BEFORE THE
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: WILLIAM C. RADER, M.D., Physician's and Surgeon's Certificate No. A22848, Respondent.	Case No. 20-2010-205857 OAH No. 2013040837

DECISION AFTER NON-ADOPTION

This matter came on regularly for hearing on February 18, 19, 20, 21, 25, 26, and 28, and March 6, 7, 10, 11, and 12, 2014, in Los Angeles, California, before H. Stuart Waxman, Administrative Law Judge, Office of Administrative Hearings, State of California.

Harinder K. Kapur, Deputy Attorney General, represented Complainant, Linda K. Whitney (Complainant), Executive Director of the Medical Board of California (Board).

Complainant has alleged seven causes for discipline against Respondent for gross negligence (Bus. & Prof. Code[1] § 2234, subd. (b)), repeated negligent acts (§ 2234, subd. (c)), false and/or misleading advertising (§ 2271), disseminating false or misleading statements (§ 651, subd. (a), (b)(1), (b)(2), (b)(3), and (b)(7)), dishonesty or corruption (§ 2234, subd. (e)), general unprofessional conduct (§ 2234), and violation of a provision or provisions of the Medical Practice Act (§ 2234, subd. (a)). The allegations were made in connection with Respondent's advertising for, recommending, and or participating in the use of fetal stem cell therapy on human beings.

Respondent was present on each day of the hearing and was represented by Robert L. Shapiro, Fred D. Heather, and Alexander M. Kargher, Attorneys at Law.

Oral and documentary evidence was received. The record was closed on March 12, 2014, and the matter was submitted for decision.

[1] All statutory references are to the Business and Professions Code unless otherwise indicated.

The proposed decision of the administrative law judge was submitted to Panel "B" of the Medical Board of California (hereafter "Board") on April 7, 2014. After due consideration thereof, the Board declined to adopt the proposed decision and thereafter on May 6, 2014 issued an "Order of Non-adoption of Proposed Decision." On June 10, 2014, the Board issued an "Order Fixing Date for Submission of Written Argument." On August 29, 2014, the Board issued a "Second Amended Notice of Hearing For Oral Argument[2]" setting the hearing date for September 24, 2014.

The time for written and oral arguments in this matter having expired, written argument having been filed by Complainant only and both parties presented oral arguments. Such written and oral arguments, together with the entire record, including the transcript of said hearing, having been read and considered, pursuant to Government Code Section 11517, the Board hereby makes the following decision and order:

FACTUAL FINDINGS

1. On June 25, 1968, the Board issued Physician's and Surgeon's Certificate Number A22848 to Respondent. The license was in full force and effect at all relevant times. It will expire on March 31, 2014, unless renewed. The license bears no history of discipline.

Respondent's Background and Present Work

2. Respondent graduated from Lafayette College with a Bachelor of Science Degree in business administration in 1959. Dissatisfied with his participation in his family's wholesale drug company, he took prerequisite courses and then enrolled in medical school at State University of New York at Buffalo, graduating with honors in 1967. Following an internship and psychiatric residency at the University of Southern California/County of Los Angeles Medical Center, he served in the United States Navy as a Chief Medical Officer, earning a Naval Commendation in 1973 for work in the alcohol addiction program. Respondent entered the private practice of psychiatry in 1974.

3. During his professional career, Respondent established programs in alcoholism and eating disorders at San Pedro Hospital and Redondo Beach Hospital, a rape survivor program, a program to assist hemodialysis patients obtain more appropriate personal treatment, and an HIV program in Mexico. He has made numerous television appearances in his professional capacity, and he co-hosted and produced his own television show.

4. In 1995, having become interested in stem cells, Respondent traveled to Ukraine to serve a one-year "fellowship" (Respondent's term) with a group of physicians and scientists experienced in the field. The fellowship involved his observing all aspects of stem cell therapy, including harvesting, separating, analyzing, freezing, and delivery. However, Respondent denies having actually participated in any of those activities. He testified that the Ukrainian physicians had been performing this work for 20 years, had injected 20,000 patients with stem cells, and had

[2] Previous Notices of Hearing For Oral Arguments were issued on June 24, 2014 and on August 15, 2014

published 1,700 studies.[3] Yet, despite that body of work, they were frustrated because "no one in the West would listen to them." (Respondent's testimony.)[4] The cells being used were neuronal and hematopoietic CD 34+ cells originating in the liver. They were fetal stem cells, meaning they were harvested from aborted fetuses at 8-12 weeks gestation. Respondent explained that neuronal cells were capable of becoming any of the four cell types found in the brain, and that hematopoietic CD 34+ cells were capable of becoming any of the 200 cell types occurring within the body. Respondent was not awarded a certificate at the completion of the Ukrainian fellowship because, as he stated, it was not "that formal." He was "just there to observe." (Respondent's testimony.)

5. While in Ukraine, Respondent became acquainted with and later associated with other physicians in the country of Georgia who were engaged in the same work. He was more comfortable with the physicians and equipment there than with those in Ukraine. He now obtains the stem cells used by his company from Georgia.

6. Respondent testified that he sent an emissary to China to go through "all the medical libraries" to learn of the research being done with fetal stem cells in that country. Respondent did not identify the emissary or explain the extent or result of his/her work.

