been characterized by increasing requirements for meticulous documentation for compliance with narrow interpretations of regulations and policies, often with punitive sanctions, accompanied and perhaps exacerbated by a drumbeat of assertions that the regulatory system is broken.
>
> The source of these problems include OHRP and the FDA because they appear to threaten institutions with draconian penalties for minor infractions.

[859] According to Staff, this issue is applicable to Patients G and Q-BB.

[860] Complaint at 32; Staff's Closing Argument at 71.

[861] 22 TAC § 200.3(7)(A) and (B).

adverse events. In large part, Staff relied on the 2013 FDA inspection report and warning letter. In addition, the issue regarding adverse events has been discussed previously. Unless the side effect of ANP treatment was unknown, unexpected, and causally related to ANP, Respondent did not need to report it.

1. Patient V[862]

Staff argues that Patient V, a child being treated at the Clinic under Protocol BT-10, only obtained a partial response, not a complete response as Respondent reported. However, Staff cited no credible support in the patient's medical record for this position. Therefore, the ALJs find insufficient evidence to support Staff's allegation that Respondent misrepresented this patient's response to treatment.

2. Patient R

Dr. Wetmore questioned Respondent's finding that Patient R experienced a "CR," meaning complete response because, in her opinion, the imaging showed a progressing tumor mass. Staff also represented that Patient R's July outside radiology report was missing. However, the clinical records for Patient R admitted into evidence included the July radiology report from Innovative Radiology, PA. According to the outside radiologist, "complete remission" was obtained on July 24, 2010.[863]

Dr. Wetmore also opined that Patient R suffered numerous adverse events, including somnolence, frequent vomiting, three ANP overdoses, and persistent headaches and hypokalemia.[864] These were all side effects included on the Informed Consent and therefore were expected and known side effects of this treatment. Accordingly, the ALJs find insufficient

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[862] Staff Ex. 36 did not have any portion highlighted. In conformance with Order No. 34, if a party failed to highlight the relevant material in the documentation, it is deemed irrelevant.

[863] Staff Ex. 45 at 35979.

[864] Staff Ex. 68.03 at 131-133.

evidence to support Staff's allegations that Respondent misrepresented Patient R's tumor response or failed to report the adverse events Patient R experienced while undergoing treatment.

3. Patient W

Patient W was on Protocol BT-09 and was classified as having a CR, which requires the complete disappearance of all tumors for 4 or more weeks as long as the patient is off steroids. Although Staff maintains that Patient W did not meet the criteria because the patient was taking high levels of corticosteroids, Patient W's medical records in evidence do not reflect that Patient W received corticosteroids within 4 weeks of Respondent's evaluation.[865] Therefore, the ALJs find Patient W's clinical record in evidence does not support Staff's allegations that Respondent inaccurately reported the tumor response as CR. Similarly, the ALJs find Patient W's medical records in evidence do not establish that Respondent improperly measured the tumors.[866] The side effects that Patient W experienced while being treated with ANP were not unknown or unexpected. Therefore, the ALJs find the evidence is insufficient to establish that Respondent did not properly report them.

4. Patient Y

Staff alleged that Patient Y did not meet the criteria for PR (partial response) under Protocol BT-09 because of her corticosteroid use. However, Patient Y's clinical records in evidence do not indicate what dosage, if any, the patient received of corticosteroid. Therefore, Staff presented insufficient information about corticosteroid use for the ALJs to find that Respondent misrepresented this patient's tumor response.

Although Staff asserts that Patient Y's imaging reports were inconsistent or missing and that this patient experienced side effects that Respondent failed to report, Patient Y's clinical records reflect that Respondent relied upon an outside radiologist to confirm that Patient Y had a

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[865] Staff Ex. 37.

[866] Staff Ex. 37.

"partial response" to treatment.[867] The ALJs find that Staff presented insufficient evidence to show that Respondent misrepresented Patient Y's tumor response or failed to report all adverse events that Patient Y experienced.

5. Patients Q, Z, AA, and BB

Patients Q, Z, AA, and BB received ANP treatment under Protocol BT-10, and were classified by Respondent as SD.[868] Staff alleges that Respondent misclassified these patients' response to treatment because they were using corticosteroids. Staff also maintains the imaging reports were "suspect,"[869] and that these patients had several ANP-attributed side effects that Respondent under-reported to the IRB.[870] Staff also asserted Patient Z's tumor was growing and that Respondent incorrectly included a period when Patient Z had a tumor resection to determine the patient was SD. Finally, Staff questioned the propriety of changing the grading of Patient AA's adverse event associated with her death on August 31, 2009, from a Grade 5 (death) to a Grade 4 (life threatening).

In evaluating a tumor's response to treatment, Protocol BT-10 does not prohibit the patient from taking steroids. The RANO criteria, however, restricts steroid use to either stable or decreasing amounts. Patient Q's records indicate that the patient received Decadron usually at .5 mg PO q.i.d.[871] However, the evidence is unclear what amount of Decadron would be acceptable under the RANO criteria. Therefore, the ALJs find that Staff failed to provide sufficient credible evidence to show that Respondent used corticosteroids improperly when classifying Patient Q under Protocol BT-10.

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[867] Staff Ex. Vol. 38 at 26759.

[868] Staff Ex. 31 at 20952-20953. The clinical records for Patient Q is Staff Ex. 42; Patient Z is Staff Ex. 43; Patient AA is Staff Ex. 44; and Patient BB is Staff Ex. 41.

[869] Staff's Closing Argument at 70.

[870] Staff Ex. 68.03 at 130-131.

[871] Staff Ex. 42 at 32958-59, 32942, 32939, 32938, 32937, 32924, 32922, 32921, 32911, 32907, 32905,

As for Respondent's radiology reports included in Patient Q's progress notes, it is evident that Respondent's measurements are inconsistent with the outside radiologist's. The following reflect the measurements taken of the brainstem non-enhancing mass.

Date	Respondent[872]	Outside Radiologist[873]
11/14/08	2.5 x 1.5	3.0 x 1.8 x 2.9
01/07/09	2.5 x 1.5	Not Present
03/13/09	2.5 x 1.5	Not Present
04/20/09	2.5 x 1.5	3.6 x 3.4 x 2.1
06/18/09	2.8 x 1.6	5.2 x 3.0 x 4.1
07/24/09	3 x 1.8	5.2 x 3.4 x 4.5

The substantial differences between the outside radiologist's measurements and Respondent's measurements were not reasonably explained. Therefore, the ALJs find that Staff proved by a preponderance of the evidence that Respondent inaccurately reported Patient Q's tumor's measurements causing the classification of the tumor's response to treatment to be in error.

Patient Z, a teenage girl with brain cancer, was treated at the Clinic from December 2008 to May 2009. She previously had undergone a right parietal occipital craniotomy.[874] On June 18, 2008, a MRI taken at Nationwide Children's Hospital showed a significant increase in the size of the recurrent mass. The mass measured 2.7 cm x 2.1 cm x 2.0 cm.[875] Another tumor MRI was taken in December 2008 before the patient came to the Clinic. At that time the tumor measured 4.7 cm x 3.4 cm x 3.7 cm, indicating another significant increase in the tumor size.[876]

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[872] Staff Ex. 42 at 33615, 32940, 32927, 32917, 32908, 32901.

[873] Staff Ex. 42 at 33616-33622, 33625-26.

[874] Staff Ex. 43 at 34229.

[875] Staff Ex. 43 at 34299.

[876] Staff Ex. 43 at 34223.

On January 15, 2009, Patient Z's MRI taken by an outside radiologist revealed that the tumor measured 4.7 cm x 3.5 cm x 3.7.[877] Respondent measured the mass as 4 x 4.7.[878] The outside radiologist reported that the February 19, 2009 MRI measured the tumor mass as 4.1 cm x 4.0 cm x 4.8 cm, and found that the mass had increased slightly in the medial to lateral dimension, but had no appreciable change in the anterior, posterior, or superior to inferior dimensions.[879] Respondent measured the tumor at 4 x 4.7.[880] The April 2, 2009 MRI reported that the mass measured 5.6 cm x 4.2 cm x 4.5 cm.[881] Respondent reported that the tumor mass was 4.3 x 5.3.[882] Patient Z underwent a craniotomy in late May and was discontinued from the clinical trial Protocol BT-10 by June 4, 2009.[883]

Despite Staff's claim that Respondent took credit for the reduction in tumor size based on the May 2009 craniotomy, Respondent's report regarding the tumor measurements stated in the comment section that "[t]he patient underwent craniotomy with tumor debulking on May 27, 2009."[884] In the patient's progress notes regarding the July 2009 MRIs, Respondent documented that the patient's "[r]ight occipitoparietal enhancing lesions were surgically removed" and that the MRIs were post-operative.

As discussed before, Protocol BT-10 required that the investigator document the tumor's response to treatment as either a complete response (CR), a partial response (PR), or a progressive disease (PD). All other situations were considered stable disease.[885] Based on the medical record in evidence, Respondent properly recorded the tumor response as "stable disease"

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[877] Staff Ex. 43 at 34217.