7. Since returning to the United States, Respondent has been an advocate for the use of fetal stem cell therapy in human patients to which end he has, among other things, formed three companies (Dulcinea Institute, Medra, Inc., and Stem Cell of America, Inc.), published a book (Rader, Blocked in the U.S.A. The Stem Cell Miracle (2010)), and maintained three websites. He opened offshore clinics to enable people he hired to perform stem cell transplants on patients who came to him in the United States. His first clinic was located in Nassau, Bahamas. He moved his clinic to the Dominican Republic after Bahamas officials requested he perform double-blind studies on stem cell therapy. In 2007, after changing locations twice in the Dominican Republic, he moved his operation to Tijuana, Mexico. The clinic in the Dominican Republic remained open a brief time after Respondent opened his clinic in Tijuana.

8. During the time Respondent's company was operating under the name Medra, Inc., a number of people began posting negative reviews of Respondent and his stem cell therapy on Internet chat lines. Thereafter, the television show 60 Minutes aired a segment on "con men" (Respondent's term). During that segment, Medra, Inc.'s name was shown on the screen. It was then that Respondent closed Medra and opened Stem Cell of America in its stead. The change required only the updating of the website. The operation and the marketing strategy remained the same.

9. Respondent explained that all three of his organizations operated in the same manner with only two differences. (1) Initially, potential stem cell recipients paid for the treatment in advance by sending payment via wire transfer to the Bahamas. Now they pay in

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[3] None of those studies was offered in evidence at the administrative hearing.

[4] Much of Respondent's testimony regarding his time in Ukraine consisted of statements made to him by other physicians and scientists. Those hearsay statements are not accepted for the truth of the matter asserted.

advance by sending the payment to a bank in the United States. (2) The price for a treatment was initially $25,000, but it is now $30,000.

10. Respondent denies serving as the physician of any patient who expresses an interest in or receives stem cell therapy. He denies ever having performed a stem cell transplant on any patient. Instead, he trains physicians outside of the United States (presently in Mexico) in the theory and procedures of fetal stem cell therapy. The training he provides lasts approximately one week. It consists of a "long lecture" (Respondent's term), followed by questions and answers. He then observes the foreign physicians perform the treatment. He will intervene in their treatment if necessary. Respondent provided the physicians with his book and paperwork similar to that provided to potential stem cell recipients.

11. Respondent views his role in his organization as the owner who chooses the employees, searches for physicians who practice outside of the United States, and gets information to the public. He does not view himself as the physician to the patients who seek fetal stem cell therapy from his company. Therefore, he does not request medical records from the patients' other physicians, and he does not perform a good faith physical examination before recommending the therapy he espouses. He does not speak with patients' other physicians because he believes those physicians would react negatively, if they chose to speak with him at all. In his testimony, Respondent did not mention any patient he considered unfit for fetal stem cell therapy except for those with complete spinal cord injuries.[5]

12. Respondent operates an office in Malibu, California. Individuals interested in stem cell therapy almost never go to that office. Generally, they become aware of his service through either the company's website or Respondent's own website. They telephone the number on the website and speak with a staff member who provides information about the therapy and offers to send the individual Respondent's book. Either then or in a subsequent call, the individual may request to speak with Respondent personally, and Respondent takes or returns the call, answering all questions posed to him, including whether Respondent believes based on his experience and the information provided by the individual, that the individual might be a good candidate for stem cell therapy. If the individual wishes to undergo the treatment, he/she is asked to fill out and return the company's nine-page medical history questionnaire form. Respondent's criteria for referring the individual to Mexico[6] for treatment are (1) the individual must have exhausted all traditional and alternative forms of treatment, and (2) there is no remaining hope of recovery. However, Respondent does not request medical records from the individual's treating physician(s) to determine the nature or extent of the condition, which treatment approaches have been tried, what the current treatment is and its efficacy, or any other pertinent information. He does not see the individual before the day of the treatment. He does not perform a good faith physical examination on the individual because he does not believe it is necessary since the individual has already been diagnosed, and because, as a psychiatrist, he could not add anything to the diagnosis. As a result, Respondent does not know whether the information the individual

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[5] He testified that incomplete spinal cord injuries are very treatable with fetal stem cell therapy but that complete spinal cord injuries (fully-severed spinal cord) are not.

[6] Respondent presently operates only one clinic which is located in Tijuana, Mexico.

provides to him is factually/medically accurate or even if the individual is lying to him.[7]

13. According to Respondent, once his threshold criteria have been satisfied, he sends his chart[8] and the medical history questionnaire to his physicians in Mexico to determine whether the individual is an appropriate candidate for stem cell therapy. The patient is not given the option of choosing a physician in Mexico. Despite the fact that the Medical History Form contains the word, "Confidential" in its title, Respondent does not ask the individual to complete an authorization for release of medical records, and he does not inform the individual that the medical history questionnaire is being sent to another physician, or that he is referring the individual to a physician Respondent hired and pays. Nor is the patient informed of who is making the decision regarding whether he/she will be accepted for treatment. However, aside from Respondent's testimony, there was no evidence offered to show that documents are sent to the physicians in Mexico to decide whether to accept the patient, and some evidence indicated that it did not and does not occur. Respondent believes there are no contraindications to the treatment other than possible effects of medication the patient is taking (e.g., heparin may cause bleeding). Therefore, it is difficult to understand why Respondent does not make the decision whether the patient is an appropriate candidate for the therapy.

14. The patient pays the entire fee in advance. The fee is presently $30,000. The fee can be adjusted downward on what Respondent referred to as a sliding scale. Fee reductions must be approved by Respondent's wife. Additional treatments are given at a reduced rate. The fee covers the treatment, the stem cells, information from Stem Cell of America, assistance with travel arrangements, on-site transportation, overhead, and Respondent's "expertise." (Respondent's term.)