[878] Staff Ex. 43 at 34203.

[879] Staff Ex. 43 at 34215.

[880] Staff Ex. 43 at 34203.

[881] Staff Ex. 43 at 34209.

[882] Staff Ex. 43 at 34203.

[883] Staff Ex. 43 at 33815.

[884] Staff Ex. 43 at 33754, 33812, 34204.

[885] Staff Ex. 31 at 20952-20953.

because the tumor had not increased in size at least 25%. The medical records also reflect that the Clinic kept records of the adverse event that Patient Z experienced while on treatment.[886]

Respondent's tumor measurements for Patient Z were similar to the outside radiologist's and in conformance with protocol for the clinical study. Based on the medical records admitted into evidence, the ALJs find insufficient evidence to show that Respondent inaccurately reported Patient Z's tumor measurements or the response to treatment.

According to Staff, Respondent mischaracterized Patient AA's response to treatment as SD (stable disease) and improperly changed the grading of the adverse event that occurred the day Patient AA died. On September 8, 2009, Dr. Jose Eguiguren sent Dr. Weaver an email stating that he saw Patient AA on August 26, 2009, and that there was evidence of "neurologic deterioration."[887] According to Dr. Eguiguren, the cause of death may have been due to "a pulmonary embolism secondary to decrease mobility due to weight gain due to Decadron."[888] The Clinic initially reported that the severity of the event was death, but Respondent changed it on January 14, 2014 to life-threatening. It is unclear from the medical record why Respondent changed the severity of Patient AA's adverse event after almost five years.[889] Without a significant reason for such a change in Patient AA's medical records, the ALJs find that Respondent improperly changed the severity of the adverse event from death to life-threatening.

Respondent reported that on July 19, 2007, Patient BB was "SD," but he changed the response to "non evaluable" on October 22, 2014, because Patient BB was on high dosages of steroids.[890] Based on Respondent's re-evaluation, the ALJs find that the original misclassification was inaccurate, but that the evidence does not establish that Respondent intentionally misrepresented that Patient BB was SD.

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[886] Staff Ex. 43 at 33767-33770.

[887] Staff Ex. 44 at 34424.

[888] Staff Ex. 44 at 34424.

[889] Staff Ex. 44 at 34350.

[890] Staff Ex. 41 at 32794, 32796.

6. Patient X

Patient X was treated under Protocol BT-21. Although Respondent classified Patient X as being CR, he kept Patient X on fluctuating levels of corticosteroids. The criteria for a therapeutic response required a "complete disappearance of all contrast enhancing tumor on neuroimaging studies, and ancillary radiographic studies if appropriate for 4 weeks or longer. Patient is off corticosteroids."[891] Respondent reported that Patient X had a CR to the treatment on September 5, 2005.[892] The last progress note in evidence was from April 1, 2005. At that time, Dr. Weaver was decreasing the dose of Decadron the patient had previously been taking. The clinical records in evidence do not show that Patient X was on any corticosteroids five months later. Therefore, the ALJs find that Staff presented insufficient evidence to establish that Patient X was on corticosteroids at or near 4 weeks before Respondent reported the tumor response.[893]

Staff also asserts that Respondent mischaracterized Patient X's tumor response because he incorrectly based the CR classification on PET scan results and not on the MRI results that showed tumor progression.[894] However, a review of the outside radiology reports correlates closely to Respondent's tumor measurements.[895] Based on the clinical records, the ALJs find insufficient evidence to establish that Respondent improperly measured Patient X's tumor or improperly reported the therapeutic response to treatment as CR.

This patient also experienced numerous side effects, including one ANP overdose.[896] However, the ALJs find that Staff provided insufficient evidence to show that Respondent failed to report these side effects experienced by Patient X as adverse events.

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[891] Staff Ex. 32 at 21876.

[892] Staff Ex. 40 at 32289.

[893] Staff Ex. 40 at 31742.

[894] Staff Exs. 65, V. 14.L.09 at 46138-46140; 68:03 at 116-118.

[895] Staff Ex. 40.

[896] Staff Ex. 68.03 at 141-142.

E. Inadequately Training Subordinates About Adverse Events[897]

Staff maintained that, between February 2001 and July of 2012, 11 patients experienced ANP overdoses due to mistakes made by the patient or the patient's parents or from pumps malfunctioning. Staff contends that Respondent failed to adequately implement a patient retraining program or to train and retrain his subordinates adequately. In addition, Staff argues that Respondent failed to train his subordinates about adverse events.

Respondent contends that those involved in clinical trials at the Clinic were adequately trained to report adverse events. Anita Shrout, a physician assistant at the Clinic, testified that she was trained to, and understood that she was to, document and grade any adverse events that a patient experienced in the patient's medical records in accordance with the proper protocol for the clinical study. Then she would discuss the event with the patient's physician.[898]

Barbara Szymkowski, a research associate at the Clinic, likewise indicated that she understood the duty to report adverse events "to the investigator right away."[899] Marilyn Threlkeld testified that unless the physician or patient requested otherwise, she called the ANP patients daily to discuss their conditions.[900] Dr. Marquis confirmed that patients had to be called at a minimum of once a week and if they reported any complications, a physician was immediately involved.[901] Drs. Burzynski and Marquis affirmed that they understood their obligation to report adverse events.[902] Dr. Gregory Burzynski also testified that he knew he was required to report any serious adverse events related to the ANP treatment.[903]

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[897] According to Staff, this issue is applicable to Patients G and Q through U.

[898] Staff Ex. 66.M at 5-6.

[899] Staff Ex. 66.J at 14.

[900] Staff Ex. 66.K at 8-9.

[901] Tr. Vol. 13 at 37-39.

[902] Tr. Vol. 13 at 46; Staff Ex. 66.II at 145-146.

[903] Staff Ex. 66.GG at 201-202.

The ALJs find that Staff presented insufficient evidence to establish that Respondent failed to adequately training his subordinates about adverse events.

Staff claims that Respondent failed to retrain the Clinic staff and patients after an ANP overdose, but Respondent pointed out that the overdose reports document that after any ANP overdose, the patient or the patient's parents were retrained.[904] Many overdoses occurred because the person operating the pump was tired or confused, not that they did not know how to properly operate the pump. In addition to the in-clinic training, Respondent pointed out that each patient on ANP was given a 63-page packet of information on administering ANP.[905]

Based on the credible evidence, the ALJs find insufficient credible evidence to prove that Respondent failed to properly train or retrain the patients, their family, or the staff on proper pump use.

F. Failing to Properly Consider and Report the Effect of Corticosteroids in Patient G's Treatment

Staff alleges that Respondent failed to ensure that the protocols were followed to isolate the impact of corticosteroids on tumor response. Staff argues that by prescribing high and fluctuating levels of steroids to Patient G, Respondent failed to follow the BT-09 guidelines for steroid use with ANP, and did not take Patient G's steroid use into account when interpreting imaging results.

Dr. Wetmore testified that Respondent failed to caution Patient G and her mother about the concurrent use of steroids and the continued course of ANP. She stated that the persistent use of corticosteroids also complicated the interpretation of the MRI results because it can change the way a tumor looks on MRI with no other intervention. She opined that this misinterpretation of the MRI images caused the accurate tumor response to be repeatedly

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[904] *See, e.g.*, Staff Exs. 46 at 36217 ("father was retrained"); 45 at 35071 ("Mother was retrained"); 39 at 27034 ("patient was retrained on proper tubing use").

[905] Staff Ex. 60 at 44298-44360.

misrepresented to Patient G's mother. Dr. Wetmore testified that she saw no indication in the records that the Clinic considered the contribution of the effect that the corticosteroids may have had on interpretation of the MRI scans. In addition, she stated that Respondent, as a physician involved in a clinical investigation of ANP, needed to be absolutely certain to document and properly attribute all of the adverse events so that there was no confusion about what might have been or not have been attributable to the medication. He also had to be very careful not to interpret the data so as to sway the outcome of the study. [906]

Dr. Burzynski testified that taking of steroids is common for persons with brain tumors because they can temporarily decrease the swelling around the tumor and make the patients more comfortable. He stated that a typical side effect of steroids is fluid retention manifested as swelling of the abdomen and legs, and, in his opinion, Patient G's edema and weight gain were attributable to her taking of the steroids and not from the ANP, which usually is accompanied by fluid loss rather than retention. [907]

In regard to the effect of steroids on tumor growth, Dr. Burzynski noted that, as of 1993, it was not known if steroids might cause shrinkage of a tumor, so patients were required to be completely off steroids to determine if there had been a complete response to a treatment where the tumor had disappeared for a period of four weeks. However, beginning in 2012, the National Cancer Institute established a new classification called RANO that permitted the use of steroids to maintain neurological stability of the patients. Under this new definition, the dosage of steroids is limited to the amount necessary to provide neurological stability of the symptoms, which must be determined on an individual basis. Dr. Burzynski explained that this change was implemented because it was proven that while steroids cannot shrink the tumor, they can shrink the edema around the tumor. [908]

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[906] Staff Ex. 68.01 at 88; Tr. Vol. 6 at 159-162.