15. The patient may make travel arrangements independently, or Respondent's staff assists the individual with travel arrangements through a specific travel agency the staff uses exclusively. The treatments are delivered one day per month, usually on a Saturday. The individual travels to San Diego where he/she is picked up by a van operated by and/or paid for by Respondent and/or his company (presently Stem Cell of America) and taken across the border to the clinic. The treatments are administered by a physician or by non- physician medical personnel.

16. The stem cells transplanted into the patient belong to Respondent and/or his company. Respondent orders the stem cells from the laboratory in Georgia, and they are flown to Mexico, frozen in liquid nitrogen, at his company's expense. Only CD34+ hematopoietic cells are used. Respondent insists that only the stem cells he orders may be used on the patient. If one of the hired physicians chooses to obtain stem cells from another source, Respondent will no longer refer patients to that physician. If the patient desires to obtain stem cells from another source, Respondent will not refer that patient to his physicians in Mexico.

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[7] At the administrative hearing, Respondent testified that he would be untroubled by such a lie. That testimony is inconsistent with his two purported criteria for referral of patients to Mexico.

[8] According to Respondent, the chart consists of notes on the initial discussion with the prospective recipient, the medical history questionnaire, and any other ancillary information.

17. As stated above, the physicians in Mexico have been trained in the theory and procedure of stem cell transplantation by Respondent over the course of approximately one week. Respondent hires and pays the physicians who perform their duties as independent contractors. Aside from those physicians, the clinic hires medical and non-medical staff. Respondent has the authority to fire the physicians and the staff members should he so desire.

18. After the patient has paid for the treatment and traveled to the clinic in Tijuana, he/she is presented with a consent form. The form is on Stem Cell of America letterhead (or the Medra or Dulcinea Institute letterhead for earlier uses). The form was composed by an attorney at Respondent's direction. Among other things, the consent form contains the following language:

> I understand that Dr. Rader has [a] financial interest in the (FCTP) [Fetal Cell Therapy Program]. I further understand that Dr. Rader will not administer or participate in the application of any medical treatment or other aspect of the (FCTP). I will be treated solely by doctors in the Mexico [*sic*]. I also agree that I will not disclose any information; including but not limited to, an individual or public (media, web site or posting) basis, any facts regarding my own or any other patients['] treatment pertaining to Fetal Stem Cell therapy, or any other knowledge that I have acquired from Medra [or Dulcinea Institute or Stem Cell of America], its staff, any of its affiliates or associates, without the express consent of a corporate officer of Medra [or Dulcinea Institute or Stem Cell of America].

(Exhibit 7, AGO 02156.)

19. The consent form also contains the following language: "Dr. Rader or his assistant has answered all of my questions and I understand the (FCTP) therapy including the possibility of adverse reactions, which might result from the therapy, and possible damage, which might be caused, [sic] by the therapy." That language is contrary to that in Respondent's book and on his websites to the effect that fetal stem cell therapy carries no risk of negative effects. No specific risks, such as those associated with a spinal tap or lumbar puncture, are addressed in the consent form. The form also informs the patient that the treatment is experimental and that Respondent is willing to speak with the patient's treating physician. Since the patient has already paid the fee and traveled to the clinic in Mexico before seeing the consent form, he/she sometimes feels that there is little choice but to sign the form and go forward with the treatment, even if the information on the form is disconcerting or even unacceptable.

20. Respondent's name is the only name that appears on the consent form other than the name of his company. The patient is not asked to sign a consent form naming the physicians or staff in Mexico.

21. Respondent is present in the clinic when the patient undergoes the treatment. He meets with the patient after the patient signs the consent form and answers questions about the consent form at that time. Among other things, he tells the patient the method of delivery and that

the procedure is not painful. He does not discuss with them the potential for a placebo effect.[9]

22. As part of the preparation for the treatment, the physicians or staff in Mexico take the patient's vital signs including his/her oxygen saturation.[10] Thirty million cells are transplanted for each patient. Delivery is made subcutaneously, intravenously, or intra-thecally (epidural). The physicians do not perform a good-faith physical examination on the patient. Respondent does not believe it would serve any purpose since one was performed by the patient's primary physician.

23. Respondent meets with the patient again immediately following the treatment. He asks how the procedure went and how the patient is feeling, and he answers any questions the patient has. He then hugs the patient and wishes him/her a good trip back. The van then returns the patient to San Diego. Before the patient leaves, he/she is given a telephone number to call if a problem arises. That number is Respondent's cellular telephone number.

24. Respondent testified that the physicians in Mexico maintain their own records, but that he has never seen them. That testimony was not credible. No such records were offered in the administrative hearing, and no patient testified to any such records. Respondent did not testify as to the basis of his knowledge that such records are kept. Further, it is difficult to understand how Respondent would not see any documentation during the many procedures he has observed, especially in light of the fact that he trained the doctors in Mexico, that he pays them, and that he has the authority to fire them. Since Respondent disavows being the physician to any patient undergoing fetal stem cell therapy, one would expect that he would be eager to see documentation that could serve as indicia for the absence of the physician/patient relationship on his part and the establishment of the physician/patient relationship between the patient and the physician in Mexico.

25. Respondent maintains a follow-up department in his business that contacts the patients two weeks post-treatment and every three months thereafter to find out how the patient is doing and to inquire as to whether the patient has noticed any improvement. Although Respondent testified that the purpose of that contact is to ensure customer satisfaction, as part of the follow-up, he makes himself available to speak with the patients and answer their questions, and he decides whether additional treatments could be beneficial and are indicated for the patient. He is therefore performing a medical, rather than a customer service function.