[907] Tr. Vol. 7 at 293-295.

[908] Tr. Vol. 8 at 29-39.

Respondent points out that Protocol BT-09 for the Phase II study of the use of ANP for the treatment of patients with brain tumors provides that the use of any steroids concomitant with ANP does not render the patient ineligible for the study but must be documented, and that the use of corticosteroids is permitted to reduce symptoms and signs attributed to cerebral edema. [909] Protocol BT-21 repeats these statements.[910]

The medical records consistently discuss the fact that Patient G was continuing to use steroids during her treatments with ANP, and even discussed the side effects that could be attributed to her use of steroids. During the course of treatment, Respondent sought to wean her off the steroids. Clearly Respondent took Patient G's use of steroids into account when determining her treatment. Respondent has pointed to nothing in the record that states that the effect of the steroids on the MRI scans was considered by Clinic personnel when they were interpreting the scans that indicated an increase in the size of the tumor. However, based on Dr. Burzynski's testimony, the effect of steroids would be on the edema surrounding the tumor and not on the tumor itself. As a result, the effect of the steroids should not have an effect on determining whether a tumor is increasing or decreasing. Accordingly, the ALJs find that Staff failed to establish that Respondent ignored the impact of the corticosteroids Patient G was taking on the interpretation of the MRI.

G. Failing to Inform Patient G of Additional Costs

Staff alleges that the informed consent forms in the single patient protocol failed to adequately inform Patient G of additional costs she might incur in her treatment.

In a Warning Letter dated December 3, 2013, Thomas N. Moreno stated, among other things, that the informed consent forms for the patients included in the Phase II clinical study of ANP did not contain a statement regarding any additional costs to the subject that may result in participating in the research and that the subjects were presented with a billing statement only

[909] Staff Ex. 30 at 20185, 20191.

[910] Staff Ex. 32 at 21843, 21851.

after they had consented to participate in the research, thereby denying them the opportunity to make an informed decision regarding their participation in the study.[911] On July 1, 2014, in a letter, Sean Y. Kassim, Acting Director of the Office of Scientific Investigations of the Office of Compliance of the Center for Drug Evaluation and Research of the FDA, stated that while certain of the items noted in the December 3 Warning Letter still needed correction, other items, including the informed consent corrective action, were adequate.[912]

Staff argues that this two-part consent process, consenting to the research and then being presented with the costs, did not allow Patient G to make a fully informed decision about whether to participate in the clinical study. Staff asserts that she should have been informed about all the financial obligations at the time she was considering treatment, not after she had already agreed to participate. According to Staff, this two-part consent process is inadequate under 22 TAC § 200.3(7)(C).

The Treatment Billing Agreement signed by Patient G on August 31, 2012, her first day at the Clinic, sets forth the initial consultation fees; laboratory testing fees; a deposit to start the regimen of evaluation, daily patient assessment, review of diagnostic tests, regimen plan and treatment analysis, follow-up visits, telephone conferences, IV instruction and necessary medical supplies; IV medication fees; a deposit for the IV pump; and a monthly deposit for case management.[913]

Patient G was presented with the costs of treatment on August 31, 2012. Approval for Patient G to participate in the single patient protocol was given on September 6, 2012. The first infusion of ANP was made on September 12, 2012. Clearly, Patient G was informed of all the costs involved in her treatment before she began receiving the ANP. Accordingly, Staff has failed to establish that Respondent violated 22 TAC § 200.3(7)(C) in regard to Patient G.

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[911] Staff Ex. 12 at 7149-7164.

[912] Staff Ex. 16 at 10106-10130.

[913] Staff Ex. 7.06.M at 3522 – 3525.

H. Inadequate and Inaccurate Patient CC's Case History

This allegation actually involves Patient DD but the Complaint referred to Patient CC.[914] Patient DD was not included in Staff's allegations. Staff recognized that it failed to provide Respondent proper notice of a claim concerning Patient DD. Pursuant to Texas Government Code § 2001.052, the ALJs find Staff failed to give Respondent proper notice of this claim, and therefore it will not be considered.

I. Violations of Federal Regulations as Clinical Investigator

According to Staff, Respondent engaged in unprofessional and dishonorable conduct likely to deceive or defraud the public by committing acts that violate state or federal laws connected with Respondent's practice of medicine;[915] failing to conduct clinical investigations that were competently designed as part of a systematic program under accepted standards of scientific research with the aim being to produce scientifically valid and significant data;[916] and by violating federal regulations that protected the health and safety of human research subjects and governed the administration of clinical trials for pharmaceuticals.

Respondent agrees that the FDA issued *preliminary* findings that certain federal regulations were violated, but emphasized that he responded to all of the FDA inquiries until the issues were resolved. Dr. Burzynski testified that he took remedial measures to fix and correct any issues that the FDA had, including the issues raised in the December 3, 2013 Warning Letter.[917] Staff's expert, Dr. Fost, even confirmed that perfect compliance with FDA regulations is not possible.[918] Violations in some form or fashion almost always occur. Staff presented no

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[914] Complaint at Section III.C.20.v.12.a.

[915] Code 164.053(a)(1).

[916] Code 164.051(a)(3), regarding violations of 22 TAC § 200.3(7).

[917] Tr. Vol. 9 at 181 ("[We] responded to every one of the [FDA] allegations and we took immediate correction action . . . [including] implementing changes in the protocol and implementing changes in the standard operating procedure and preparing new standard operating procedure.").

[918] Tr. Vol. 1 at 186.

evidence to show that the FDA has taken any final action against Respondent or terminated the study. Respondent continues to serve as the principal investigator for these clinical trials.

Based on the evidence presented in this hearing, the ALJs find that Staff failed to show that Respondent violated his ethical duty and responsibilities as a clinical investigator.

XI. AGGRAVATING AND MITIGATING FACTORS

A. Aggravating Factors

Board Rule 190.15(b) states that the following factors may be considered as aggravating factors that warrant more severe or restrictive action by the Board: (1) harm to one or more patients; (2) the severity of patient harm; (3) one or more violations that involve more than one patient; (4) economic harm to any individual or entity and the severity of such harm; (5) increased potential for harm to the public; (6) attempted concealment of the act constituting a violation; (7) intentional, premeditated, knowing, or grossly negligent act constituting a violation; (8) prior similar violations; (9) previous disciplinary action by the Board, any government agency, peer review organization, or health care entity; (10) violation of a Board order; and (11) other relevant circumstances increasing the seriousness of the misconduct.

Staff argues that the aggravating factors relevant in this proceeding include harm to one or more patients, the severity of patient harm, one or more violations that involve more than one patient, economic harm to any individual or entity, increased potential for harm to the public, prior similar violations, and previous disciplinary action by the Board.

1. Severity of harm, harm to one or more patients, and one or more violations that involve more than one patient

As indicated above, (1) there is insufficient evidence that any of Respondent's patients suffered actual harm to their health by a violation of the standard of care or having inadequate records; (2) there is insufficient evidence that any of Respondent's patients were actually harmed

by his failure to ensure that RAs Rakhmanov, Tikhomirova, and Acelar did not directly or indirectly represent to the public that they were authorized to practice medicine, (3) there is insufficient evidence that any of Respondent's patients were actually harmed by his allowing RA Acelar to practice medicine without a license; (4) there is insufficient evidence to show that any of Respondent's patients were economically harmed by his failure to disclose his ownership interest in the pharmacies; and (5) there is insufficient evidence that any of Respondent's patients were economically harmed by having inadequate medical records to support Clinic charges. In addition, Respondent's failure to obtain timely and/or adequate informed consents involved more than one patient: Patients A through C and E through G.

2. Increased potential for harm to the public

As discussed above, unless corrected for the future, the following actions by Respondent could represent potential harm to the public: (1) failing to ensure that research associates did not directly or indirectly represent to the public that they were authorized to practice medicine, (2) allowing a research associate to practice medicine without a license; (3) failing to disclose his ownership interest in the pharmacies; and (4) failing to have adequate medical records to support Clinic charges. .

3. Prior similar violations and previous disciplinary action by the Board

On August 31, 1994, the Board suspended Respondent's license for a period of ten years, but probated the suspension. The basis of the action was that Respondent had treated patients with ANP in violation of the laws in effect at that time and had made false advertisements about ANP. The order was upheld by the Third Court of Appeals on February 7, 1996.

As discussed above, Respondent did not treat patients with ANP in violation of the laws in effect during the time period covered by this Proposal for Decision and did not make false advertisements about ANP during the time period covered by this Proposal for Decision.

B. Mitigating Factors

Board Rule 190.15(b) states that the following factors may be considered as mitigating factors that warrant less severe or restrictive disciplinary action: (1) self-reporting or voluntary admission of violation; (2) implementing remedial measures to correct or mitigate harm caused by a violation; (3) admitting wrongdoing and willingness to cooperate with the Board; (4) rehabilitative potential; (5) prior community service and present value to the community; (6) participating in continuing medical education, (7) other relevant circumstances reducing the seriousness of the misconduct; and (8) other relevant circumstances lessening the physicians responsibility for the misconduct.

Mitigating factors relevant in this proceeding include Respondent's rehabilitative potential, his present value to the community of terminally ill cancer patients, and his contribution to the advancement of cancer research.

1. Rehabilitative Potential

Respondent has devoted his career as a physician to finding a cure for cancer. In that endeavor, he worked at Baylor College of Medicine and received funding from the National Cancer Institute (NCI) to research the link between peptides in blood and cancer growth. After Respondent opened the Clinic in 1977, he focused on treating terminally ill cancer patients, those patients who either chose not to try traditional cancer treatment or tried conventional cancer treatment and were not cured. In 1990, Respondent began providing what has since become known as personalized therapy to treat the cause of the cancer.

Respondent discovered and patented a new drug, ANP. In 1993, the FDA approved ANP for a clinical trial with Respondent serving as the investigator. Since that time, the FDA has approved approximately 65 prospective clinical trials and one retrospective clinic trial with Respondent serving as the principal investigator.[919]

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[919] Tr. Vol. 7 at 63.

It is uncommon for a person who has discovered an investigational drug to be able to run clinical trials without the financial support of a pharmaceutical company or NCI.[920] According to Dr. Levin, Respondent has completed phase II FDA trials and the FDA has given permission on some to proceed to phase III trials.[921] In Dr. Levin's opinion, Respondent is a "medical pioneer." Because of Respondent's research on ANP and its analogues such as PB, Dr. Levin stated that "there is now acceptance of the fact that these compounds have anti-cancer activity." Using targeted agents in combination is a therapeutic leap.[922] Dr. Levin stated:

> Dr. Burzynski should be credited for discovering a family of compounds which have shown anti-cancer activity and have had impressive results in patients treated in clinical trials, at least in the parameter in having long-term survivors in brain tumors where surviving the disease is relatively uncommon.[923]

Based on the evidence, the ALJs find that Respondent is a dedicated and innovative physician who wants to continue treating advanced cancer patients and to continue to serve as the investigator in ANP clinical trials approved by the FDA. The violations that Respondent committed are not so severe that they are not rectifiable. Therefore, the ALJs find that Respondent has rehabilitative potential.

2. Prior Service and Present Value to Community of Terminally Ill Cancer Patients[924]

Respondent's practice was and is predominantly treating terminally ill cancer patients who have unfavorable prognoses. Several patients traveled at their own expense to testify on his behalf.

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[920] Resp. Ex. 165; Staff Ex. 168.01 at 8.

[921] Resp. Ex. 165 at 71.

[922] Resp. Ex. 165 at 70, 72.

[923] Resp. Ex. 165 at 70.

[924] The ALJs requested that Respondent only call a few of his former patients to testify. However, several of Respondent's former patients and their families appeared at the hearing to support him.

Ms. Manning was 53 years old in 2009 when she was diagnosed with stage IV mantle cell non-Hodgkin's lymphoma. Her oncologist in Arizona told her that no one lives very long with this disease, and if she did nothing, she would die in a year. However, if she underwent the "strongest chemo in the hospital and bone marrow – bone marrow transplant twice," she might live three years.[925] Ms. Manning sought a second opinion from physicians at the University of Arizona and M.D. Anderson Cancer Center and was give the same prognosis. She explained that she decided against this course of treatment because even after enduring chemotherapy and the bone marrow transplants, she would only live three years, and most of that time she would have been sick or in the hospital.

According to Ms. Manning, she and her family began investigating alternative treatments. Ultimately, after conferring with the mother of one of Respondent's patients, Ms. Manning elected to be treated by Respondent. Ms. Manning began treatment at the Clinic in April 2009. This treatment, she explained, continued for a year and a half, and then she took PB for an additional 6 months. According to Ms. Manning, she met with Respondent, three other physicians, and an assistant. One of the physicians explained to her what side effects could be caused by the drugs she would be taking and that the drugs were being prescribed "off label." According to Ms. Manning, at the end of treatment she figured out that it cost less than doing the treatment that had originally been recommended, except that insurance did not cover the Clinic's treatment.[926] Ms. Manning emphatically stated that she would not still be alive without Respondent.[927]

Ms. Ressel is the mother of a child who survived cancer. She testified that her daughter was 11 years old when she was diagnosed in 1996 by physicians at Children's Hospital in St. Louis with a brain stem tumor known as DIPG that was inoperable. Her child's prognosis was poor, the child only had 8 to 18 months to live, according to Ms. Ressel, and the only

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[925] Tr. Vol. 13 at 86.

[926] Tr. Vol. 13 at 102-103.

[927] Tr. Vol. 13 at 107.

treatment offered was radiation therapy that would not have prevented her child's death.[928] When she learned about Respondent's success with treating brain cancer, Ms. Ressel said, she immediately made an appointment. After the initial consultation with Respondent, her daughter was enrolled in a clinical trial for ANP.[929]

According to Ms. Ressel, her daughter received ANP treatments for about a year and 10 months. After five weeks, her daughter began to improve. Although her daughter experienced some side effects, Ms. Ressel said that they were not as bad as the side effects she had been told would happen with radiation therapy. Because of Respondent's treatment, her child had a happy childhood and was able to play with her friends even while she was getting treatment. Her child is now 31 years old and has two children.[930] Ms. Ressel testified that Respondent is "a true humanitarian," who saved her child's life.[931]

Ms. McGee is from Bozeman, Montana. On May 11, 2011, she was diagnosed at the Mayo Clinic with Stage IV esophageal cancer that had spread throughout her torso. Her doctor told her she had less than a 2% chance of survival and that he had other doctor friends who had esophageal cancer and had chosen not to be treated.[932] When her daughter told her about Respondent, Ms. McGee made an appointment. Ms. McGee said that the Clinic used genetic-targeted therapy to treat her cancer and within four months of starting treatment at the Clinic, her PET scan showed that her cancer was almost gone. Her last treatment was March 2012, and she has been cancer-free ever since.[933]

Mary Michaels testified that her son was treated by the Clinic from 1987 to 2001. In November 1985 her son was 4 years old and was diagnosed with optic hypothalamic glioma

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[928] Tr. Vol. 13 at 130-131.

[929] Tr. Vol. 13 at 134-135.

[930] Tr. Vol. 13 at 128-129, 138-139.

[931] Tr. Vol. 138.

[932] Tr. Vol. 11 at 12-13.

[933] Tr. Vol. 11 at 28-29.

astrocytoma. He underwent a craniotomy, and the biopsy supported the diagnosis.[934] She recalled that the doctors told her that her son was too little to receive chemotherapy, but that he could be treated with radiation. However, the doctors explained that radiation therapy would cause her son to go blind and he would experience hearing loss and some brain damage.[935]

Before coming to the Clinic, Ms. Michaels said, she sent her son's scans to a physician at Mayo Clinic who was doing robotic-assisted brain surgery to see if anything could be done to save her son. The physician told her that no matter what she did, her son was going to die of the tumor. He told her that "it was the largest tumor he had ever seen in anyone at any age."[936] She also saw several other physicians, including a physician at the Cleveland Clinic, but found no one able to help her son.[937]

When she heard about Respondent, Ms. McGee said, she sent him a packet with her son's medical records. A week later, she heard from the Clinic, and shortly thereafter her son began treatment with ANP. According to Ms. McGee, the level of care at the Clinic "was unlike anything we had seen before. Besides being very professional and very – knowing what they were doing . . . they were very caring."[938] The side effects that her son experienced, Ms. McGee recalled, were minor.[939] Her son remained on treatment with the Clinic for about 10 years, until about 2000. According to Ms. McGee, he never missed a day of school. Her son is now an RN/BSN, works in the emergency room in Pontiac, Michigan, and is a personal trainer for children with learning disabilities. His cancer has been in remission for about 16 years. Ms. McGee pointed out that her son was sitting in the hearing room and is alive because of Respondent. She stated:

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[934] Tr. Vol. 10 at 114-115.

[935] Tr. Vol. 10 at 99-100.

[936] Tr. Vol. 10 at 101-102.

[937] Tr. Vol. 10 at 103.

[938] Tr. Vol. 10 at 109.

[939] Tr. Vol. 10 at 113.

> [E]very day there's someone in some emergency room somewhere or some doctor's office or hospital that's getting the diagnosis that Paul got, and I know that hopeless feeling that you have and it's horrible. . . . And those people have no hope. We didn't have hope in 1985; but in 2016, there's still no hope. If they don't have Dr. Burzynski, those kids are going to die and those families will never be the same. He's the only hope for people that get that kind of cancer."[940]

Mary Jo Siegel was another Clinic patient. In 1990, Ms. Siegel was 40 years old when she was diagnosed with non-Hodgkin's lymphoma, Stage IV.[941] She recalled that her doctor at UCLA told her that she had a "fatal cancer and that they would treat me for a while with chemo and radiation but eventually I would die of the disease."[942] The prognosis was poor. According to Ms. Siegel, she and her husband then went to the top lymphoma specialists at USC, Stanford, and the Dana-Farber Cancer Institute at Harvard. All of these doctors told her that "she had a fatal prognosis," and offered her no hope.[943] Her husband had heard about the Clinic, so they made an appointment.