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[9] The placebo effect would itself be a negative and even dangerous effect in that it could cause a patient to postpone other, possibly efficacious, treatment simply because he/she feels better, even though the disease process progresses unabated.

[10] Respondent testified that he does not know why they choose to do so and that he did not teach them to take vital signs as part of the pre-treatment procedure. He also stated that the physicians have not told him why they decided to do it, and he has not asked them why. That testimony was not credible in light of the tight controls he maintains over his business, the importance he places on making the procedure appear completely risk-free, and the fact that he trained, hired, and pays the physicians and can fire them at will if he is dissatisfied with their work.

26. Respondent requires his patients not to speak to others about the treatment or Stem Cell of America because he feels that the patients and he would be unsafe from hostile anti-abortion advocates. When asked how he reconciles that with the great emphasis he places on informing people of the benefits of fetal stem cell therapy in his book and on his websites, he testified that a balance must be struck. In his doing so, it is difficult to determine where Respondent places the fulcrum. The evidence adduced at the hearing leads to the inference that he places it between his statements and those of his patients unless those patients are offering testimonials about Respondent and/or his stem cell therapy for his websites.

The Experts

27. Complainant offered the expert testimony of Harley Ian Kornblum, M.D., Ph.D. Dr. Kornblum is a Professor of Psychiatry,[11] Molecular and Medical Pharmacology and Pediatrics at the David Geffen School of Medicine at the University of California, Los Angeles (UCLA), and is the Director of the UCLA Neural Stem Cell Research Center. He is a diplomate of the American Board of Psychiatry and Neurology with Special Competence in Child Neurology. He has won numerous honors and awards. He is the past and present holder of numerous research grants. His work has been published more than 100 times. In addition to his extensive research in stem cell science, Dr. Kornblum sees both adult[12] and pediatric patients. Dr. Kornblum has never before served as an expert witness in a litigated matter.

28. Complainant also offered the expert testimony of Robertson Parkman, M.D. Dr. Parkman is a Professor of Pediatrics and Microbiology at the Keck School of Medicine, University of Southern California. He is a former Associate Professor of Pediatrics at the Harvard Medical School. He is certified by the American Board of Pediatrics and the American Board of Allergy and Immunology. He has extensive research and clinical experience. He has over 200 publications to his credit. Dr. Parkman has never before served as an expert witness in a litigated matter.

29. Respondent offered the expert testimony of Susana G. Duncan, M.D., ABPM&R, FAAPM&R. Dr. Duncan is a practitioner specializing in sports, pain and rehabilitation medicine in New York, New York. She is a diplomate of the American Board of Physical Medicine & Rehabilitation and the National Board of Medical Examiners, Part 3. She has engaged in five research projects, including residency research, the most recent ending in 1997. Between 1972 and 1982, she was a contributing editor and then senior editor of New York Magazine in which she published articles on science, medicine, psychology and sociology. She has four medical publications to her credit. Like Drs. Kornblum and Parkman, Dr. Duncan has never before served as an expert witness in a litigated matter.

30. Dr. Duncan has not practiced in California, and she does not profess knowledge of the standard of care for physicians and surgeons in California. However, she was not

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[11] Dr. Kornblum's psychiatry professorship is an administrative position. He does not practice psychiatry.

[12] Dr. Kornblum's adult patients comprise between one and five percent of his clinical practice.

challenged on that issue, and no claim was made that the standard of care with respect to stem cell therapy differs between California and New York. Her opinions are therefore welcome in this proceeding. However, she lacks first-hand research and clinical experience with stem cells. The basis of her expertise is limited, for the most part, to 250 hours spent reading journal articles, reading Respondent's book, and discussing the issues with Respondent.

31. On balance, based on their education, training and experience, both as researchers and clinicians, coupled with their thoughtful and authoritative reasoning, the opinions of Drs. Kornblum and Parkman are more convincing than those of Dr. Duncan.

A Word About Medical Evidence

32. Clinical trials such as double-blind studies derive evidence from planned experiments based on methodologies designed to rule out as many variables as possible. Some use human subjects. Others use animals lower on the evolutionary ladder. The results are subject to statistical analysis. Because the methodologies are established, the experiments can be replicated to determine the reliability of the data.

33. Empirical evidence is based on observation. It is less structured than clinical trials, but consistent results do have value. However, because variables are, for the most part, not controlled, cause and effect can be difficult to establish. Therefore, results based on empirical evidence should be subject to replication in a controlled setting. Dr. Parkman credibly opined that, for such evidence to be reliable there must be biological evidence of change rather than an expression by the patient that he/she feels better.

34. In his book and on his websites, Respondent claims to have successfully treated 2,000 patients with fetal stem cell therapy.[13] However, in the absence of controlled studies replicating those results, too many variables exist to extrapolate those results to the general population.

Basic Information About Stem Cells

35. A great amount of time was spent during the administrative hearing discussing the complex science of stem cell research and therapy. However, not all of the information need be addressed in this Decision. The main issues in this case are whether Respondent deviated from the standard of care in his dealings with potential and actual stem cell recipients, whether he engaged in false or misleading advertising, and whether he committed dishonest or corrupt acts. Although a certain amount of knowledge regarding stem cell science is necessary to determine at least some, if not all, of those issues, the summary below covers the information necessary to make those determinations.