According to Ms. Siegel, she received treatment with ANP at the Clinic from 1992 to 2004. She has been a cancer survivor for 21 years and now only goes to the Clinic for an annual check-up.[944] Over those 21 years, Ms. Siegel was able to watch her children grow up and now has grandchildren.[945] Ms. Siegel stressed that she is healthy and happy today because of Respondent's treatment.

The ALJs find that Respondent has been of significant value to the community of terminally ill cancer patients who either rejected conventional treatment or had conventional treatment fail. The ALJs are aware that, as with conventional cancer treatment, not every patient will have a positive response to Respondent's cancer treatments. But based on the evidence

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[940] Tr. Vol. 10 at 116.

[941] Tr. Vol. 10 at 148-149.

[942] Tr. Vol. 10 at 149.

[943] Tr. Vol. 10 at 149-151.

[944] Tr. Vol. 10 at 153-154.

[945] Tr. Vol. 10 at 162-163.

presented, several patients have had positive results from his treatments some of which have become more accepted and mainstream.

XII. FINDINGS OF FACT

Factual Background

1. Stanley Burzynski, M.D. (Respondent or Dr. Burzynski) is a physician who holds Texas Medical License No. D-9377 that was issued by the Texas Medical Board (Board) in 1973.

2. Respondent graduated from medical school in 1967, and received a biochemist doctorate in 1968 before immigrating to the United States in 1970.

3. Between 1970 and 1977, Respondent worked at Baylor College of Medicine doing cancer research.

4. In 1977, Respondent opened the Burzynski Clinic (Clinic), a private medical practice in Houston, Texas, to treat cancer patients.

5. Respondent is not a board-certified oncologist, although he has treated cancer patients for almost 40 years.

Procedural History

6. Staff of the Board (Staff) filed the initial Complaint in this contested case on December 11, 2013, which was subsequently amended twice. The Second Amended Complaint (Complaint) filed on November 14, 2014, contains Staff's notice of the allegations against Respondent.

7. On August 21, 2014, Respondent filed a motion for summary disposition requesting that Staff's claims relating to alleged violations of federal regulations be dismissed.

8. Order No. 7 issued on September 10, 2014, granting Respondent's motion in part, held that Staff's alleged violations of non-criminal FDA-regulations pertaining to clinical studies of investigational new drugs are not subject to disciplinary action by the Board under 22 Texas Administrative Code (TAC) § 190.8(2)(R).

9. On September 24, 2015, Staff mailed the notice of hearing to Respondent. The notice of hearing contained a statement of the time, place, and nature of the hearing; the legal authority and jurisdiction under which the hearing was to be held; a reference to the particular sections of the statutes and rules involved; and a short plain statement of the factual matters asserted.

10. Respondent received adequate notice of the hearing, including its time, place, and nature.

11. The hearing on the merits convened on November 19 through 20, and 23 through 25, 2015, January 19, and May 3 through 6, and 9 through 12, 2016, before Administrative Law Judges Catherine Egan and Roy G. Scudday in the William P. Clements Building, 300 West 15th St., Austin, Texas. Attorneys Lee Bukstein, Amy Swanholm, Barbara Jordan, and Christopher Palazola represented Staff. Attorneys Dan Cogdell, J. Dennis Hester, J. Gregory Myers, and Melanie Rubinsky represented Respondent. The record closed on August 15, 2016, with the filing of the parties' closing arguments and highlighted exhibits.

The Clinic During the Relevant Period

12. The Clinic employed about 150 people, including three board-certified oncologists (Drs. Jai Joshi, Jose Valladares, and Zanhua Yi), two internists (Drs. Robert Weaver and Gregory Burzynski), one family practitioner (Dr. Alejandro Marquis), and several research associates who were unlicensed foreign-trained doctors.

13. In the beginning of 1990, Respondent began providing gene-oriented treatment with personalized treatment to the Clinic's cancer patients. This purpose of this approach was to treat the cause of the cancer, abnormal genes, instead of the type of cancer.

14. Approximately 95% of the Clinic's cancer patients had terminal diagnoses, many of whom had tried other treatment protocols without success.

15. Each patient at the Clinic was assigned a team of health care providers that included an oncologist, either an internist or family practitioner, and a research associate, all of whom met with the patient and Respondent at the initial consultation to discuss the proposed treatment plan.

Burzynski Research Institute/Institutional Review Board

16. In 1993, the Federal Drug Administration (FDA) approved a clinical trial for the investigational drug antineoplaston (ANP) in the treatment of cancer patients. Over the years, Respondent has engaged in 65 prospective clinical trials and one retrospective clinical trial.

17. The Burzynski Research Institute (BRI), of which Respondent is the president and 80% owner of the shares, was created in 1983 to be involved in basic and clinical research on ANP and to sponsor FDA-approved clinical trials.

18. The Institutional Review Board (IRB) was also created in 1983 to supervise the ethical conduct of clinical studies by approving or disapproving clinical trial protocols; approving or disapproving patient participation in clinical trials pursuant to those protocols; collecting data on the toxicity and the response of the investigational agent; and evaluating data on the efficacy of the investigational agent.

19. Neither Respondent nor any of the Clinic's employees are members of the IRB.

Standard of Care

20. In September 2010, Patient A, a 67-year-old man, was given a preliminary diagnosis of Stage IV colon cancer with metastases to the liver. This type of cancer is uniformly fatal, with the medium survival rate being approximately five months.

21. Patient A declined the conventional cancer treatment of surgery and chemotherapy.

22. Patient A had an initial consultation at the Clinic on October 7, 2010.

23. Patient A was treated by the Clinic from October 2010 through October 2011, and died on November 4, 2011.

24. Patient B was a 56-year-old man from the Ukraine who was diagnosed on December 12, 2010, with glioblastoma, grade IV, a fast-growing, aggressive central nervous system tumor that forms on the supportive tissue of the brain.

25. Patient B had debulking surgery on December 20, 2010 to remove as much of the tumor as possible, but rejected the conventional treatment of radiation therapy and chemotherapy with Temodar (temozolomide).

26. On February 7, 2011, Patient B travelled from Germany to the Clinic with his personal physician, Dr. Demetri Brandt, to meet with Respondent.

27. After discussing various treatment options, Patient B and Dr. Brandt elected to follow Respondent's recommended treatment.

28. From February 7 through March 4, 2011, Patient B was treated at the Clinic with medications as directed by the Clinic's oncologist, Dr. Valladares, that included sodium phenylbutyrate (PB), Votrient, Avastin, and Tarceva.

29. On March 4, 2011, Patient B left the Clinic and went to Germany, where Dr. Brandt began treating Patient B with ANP.

30. On July 6 through 7, 2011, based on Respondent's recommendation, Patient B was administered Afinitor, Sprycel, and Nexavar while under Dr. Brandt's care.

31. Dr. Brandt stopped treating Patient B with ANP at the end of September 2011. Patient B died on December 18, 2011.

32. In 1986, Patient C was a 42-year-old man who was diagnosed with Stage II A Nodular sclerosing Hodgkin's disease for which surgical and radiotherapy were successful.

33. On April 19, 2010, Patient C was diagnosed with cancer in his left lung.

34. Although Patient C's local oncologist recommended chemotherapy, Patient C chose to consult with the Clinic on May 11, 2010.

35. After the initial consultation among Patient C, Respondent, and Dr. Joshi, Patient C was treated at the Clinic from May 14 through 20, 2010, with a regimen of PB, Tarceva, Nexavar, Avastin, and Decadron (dexamethasone).

36. On May 20, 2010, Patient C left the Clinic and returned to his home, where he was under the care of his personal oncologist, Dr. Thomas Waits, who continued the treatment protocol begun at the Clinic until October 2011, when Dr. Waits chose to no longer continue the recommended treatments.

37. Patient D, a 28-year-old male, was diagnosed on May 13, 2010, with brain cancer (pleomorphic xanthoastrocytoma, grade II) for which he had a surgical resection.

38. Imaging studies taken on November 26, 2010, showed that Patient D had new lesions in his brain and spine.

39. On January 10, 2011, Patient D's oncologist recommended chemotherapy treatment with Temodar and radiation. This treatment was continued through April 6, 2011, until it was stopped because Patient D was experiencing adverse reactions to the treatment.

40. On June 7, 2011, Patient D visited the Clinic for a consultation.

41. On July 1, 2011, Patient D declined to follow Respondent's treatment recommendations and left the Clinic.

42. Patient D never received treatment at the Clinic.

43. Patient E, a 67-year-old male, had chromophobic type renal cell carcinoma (kidney cancer) with multiple recurrences.

44. On September 7, 2011, Patient E had an initial consultation at the Clinic.

45. At Respondent's recommendation, Patient E began treatment with the following medications: PB on September 8, 2011; Xgeva on September 13, 2011; Afinitor on September 14, 2011; and Sutent on September 15, 2011.