36. Depending on the gestational stage, stem cells may be embryonic (up to

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[13] His testimony at the hearing was essentially the same except that he denied ever treating any patient, and claimed he only referred patients to other physicians out of the United States, whom he trained, hired and paid.

approximately six weeks), fetal (six to twelve weeks), or somatic or adult (beginning at approximately 13 weeks). Somatic cells are not at issue in this matter.

37. Respondent claims he uses only neuronal fetal stem cells for stem cell therapy. He does so because they are "pluripotent," meaning they are capable of differentiating into any of the more than 200 cell types in the human body, and because they are "anti-allogenic," meaning that they are not susceptible to rejection by the host, host vs. graft disease, a condition in which the recipient's immune system attacks the new cells and prevents a graft from occurring, or to graft vs. host disease, a condition in which the immunologically-incompatible cells attack the host upon their introduction into the body.[14] He bases his opinion regarding the characteristics of fetal stem cells on his training in Ukraine and his experience with over 2,000 patient treatment histories. During the hearing, his expert witness, Dr. Duncan, contradicted Respondent to a certain extent, when she explained that, unlike embryonic stem cells, fetal stem cells are not pluripotent, but they occasionally act as if they are.

38. Dr. Kornblum disagrees with Respondent. On his website, www.medra.com, Respondent claimed "Fetal Stem Cells are the cellular building blocks of the 220 cell types within the body. The Fetal Stem Cells are used by Medra remain in an undifferentiated state and therefore are capable of becoming any tissue, organ or cell type within the body." (Exhibit 35, AGO 02406.) Dr. Kornblum wrote in response to that statement:

> Only embryonic stem cells, which are derived from a blastocyst and expanded in culture and induced plu[ri]potent stem cells are pluripotent. Although Dr. Rader likely knew about induced pluripotent stem cells and embryonic stem cells in 2010, there is no indication that the cells used were either induced pluripotent or embryonic stem cells. In fact, Dr. Rader's literature specifically states that the cells were not cultured. Thus, there are no known pluripotent cells that are isolatable from the human fetus. If the stem cells provided were either truly "neuronal" or "hematopoietic," the state of the art in 2010 would indicate that the only cell types derived from these cells would be of neural or hematopoietic linages. Another point that Dr. Rader makes in the information provided is that the cells will home in to damaged areas, repair damage where needed as well as proliferate in the body. In the treatment paradigms provided, these events are highly unlikely to happen. There is some evidence that stem cells can home in on regions of acute damage in experimental animals, but this has never been shown to be true in human clinical studies of chronic brain anoxia or chronic spinal cord injury. Furthermore, intravenous or subcutaneous administration of the cells would make such "homing" of cells highly unlikely.

(Exhibit 33, AGO 01866.)

39. Dr. Parkman disagreed with Respondent regarding the claimed lack of allogenicity in fetal stem cells, and Respondent's claim that fetal stem cells are "immuno-privileged" meaning that there is no risk of rejection, host vs. graft disease or graft vs. host disease. Dr. Parkman wrote:

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[14] Graft vs. host disease makes the patient extremely ill and can be life-threatening.

Human cells express human leukocyte antigens (HLA), and therefore, the transplantation of allogeneic tissues or cells requires the testing of both donors and recipients to ensure the persistence of the donor cells and to determine if immunosuppressive drugs are required. Therefore, the Standard of Care is to HLA type the donor and recipient and, if histocompatibility differences exist, to give immunosuppressant drugs post-transplantation.

Analysis

Erythroid and myeloid cells in the fetal yolk sac first have HLA Class I (A, B) and Class II (DR) histocompatibility antigens detected at six weeks post-conception. The cells then migrate to the fetal liver where the hematopoietic cells continue to express both Class I and Class II histocompatibility antigens with 50% of adult expression by 10 weeks post-conception. Thus, the hematopoietic stem cells and hematopoietic progenitors (CD34+) present in the fetal liver at 9-12 weeks post-conception express both Class 1 (HLA-A and
–B) and Class 2 (HLA-DR) antigens.

Fetal spinal cord cells express both Class I HLA and Class II HLA histocompatibility antigens as early as six weeks of gestational age, although the frequency of Class I expressing cells is greater than that of Class II expressing antigens. The cerebral cortex anlage has lower levels of HLA expression than spinal cord cells.

Conclusion

Dr. Rader's statements that the fetal stem cells are not antigenic, i.e. do not express HLA antigens at the time the fetal stem cells are obtained at 8-12 weeks of post-conception, are not true. Therefore, the statements in his book as well as in his interview are inaccurate and represent a lack of knowledge.

[¶] . . . [¶]

The transplantation of allogeneic cells or tissues requires the administration of immunosuppressive drugs such as cyclosporine, anti-thymocyte globulin, or corticosteroids for their intermediate or long-term persistence.

Analysis

Although immunosuppressive drugs are not necessary after the transplantation of autologous or syngeneic cells (either tissues or cells), immunosuppression is required for the prolonged persistence of allogeneic cells expressing histocompatibility antigens. Since both fetal liver and spinal cord cells expressed histocompatibility antigens and their long-term persistence is expected, the lack of administration of immunosuppressant drugs will result in their rejection by the

immunocompetent patient.
(Exhibit 49, pages 2-3.)

40. The gravamen of Dr. Parkman's position is that, as a stem cell develops from the embryonic stage to the somatic stage, it begins as non-allogeneic, but acquires Class HLA-I and later the HLA-II antigens as fetal stem cells. Fetal stem cells begin to express HLA-I at six to seven weeks. Therefore, unless the cells to be infused are autologous (from the patient's own body) or are to be exchanged between identical twins, immunosuppressant drugs must be used to prevent rejection, host vs. graft disease or graft vs. host disease.

41. Dr. Duncan conceded that fetal stem cells do carry the HLA I antigen, but not to the degree that rejection, host vs. graft disease, or graft vs. host disease will occur. She pointed out that immuno-suppressant drugs are, themselves, dangerous in that they inhibit the immune system, placing the patient at risk of infection or disease he/she could otherwise have avoided. That point emphasizes what Complainant's experts explained—that science has not yet reached the point at which fetal stem cell therapy can be safely used in the treatment of human injury and disease. Respondent's claim that over 2,000 patients received fetal stem cell therapy without rejection or negative side effects is not supported by the overwhelming weight of the medical evidence.

The Patients Referenced in the Accusation

Patient J.D.[15]

42. In 1995, J.D. underwent a routine dental cleaning that resulted in a staph infection in his blood. His condition deteriorated until he was near death. Following a magnetic resonance imaging scan (MRI), he underwent an unsuccessful decompressive laminectomy at the C4-7 levels.[16] He was told his condition was irreversible and that he would probably never walk again or use his hands and arms normally. Rehabilitation efforts were unsuccessful. In 1996, through his own work-outs, J.D. was able to regain the ability to walk. However, the condition left him in constant, excruciating pain. In 2006, after trying various treatment forms including but not limited to pain management and 92 hyperbaric treatments, J.D. heard about stem cell science on television. Additional online research led him to Respondent.

43. After viewing some videos of testimonials on the Medra website, and Respondent's statement that he had successfully treated 1,500 patients, J.D. contacted Respondent. Respondent told him he had treated seven to nine spinal cord injuries with fetal stem cells and arranged for J.D. to speak with R.K., a former spinal cord injury patient he had successfully treated. J.D. offered to forward his medical records to Respondent. Respondent

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[15] The initials of the patients and those of their relatives are used in lieu of their names in order to protect their privacy.

[16] There was some testimony at the hearing that J.D. had been suffering from spinal meningitis. Dr. Kornblum testified that J.D. had contracted transverse myelitis, an inflammation of the spinal cord, but he explained that this was not necessarily his diagnosis. Other than his own records, which do not indicate any attempt at diagnosing J.D.'s, condition, Respondent's chart contains only an incomplete operative report without a reported diagnosis.

stated it would not be necessary to do so and that he felt certain he could help J.D. with stem cells. Respondent said that one million stem cells would be transplanted, that there was no risk of disease from the transplant, and that the treatment would cost $25,000.

44. When asked, Respondent told J.D. the treatment was performed outside of the United States because it was not approved by the Food and Drug Administration (FDA). However, he had applied to have it approved, and he anticipated its approval very soon. However, he did not tell J.D. that another physician would administer the treatment. J.D. assumed Respondent was his doctor.

45. J.D. and Respondent spoke again in March 2007. Respondent was encouraging, but J.D. was reluctant to undergo the treatment because of all he had been through.

46. In or around July 2007, J.D. contacted R.K. R.K. told him she had suffered a spinal cord injury which Respondent had treated with some success over three treatments three months apart. R.K. stated that the treatment had been painful, that it felt as if she was "being taken over by some entity" (J.D.'s statement), and that she lost sensation in her legs, but that it came back some time later. R.K. encouraged J.D. to undergo the therapy.

47. J.D. decided to undergo the treatment. After a number of telephone conversations with Medra personnel, he was instructed to fill out a medical history form and return it, and to wire $25,000[17] to the Dulcinea Institute via the First Caribbean International Bank, which he did after securing a loan from his bank. J.D. did not discuss the matter with his regular physicians because Respondent instructed him not to discuss the treatment with anyone, and that he would let J.D. know when it was alright to talk about it.

48. The day after J.D. arrived in the Dominican Republic, two locals wearing jeans and t-shirts picked him up in a van and took him down a dirt road to a small house in the center of a plowed field. J.D. was surprised at this because he had anticipated being taken to a medical facility. A woman standing in front of the house introduced herself as Deborah Huff-Rader, Respondent's wife. Mrs. Huff-Rader escorted J.D. to a bedroom in the house that appeared to be a normal residential bedroom as opposed to a medical treatment room. Two Spanish-speaking women were in the room. They were not wearing clothing representative of medical professionals. They did not speak to J.D. Mrs. Huff-Rader told J.D. to make himself comfortable on the bed. Respondent telephoned and said he would arrive shortly. One of the women established an IV but did not state its purpose. In 10 to 15 minutes, Respondent arrived with a vial containing a yellow liquid and told J.D., "These are your stem cells." Respondent handed the vial to one of the women and she picked up a syringe. He told J.D. to unbutton his shirt. He then placed a piece of paper on J.D.'s lap.

49. The document was a consent form. J.D. scanned it without reading it carefully. However, he was concerned about it because he had not been made aware that the treatment was experimental or that Respondent would not be performing the procedure. Nor had he been aware of the possibility of adverse reactions or possible danger as referenced in the consent form. The

[17] The $25,000 was for the treatment only. It did not include airfare or lodging.

consent form required that he not disclose any information regarding his or anyone else's treatment or any knowledge he had acquired from Medra and/or its staff absent the express consent of a Medra corporate officer. J.D. was hesitant to sign the consent form, but he had already paid for the treatment and traveled to the Dominican Republic, so he decided to proceed with the treatment. Respondent did not discuss any risks or benefits of fetal stem cell therapy with J.D. before J.D. signed the consent form.