46. Patient E ceased treatments by the Clinic on October 16, 2011.

47. On September 21, 2009, Patient F, a 66-year-old male, was diagnosed with pancreatic cancer.

48. Although Patient F's local oncologist recommended chemotherapy treatment, Patient F and his wife chose to consult with Respondent and the treatment team at the Clinic on October 8, 2009.

49. Patient F was treated at the Clinic from October 8 through November 11, 2009, with a regimen of PB, Rapamune, Zolinza, Nexavar, Xeloda, and Avastin.

50. Patient F discontinued the treatment on November 11, 2009, due to financial constraints.

51. Patient G, a 26-year-old woman, was diagnosed on July 5, 2012, with suprasellar mass brain cancer and malignant astrocytoma of the optic nerve.

52. Patient G underwent surgery on August 3, 2012, and was treated by her local oncologist with Avastin on August 24, 2012.

53. Patient G's oncologist recommended that, after surgery, she be treated with radiation therapy and Temodar, but explained the radiation would probably cause her to go blind.

54. Patient G consulted with the Clinic on August 31, 2012.

55. Patient G was ineligible to participate in a clinical trial for ANP because she had previously received chemotherapy.

56. On September 6, 2012, the FDA and IRB approved Patient G for a single-patient protocol to receive ANP.

57. From September 12 to November 26, 2012 Patient G was treated with ANP, but the treatment was discontinued because Patient G experienced consistent problems of edema in her legs.

58. In December 2012, Patient G began conventional cancer treatment in her home town with radiation, Temodar, and Avastin. The patient's records indicate that she experienced edema, severe headaches, and other severe side effects, including a hospital admission with sepsis, while on conventional treatment.

59. There is insufficient evidence to establish that Respondent violated the standard of care by:

> (a) failing to make Patients A through G aware of the potential toxicities of the combination of drugs;
>
> (b) failing to provide adequate medical rationale for treatment of Patients A through G with ANP, PB, and/or the combined use of drugs;
>
> (c) failing to provide adequate medical rationale for the evaluation, diagnosis, and treatment of Patients A through G; or
>
> (d) with the exception of informed consent regarding the below-described treatment of Patient E, providing inadequate medical documentation for Patients A through G.

60. There is insufficient evidence that Respondent violated the standard of care in the treatment of Patients A, B, C, D, F, or G.

61. In a private practice setting, informed consent forms for each drug being used concurrently to treat cancer meet the standard of care where the risks of combining the drugs are unknown.

62. Prior to his treatment at the Clinic, Patient E had experienced toxicity with Votrient that had similar tyrosine kinase parameters as Sutent.

63. Between September 13 and 15, 2011, Patient E began treatment at the Clinic with PB, Xgeva, Afinitor, and Sutent.

64. According to the Clinic's informed consent form for Afinitor that was reviewed with Patient E, the "purpose of treatment" section stated that Afinitor was a kinase inhibitor indicated for the treatment of patients with advanced renal cell carcinoma after failure of treatment with Sutent.

65. Patient E was treated with Afinitor at the Clinic before he was treated with Sutent, after which the drugs were administered together, as directed by Respondent.

66. Administering Afinitor to Patient E before treating with Sutent, and then administering them together, was a deviation from the procedure indicated in the Afinitor informed consent form that Patient E signed.

67. There is no documentation in Patient E's medical records showing that Respondent explained, or had explained, to Patient E that the treatment protocol would deviate from that set out in the Afinitor informed consent form.

68. Patient E did not have an opportunity to give his informed consent to using these two drugs, Afinitor and Sutent, in a manner different from that disclosed on the Afinitor informed consent form that he signed.

69. Because Respondent did not provide Patient E with a written explanation for the deviation in the treatment protocol set out in the Afinitor informed consent form, Patient E did not give his informed consent for being treated with Afinitor before Sutent or for the simultaneous use of both drugs.

70. Respondent's failure to ensure that Patient E received adequate information to explain that his treatment with Afinitor would be different from that disclosed in the informed consent form violated the standard of care.

Inadequate Delegation and Improper Use Of Unlicensed Practitioners

71. Respondent's son, Dr. Gregory Burzynski, is a board-certified internist licensed by the Board in January 2011.

72. Dr. Gregory Burzynski was responsible for treating internal medical problems that arose while a patient received cancer treatments at the Clinic.

73. Dr. Alejandro Marquis is a family physician licensed by the Board who worked at the Clinic from 2006 until 2014.

74. Dr. Gregory Burzynski and Dr. Marquis were responsible for assisting the treating oncologists in monitoring and communicating with Clinic patients, ensuring the Clinic

received requested laboratory tests and scans in a timely manner, and managing any side effects a patient experienced from the drugs prescribed by the treating oncologists.

75. Dr. Gregory Burzynski and Dr. Marquis were qualified by training, experience, and licensure to perform the medical services they provided at the Clinic.

76. Respondent was responsible for the supervision of the Clinic's research associates, including Tolib Rakhmanov, Mohammed Khan, Larisa Tikhomirova, Sheryll Acelar, and Lourdes DeLeon.

Tolib Rakhmanov

77. RA Rakhmanov is an unlicensed foreign-trained doctor who worked at the Clinic as a research associate from 2006 to July 2016.

78. RA Rakhmanov's job duties at the Clinic included collecting the patient's medical history, obtaining the patient's prior medical records, reviewing the informed consent forms with patients who elected to be treated at the Clinic, and communicating with the patient and the patient's local oncologist once the patient returned home.

79. RA Rakhmanov did not conduct the patient's physical examinations or diagnose and treat patients.

80. In a medical setting, by taking patient histories, signing orders, reviewing laboratory results, communicating with the patients' local oncologists as "Dr. Rakhmanov," wearing a white lab coat with a name tag identifying himself as "Dr. Rakhmanov," being addressed at the Clinic as "Dr. Rakhmanov," and signing Clinic forms, including informed consent forms, as a physician, RA Rakhmanov represented himself to the public as a licensed physician authorized to practice medicine.

81. Respondent supervised RA Rakhmanov, delegated medical acts to RA Rakhmanov, and permitted him to be misrepresented as a person authorized to practice medicine.

82. Respondent had an obligation as a physician who supervised and delegated medical acts to RA Rakhmanov to ensure that he did not misrepresent his licensure, either directly or indirectly, and he failed to do so.

83. Although RA Rakhmanov misrepresented that he was authorized to practice medicine, he only performed medical acts that he was qualified to perform and under a physician's supervision.

84. There is insufficient evidence to show that RA Rakhmanov engaged in the practice of medicine.

85. Respondent did not aid and abet RA Rakhmanov in the unlicensed practice of medicine.

Mohammed Khan

86. RA Khan, an unlicensed foreign-trained doctor, has been employed by the Clinic as a research associate since 1997.

87. Respondent was RA Khan's supervisor.

88. RA Khan worked as the Clinic's radiology technician and was not directly involved with the Clinic's patients.

89. RA Khan did not misrepresent to the public that he was authorized to practice medicine.

90. The Clinic does not take its own radiology scans, and when outside radiology films arrived at the Clinic, RA Kahn collected them, downloaded them into the computer, and then showed them to the treating physicians.

91. Although RA Khan took tumor measurements from scans he downloaded into the computer, Respondent remeasured the tumors to verify the measurements.

92. Respondent dictated to RA Khan what he wanted included in the radiology reports so that RA Khan could prepare Respondent's written report.

93. The Clinic's physicians relied on their own review of the radiologic imaging and the official radiology report to make treatment decisions.

94. Respondent did not improperly delegate medical acts to RA Khan and did not aid and abet RA Khan in the unlicensed practice of medicine.

Larisa Tikhomirova

95. Larisa Tikhomirova, an unlicensed foreign-trained doctor, worked at the Clinic as a research associate from July 2009 to May 2012.

96. On February 7, 15, and 17, 2011, RA Tikhomirova signed Patient B's informed consents as the "Physician performing consent." She was identified on Patient B's laboratory results as a physician, and signed Clinic forms as the patient's physician, including a February 7, 2011 prescription for supplements and radiology orders issued on February 7 and March 4, 2011.

97. RA Tikhomirova signed the October 8, 2009 informed consent for Patient F's pretreatment evaluation statement as the physician, and initialed the Clinic's form entitled "Food Supplements" authorizing Patient F to have certain supplements.

98. Between October 9 through 15, 2009, RA Tikhomirova signed Patient F's informed consent forms for the drugs used in his treatment as the "Physician performing consent."

99. RA Tikhomirova misrepresented to Patients B and F that she was a physician authorized to practice medicine.

100. Respondent supervised and delegated medical acts to RA Tikhomirova and permitted her to be misrepresented to the public as a person authorized to practice medicine.

101. Respondent had an obligation as a physician who supervised and delegated medical acts to RA Tikhomirova to ensure that she did not misrepresent her licensure, either directly or indirectly, and he failed to do so.

102. The medical acts that RA Tikhomirova performed were done under the supervision of a licensed physician.

103. Although RA Tikhomirova misrepresented to the public that she was authorized to practice medicine, there is insufficient evidence to establish that RA Tikhomirova was unqualified to perform the medical acts delegated to her by Respondent and the other licensed physicians.

104. There is insufficient evidence to show that RA Tikhomirova engaged in the practice of medicine.

105. Respondent did not aid and abet RA Tikhomirova in the unlicensed practice of medicine.

Sheryll Acelar

106. Sheryll Acelar, an unlicensed foreign-trained doctor, worked at the Clinic as a research associate from 2010 to 2014. At the Clinic, she was wore a white lab coat with a name tag identifying her as "Dr. Acelar," and was addressed by the Clinic staff as "Dr. Acelar."

107. RA Acelar's job duties included taking the patient histories, communicating with the patient, keeping records for Clinic physicians, ensuring that laboratory results were delivered to Clinic physicians, monitoring phone calls, and relaying messages about a patient's symptomatology in regards to the prescribed medications.

108. RA Acelar reviewed the informed consent forms for Patients C and G, including the Pretreatment Evaluation and for the drugs Avastin and PB, and then initialed the forms as a physician.

109. When RA Acelar communicated with Patient C's local oncologist, Dr. Waits, she identified herself as "Dr. Acelar."

110. Dr. Waits reasonably believed RA Acelar was the contact physician at the Clinic for Patient C, addressed her as "Dr. Acelar," and referred to her in written correspondence as "Sheryl Acelar, M.D."

111. On December 9, 2010, RA Acelar issued treatment orders in response to an email requesting permission to reduce the medication dosage that Patient C was receiving. She issued the treatment order to adjust this dosage without input from a licensed physician.

112. RA Acelar authorized Patient G's local oncologist to decrease her Decadron dosage and instructed the physician to put the patient back on ANP as soon as possible without instructions from a licensed physician to do so.

113. RA Acelar misrepresented to the public that she was authorized to practice medicine by signing informed consent forms as the patient's physician, issuing orders, adjusting dosages, and calling herself "Dr. Acelar."

114. Respondent had an obligation as a physician who supervised and delegated medical acts to RA Acelar to ensure that she did not misrepresent her licensure, either directly or indirectly.

115. Respondent permitted RA Acelar to misrepresent to the public that she was a person authorized to practice medicine.

116. RA Acelar was unqualified by licensure to make adjustments to a patient's treatment.

117. Respondent failed to adequately supervise RA Acelar by permitting her to sign medical records in the space designated for the physician's signature and allowing her to make treatment decisions regarding Patients C and G.

118. Respondent aided and abetted RA Acelar in the unlicensed practice of medicine.

Lourdes DeLeon

119. Lourdes DeLeon, an unlicensed foreign-trained doctor, has worked as a research associate at the Clinic since 2005.

120. RA DeLeon wore a white lab coat with a name tag identifying her as "Dr. DeLeon," and signed consent forms and orders in the space designated for the physician's signature, but she told Patient E and other patients when she first met them that she was not licensed in the United States.

121. There is insufficient evidence that RA DeLeon misrepresented to the public that she was a person authorized to practice medicine. There is insufficient evidence to establish that RA DeLeon was unqualified to perform the medical acts that were delegated to her by Respondent and the other Clinic physicians.

122. Respondent did not fail to supervise RA DeLeon, did not improperly delegate medical acts to her, and did not aid and abet her in the unlicensed practice of medicine.

Informed Consent

123. The Clinic's pretreatment evaluation statements given to Patients A through C and E through G represented that the patient would "be asked to sign a treatment specific consent form indicating that [he] understands that particular treatment and that [he] wished to receive that treatment regimen."

124. After the treatment plans were established, Respondent failed to ensure Patients A through C and E through G received a more specific informed consent regarding the treatment plan to review and sign.

125. On February 9, 2011, Patient B received treatment with Avastin, before he signed the informed consent form for Avastin on February 17, 2011.

126. On October 14, 2009, Patient F began treatment with Avastin, but the informed consent form was signed on October 15, 2009.

127. Respondent did not ensure that Patients B and F reviewed and signed the informed consent form for Avastin prior to having administered Avastin to them.

128. After Patient C had returned home to Indiana, he was treated by his local oncologist, Dr. Waits.

129. While under Dr. Waits care, Patient C's medication was changed.

130. The evidence is insufficient to show that it was Respondent's responsibility to secure informed consent forms for new drugs administered to Patient C while he was in the care of Dr. Waits.

Off-labeled Use of FDA-Approved Drugs

131. There is insufficient evidence to show that Respondent violated the Texas Occupations Code (Code) or any Board rule by identifying in the informed consents what uses of a drug had FDA approval rather than stating that he was using the drug "off-label."

Alternative Therapy or Clinical Trials

132. The FDA is the regulatory agency with the authority to grant an application for a clinical trial and to make sure that the clinical trial is performed in compliance with the approved protocols and the FDA regulations.

133. The FDA approved the informed consent forms used by Respondent in the FDA-approved clinical trials.

134. Any issues regarding the Clinic's consent forms used for clinical trials have been remedied through the proper process and Respondent, BRI, and the FDA. The FDA's correspondence does not, without additional evidence, establish a violation of the Code or the Board rules.

Disclosure of Ownership Interest in Pharmacies and Laboratory

135. Respondent is the sole owner of Southern Family Pharmacy and SRB Pharmacy (the pharmacies).

136. Southern Family Pharmacy was located in the same building as the Clinic.

137. Patients who received care from Respondent had their medication prescriptions filled at the pharmacies.

138. Patients who were prescribed PB and ANP could only have their prescriptions filled at the pharmacies.

139. Respondent did not disclose to his patients his ownership interests in the pharmacies.

140. The failure of Respondent to disclose his ownership interest in the pharmacies was unprofessional conduct.

141. The SR Burzynski Lab, owned by Respondent, conducted laboratory analyses of samples taken for patients treated by Respondent and Respondent's subordinates.

142. It is clear from the name SR Burzynski Lab that Respondent had some ownership interest in it.

143. The failure of Respondent to disclose his ownership interest in the laboratory was not unprofessional conduct.

Improper Charges and Retainer Demands

144. There is insufficient evidence to establish any improper charges were made by Respondent to Patients A, D, and F.

145. On February 7, 2011, Respondent charged Patient B $350 for prolonged physician services and $500 for prolonged service without contact.

146. On February 10, 2011, Respondent charged Patient B $125 for a visit with Dr. Gregory Burzynski.

147. On February 28 and March 2, 2011, Respondent charged Patient B $60 each for group health education.

148. Respondent failed to document adequate support for the above-described charges to Patient B.

149. Respondent charged Patient C $125 for each phone evaluation/maintenance held on June 23, July 2, July 13, July 27, August 10, August 17, August 23, September 27, and December 14, 2010, and August 31, 2011.

150. Respondent failed to document adequate support for the above-described charges to Patient C.

151. On September 10 and 11, 2011, Patient E was charged $95 each for after-hours medical services, and on September 16, 2011, Patient E was charged $100 for an office visit.

152. Respondent failed to document adequate support for the above-described charges to Patient E.

153. On September 16, and 23, 2012, Patient G was charged $95 each for after-hours medical services.

154. CPT Code No. 96416 requires that a nurse or other licensed health provider be continuously present when ANP is given to the patient through a pump.

155. On September 12, 2012, the medical records document that Patient G was charged $170 for a first infusion and $395 for a second infusion even though the records do not identify a health professional who was present during these two infusions.

156. From September 13 through 22, 2012, Patient G received infusions of ANP at the Clinic for which she was charged $395 under CPT Code 96416 even though the records do not identify a health professional who was present during the infusions.

157. Respondent improperly billed Patient G for infusion charges under CPT Code 96416 even though no nurse or other licensed health provider was documented as being continuously present when the ANP infusions were given to Patient G through a pump.

158. On September 29 through October 19, October 23 through 27, November 1, and November 5 through 14, 2012, Patient G self-administered the ANP infusions at home; they were not administered by a health professional at the Clinic.

159. Patient G was improperly charged $395 for each of the self-administered infusions under CPT Code 96416.

160. On September 12, 2012, Patient G was counseled by someone at the Clinic about birth control and appropriate diet while on ANP treatment, for which she was charged $60.

161. Patient G's Daily Worksheets documented that she attended ANP training from September 3 through 21, 2012, for which she was charged $60 per day of training.

162. These charges were coded as CPT Code 99078, the code to use when patients receive education from a physician in a group setting.

163. Respondent failed to document adequate support to show that a physician provided training to Patient G in a group setting.

164. Respondent failed to document adequate support for the above-described charges to Patient G.

165. The failure to document support for the above-described charges resulted in inadequate medical records for Patients B, C, E, and G.

Deceptive Marketing and Advertising

166. There is insufficient evidence to establish that Respondent used advertising statements that were false, misleading, or deceptive.

Ethical and Professional Responsibilities In Clinical Trials

167. Respondent was the principal investigator at the Clinic for all FDA-approved clinical trials.

168. Patients A through F were not participating in FDA-approved clinical trials.

169. Patient B was not treated with ANP at the Clinic.

170. There is insufficient evidence to show that Respondent failed to protect Patient G by failing to report adverse events from ANP treatments.