50. After J.D. signed the consent form, Respondent instructed the woman to give J.D. three injections in the abdomen and to place some of the liquid in the IV. Respondent gave J.D. a card stating that it bore his personal telephone number, and he instructed J.D. to call him if a problem arose. Five minutes later, the IV was disconnected and J.D. was taken back to his hotel. He returned home the next day.

51. Beginning three months after the treatment, Medra personnel telephoned J.D. occasionally to ask how the procedure had gone and how he was doing. At six months, there still had been no improvement in his condition. J.D. spoke with Respondent in February 2009. Respondent said, "You'll be normal again, I promise. I just don't know when." He told J.D. that patients occasionally required additional treatment and suggested that he go to Tijuana for another treatment. Respondent offered the second treatment at no cost to J.D.

52. J.D. decided to undergo a second stem cell treatment. The procedure in Tijuana was the same as it had been in the Dominican Republic. He had not been told his medical information would be shared with anyone outside of Medra, and he had not signed an authorization for release of his medical records. The day after his arrival he was taken to a facility next door to a mall and was directed to a cubicle containing a leather-covered lounge chair. Respondent and a local woman were present in the cubicle. Respondent's wife and another woman were outside the cubicle. No one wore medical uniforms. The woman in the cubicle established an IV. Respondent handed a consent form to J.D. and said he had to sign it or they could not proceed. He did not discuss any risks or benefits of the therapy with J.D. J.D. signed the form, and the woman placed the entire vial into the IV. At that time, J.D.'s pain spiked and he was unable to hold still. Respondent was "hovering" (J.D.'s term) over him saying he must stay still. They finally got the IV into J.D.'s vein. Respondent then said he knew what needed to be done: J.D. had to return to the Dominican Republic the next month for an epidural, and that he thought he knew a woman who could do it. J.D. is certain Respondent said "woman," not "doctor." A few minutes later, Respondent had received the entire contents of the vial. He was returned by van across the border.

53. No one from Mexico followed up with J.D. In April 2009, he received a telephone call from Terrie at Medra. He told her he still had no relief. He was undecided about returning to the Dominican Republic for a third treatment, but eventually decided to go. In July, Respondent offered the epidural at no charge.

54. Upon arriving in the Dominican Republic, J.D. was taken to a small house near the ocean. It appeared to be a private home. J.D. noticed a bar to his right when he entered. He was taken to a large room which housed a regular residential bed. Respondent instructed him to lie down on it, and he gave J.D. another consent form which J.D. signed. Respondent instructed

J.D. to face the wall and lower his pants to expose his back. Respondent did not discuss the risks or potential side effects of an epidural.

55. Two Dominican women and Respondent's wife were present. One of the women told the other to swab alcohol on J.D.'s back. Respondent then helped her identify the precise location for insertion of the syringe. The woman gave J.D. the injection. Respondent left the room, returned with two men who were dressed in jeans and t-shirts, and instructed the men to lift the end of the bed, which they did. Respondent told J.D. he had instructed them to do so to help the stem cells migrate to the area of damage. J.D. returned home the following day.

56. J.D. experienced no benefit from any of the three treatments. A subsequent open MRI showed no changes. He remains in extraordinary, constant pain today for which he takes multiple doses of MS Contin (morphine sulfate). His new neurologist explained that the science of stem cells had not progressed to the point at which stem cells could be made into the type of cells that could help him, and that there was no way the stem cell treatments J.D. received could have helped him. Shortly thereafter, J.D. viewed the 60 Minutes television show about doctors injecting stem cells for large fees with no results. He saw Medra's logo in the center of the screen.

57. A couple of months after the third treatment, J.D. developed "horrible headaches" (J.D.'s term) that lasted for hours. The evidence did not establish a nexus between the stem cell treatments and the headaches.

58. At one time during the course of their relationship, Respondent said to J.D. "I'm your doctor. You have to trust me." However, during the course of the entire relationship, over three stem cell treatments, Respondent made no effort to determine the cause of J.D.'s excruciating pain.

59. Dr. Duncan took the position that Respondent was not J.D.'s physician. Therefore, he would not be subject to the standard of care. Dr. Duncan explained that Respondent is a psychiatrist and is not in a position to evaluate an individual's physical condition or attempt to add to the diagnosis. She did not acknowledge that a physician's specialty does not limit his/her ability to practice in other areas of general or specialized medicine. She also testified that no physician-patient relationship is established absent a specific agreement between the physician and the patient. Because Respondent never specifically agreed to serve as the physician for any of the patients involved in this case, he was not the physician of any of them. However, even if he were their physician, his conduct had been within the standard of care in all respects. Dr. Duncan did not address Respondent's conduct with respect to any particular patient.

60. Dr. Kornblum opined that Respondent acted as J.D.'s physician by evaluating and recommending a specific course of treatment which was then undertaken. The evaluation was a discussion between J.D., Respondent, and Respondent's staff. It was important for Respondent to obtain J.D.'s medical records so he could better understand J.D.'s condition. Because the transplantation of stem cells was an invasive procedure, it was incumbent upon Respondent to evaluate J.D.'s medical records and to evaluate J.D. in person. As stated above, the opinions and reasoning of Dr. Kornblum and Dr. Parker are more convincing than those of Dr. Duncan.

61. Based on Dr. Kornblum's opinion and the reasons supporting it, Respondent was J.D.'s physician, and he failed to properly evaluate J.D. That failure constitutes an extreme departure from the standard of care.