171. There is insufficient evidence to show that Respondent failed to protect Patient I in the clinical trial by failing to report Patient I's adverse events in compliance with the BT-10 protocol approved by the FDA.

172. There is insufficient evidence to show that Respondent inaccurately measured Patient I's tumor response to treatment in accordance with the BT-10 protocol approved by the FDA.

173. Respondent's classification of Patient J's response to treatment as "stable disease" (SD) was in compliance with Protocol BT-10.

174. The evidence is insufficient to establish that Respondent measured Patient J's lesions inaccurately or misrepresented the tumor's progression to the child's parents.

175. There is insufficient evidence to establish that Respondent misdiagnosed Patient N's cancer or that Respondent inaccurately reported the results of Patient N's imaging studies.

176. There is insufficient evidence to show that Patients O and P participated in a clinical study or that they received ANP.

177. There is insufficient evidence to establish that Respondent misrepresented Patient S's response to ANP or skewed the results of the tumor measurements.

178. There is insufficient evidence to show that the Clinic failed to properly train Patient T's parents on how to use the pump or that Respondent misrepresented Patient T's response to ANP by skewing the results of the tumor measurements.

179. Respondent inaccurately reported Patient Q's tumor measurements, causing the classification of the tumor's response to treatment to be in error.

180. There is insufficient evidence to establish that Respondent was required to report overdoses caused by operator errors or that he failed to report adverse events that occurred as required by the clinical study.

181. Respondent did not disclose in the informed consent forms given to patients in FDA-approved clinical trials the additional costs related to ANP treatment, but he did disclose this information before initiating treatment in the billing agreement signed by each patient.

182. Respondent did not engage in unprofessional and unethical conduct by disclosing before treatment the additional costs of participating in an ANP clinical trial in a treatment billing agreement rather than in the informed consent form.

183. There is insufficient evidence to establish that Respondent failed to adequately train his subordinates about adverse events and the need to document and report them to a licensed physician.

184. There is insufficient evidence to show that Respondent failed to train and retrain patients, their families, or the Clinic staff on proper pump use for ANP infusions.

185. Respondent considered and reported the impact of Patient G's taking of corticosteroids on her treatment.

186. There is insufficient evidence to establish that Respondent failed to isolate the impact of corticosteroid use on Patient G's tumor.

187. Respondent informed Patient G of the additional costs that she might incur in her cancer treatment before she began receiving the treatment.

188. Except for Finding of Fact No. 179, the credible evidence failed to show that Respondent violated his ethical duty and responsibilities as a clinical investigator.

Aggravating and Mitigating Factors

189. Based on the above-stated findings of fact, there is insufficient evidence that any of Respondent's patients suffered actual harm to their health by a violation of the standard of care or having inadequate records.

190. Based on the above-stated findings of fact, there is insufficient evidence that any of Respondent's patients were actually harmed by his failure to ensure that RAs Rakhmanov, Tikhomirova, and Acelar did not directly or indirectly represent to the public that they were authorized to practice medicine.

191. Based on the above-stated findings of fact, there is insufficient evidence that any of Respondent's patients were actually harmed by his allowing RA Acelar to practice medicine without a license.

192. Based on the above-stated findings of fact, there is insufficient evidence that any of Respondent's patients were economically harmed by his failure to disclose his ownership interest in the pharmacies.

193. Based on the above-stated findings of fact, there is insufficient evidence that any of Respondent's patients were economically harmed by his failure to have adequate medical records to support Clinic charges.

194. Based on the above-stated findings of fact, Respondent's failed to obtain timely and/or adequate informed consent to more than one patient.

195. Based on the above-stated findings of fact, unless corrected for the future, the following actions by Respondent could represent potential harm to the public: (1) failing to ensure that research associates did not directly or indirectly represent to the public that they were authorized to practice medicine, (2) allowing a research associate to practice medicine without a license; (3) failing to disclose his ownership interest in the pharmacies; and (4) failing to have adequate medical records to support Clinic charges.

196. On August 31, 1994, the Board suspended Respondent's license for a period of ten years, but probated the suspension. The basis of the action was that Respondent had treated patients with ANP in violation of the laws in effect at that time and had made false advertisements about ANP.

197. Based on the above stated Findings of Fact, Respondent did not treat patients with ANP in violation of the laws in effect during the relevant time period and did not make false advertisements about ANP during the relevant time period. Accordingly, Respondent has not been disciplined by the Board for prior similar violations.

198. For almost 40 years, Respondent has devoted himself to treating terminally ill cancer patients who have either rejected conventional cancer treatments or had tried conventional treatments without success. Some of Respondent's treatments have become more accepted and mainstream.

199. If Respondent is unable to continue practicing medicine, critically ill cancer patients being treated with ANP under FDA-approved clinical trials or a special exception will no longer have access to this treatment.

200. Respondent's continued practice in treating advanced cancer patients is a present value to the cancer community.

201. Respondent's treatments have saved the lives of cancer patients, both adults and children, who were not expected to live.

XIII. CONCLUSIONS OF LAW

1. The Board has jurisdiction over this matter pursuant to Code title 3, subtitle B.

2. The State Office of Administrative Hearings has jurisdiction over the hearing in this proceeding, including the authority to issue a proposal for decision with proposed findings of fact and conclusions of law, pursuant to Texas Government Code ch. 2003.

3. Respondent was adequately and timely apprised of the hearing and the factual allegations against him. Tex. Gov't Code §§ 2001.051-.052.

4. Staff had the burden of proving the elements of its case by a preponderance of the evidence, while Respondent had the burden of proving the elements of any claimed exemption under the law. 1 TAC § 155.427.

5. The Board has authority to take disciplinary action against a licensee who violates the statutes or rules regarding physicians, or has failed to practice medicine in an acceptable professional manner consistent with public health and welfare. Code § 164.051(3), (6).

6. Non-criminal FDA regulations pertaining to clinical studies of investigational new drugs are not subject to disciplinary action by the Board under 22 TAC § 190.8(2)(R).

7. Respondent is subject to sanction for failing to document the risk factors of, or explain the deviation from, the prescribed treatment plan, and to give Patient E the opportunity to give his informed consent to the simultaneous use of two specific drugs, in violation of 22 TAC §§ 165.1(a)(5), (7) and 190.8(1)(I).

8. Respondent is subject to sanction for failing to supervise RAs Rakhmanov, Tikhomirova, and Acelar to ensure that they did not represent to the public that they were authorized to practice medicine, in violation of Code §§ 164.052(a)(5) and 164.053(a)(8), (9).

9. Respondent is subject to sanction for aiding and abetting RA Acelar in the unlicensed practice of medicine, in violation of Code §§ 164.052(17) and 164.053(a)(9).

10. Respondent is subject to sanction for failing to give Patients A through C and E through G a more specific informed consent form regarding the treatment plan to review and sign, and for failing to timely obtain informed consent for Avastin from Patients B and F, in violation of 22 TAC §§ 190.8(1)(G), (H) and (I) and 200.3(2).

11. Respondent is subject to sanction for failing to disclose his ownership interest in the pharmacies to his patients in violation of 22 TAC § 190.8(2)(H).

12. Respondent is subject to sanction for failing to maintain adequate medical records to support charges to Patients B, C, and E, in violation of 22 TAC § 165.1(a)(9).

13. Respondent is subject to sanction for failing to maintain adequate medical records to support charges to Patient G, in violation of 22 TAC §§ 165.1(a)(9) and 190.8(2)(J).

14. Respondent is subject to sanction for inaccurately reporting Patient Q's tumor measurements, causing the classification of the tumor's response to treatment to be in error, in violation of 22 TAC § 200.3(7)(A).

15. Aggravating and mitigating factors may be considered by the Board in disciplinary actions. 22 TAC § 190.15.

SIGNED October 12, 2016.

ROY G. SCUDDAY
ADMINISTRATIVE LAW JUDGE
STATE OFFICE OF ADMINISTRATIVE HEARINGS

CATHERINE C. EGAN
ADMINISTRATIVE LAW JUDGE
STATE OFFICE OF ADMINISTRATIVE HEARINGS

APPENDIX A
LIST OF MEDICINES

BURZYNSKI BOARD MATTER

Chemotherapeutic Agent Key

Brand Name	Generic Name
Afinitor	everolimus
Alimta	pemetrexed
Avastin	bevacizumab
Buphenyl	sodium phenylbutyrate
Camptosar	irinotecan
Eloxatin	oxaliplatin
FOLFOX or Oxaliplatin	Combination -- Folinic Acid and Fluorouracil
Gemzar	gemcitabine
Nexavar	sorafenib
Paraplatin	carboplatin
Rapamune	sirolimus
Sprycel	dasatinib
Sutent	sunitinib
Tarceva	erlotinib
Temodar	temozolomide
Vectibix	panitumumab
Votrient	pazopanib
Xeloda	capecitabine
Xgeva	denosumab

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Zolinza	vorinostat
OTHER:	
Decadron	dexamethasone
Benadryl	diphenhydramine
Valtrex	valacyclovir