62. Dr. Kornblum also opined that Respondent failed to discuss the risks and benefits of fetal stem cell therapy with J.D. That opinion is consistent with Respondent's testimony and steadfast position that he does not discuss them with the patient because there are no risks associated with the treatment. Dr. Parkman opined that, because fetal stem cells are not anti-allogenic, Respondent's failure to administer immunosuppressive drugs constitutes an extreme departure from the standard of care. (Exhibit 9, AGO 02247.) Respondent's decision against administering immunosuppressive drugs to J.D. posed a risk he should have disclosed. Respondent's failure to discuss with J.D. the risks and benefits of the treatment he received constitutes an extreme departure from the standard of care.

63. Complainant also alleged with respect to Patient J.D. that Respondent deviated from the standard of care by "recommending that patient J.D. undergo a fetal stem cell treatment when there was no medical evidence that such treatment could benefit patient J.D." (Accusation, p. 10, para. 36A.) Complainant did not sustain her burden of proof on that issue. Although there was no evidence in the form of clinical studies to support Respondent's position, Respondent relied on empirical evidence in making his recommendation. Both Drs. Kornblum and Parker conceded that empirical evidence can be of value in certain situations. Thus, there was not a complete absence of evidence, only a lack of formal evidence.

Patient. J.S.

64. J.S. is a 35-year-old man who was involved in a motorcycle accident on April 15, 2006. He suffered a C6-7 crush injury in the accident that left him paralyzed from the chest down. He is confined to a wheelchair. Following the accident, his mother became his primary caregiver. J.S.'s injury is considered an incomplete spinal cord injury meaning that some signals to and from the brain are still able to traverse the damaged spinal cord.

65. Over time, through occupational therapy and physical therapy, J.S. gradually gained strength and was eventually able to drive a handicap van. However, physical therapy was expensive, and it eventually stopped yielding its earlier benefits.

66. J.S.'s mother, P.S., began researching alternate therapies for her son and became interested in stem cell therapy. She contacted a neurosurgeon who told her the research had not yet progressed to the point that stem cells could help J.S. However, P. S. continued to research the issue, and an Internet search led her to the Medra website. After watching the videos on the website, she discussed the possibility of stem cell treatment with her son who expressed an interest. P.S. then e-mailed Medra on his behalf and was contacted by Medra personnel. Following a few telephone conversations, they sent P.S. a patient information form to be filled out and returned.

67. In June 2008, P.S. spoke with Respondent who told her he had treated

approximately 35 spinal cord injury patients and all had improved although not all were walking. He explained that he did not treat individuals with complete spinal cord injuries. He stated he was the only one in the world performing the stem cell transplantation procedure, that his stem cells proliferated forever, and that they were never rejected. He told her that her son was certain to improve with his treatment because of his age and physical condition. However, another employee at Medra had told P.S. that there were no guarantees of improvement.

68. On another occasion, Respondent spoke directly with J.S. Respondent told J.S. that stem cells would work well with an incomplete spinal cord injury such as his. He did not further discuss the risks or benefits of the treatment, and he did not tell J.S. how the cells would be injected. J.S. asked if Respondent wanted to speak with his physicians. Respondent said it would not be necessary.

69. J.S. and his mother agreed that he should undergo the procedure. P.S wired $30,000 to the Dulcinea Institute in the Bahamas with the understanding that Respondent was J.S.'s doctor. The $30,000 was to cover the treatment only, exclusive of travel expenses. P.S. was not told that J.S.'s medical information would be shared with others. She and her son then flew to the Dominican Republic.

70. No one appeared to greet them upon their arrival. They took a shuttle bus to their hotel, but it did not have a ramp. Two men lifted J.S. from his wheelchair and put him on a seat without a seat belt. The following day, they were picked up by a van to go to the treatment site. Two men pushed J.S. up a makeshift wooden ramp into the van. He was not strapped in. They were taken to an area of new residential construction where they entered a completed house. They were greeted by a man and a woman, who identified herself as Deborah Rader. She told J.S. and his mother that Respondent had a prior engagement in the United States and was unable to attend the procedure. That surprised J.S. because Respondent had informed him by telephone that he would be present and would perform the procedure himself.

71. J.S. was taken to a bedroom of the house that was furnished with a residential bed and nightstand. It had an adjacent bathroom. J.S. chose to stay in his wheelchair and did not transfer to the bed. A woman established an IV and took a small blood sample. She left and returned approximately 10 minutes later with a container. While J.S. and P.S. were waiting for her to return, they were given two forms. The first was a consent form. The second was a form according to which they were to promise not to disclose any information. P.S. signed the consent form on her son's behalf. However, she wanted to tell everyone about their experience, so she refused to sign the second form. Shortly thereafter, Respondent's wife brought a telephone to P.S. and told her Respondent was on the line. Respondent explained that the pharmaceutical companies would attempt to shut him down if they learned what he was doing.

72. P.S. signed the consent form after discussing it with J.S. She signed it even though she had not been told Respondent would not be there and that other doctors would be involved. She thought Respondent would perform the procedure. She had not been advised of the possibility of an adverse reaction. She had not been told the treatment was experimental. She had been told only that there was no guarantee of improvement and that the treatment was not legal in the United States.

73. Once both forms had been signed, the woman gave J.S. two injections in his abdomen and placed the remainder of the material in the IV. This was done in the absence of a physical examination or the taking of J.S.'s vital signs. Following the treatment, Respondent's wife told J.S. that Respondent wanted to speak with him. In a brief telephone conversation, Respondent asked J.S. how the treatment went, and that he was sorry he had been unable to be there. A few minutes later, another van came to return J.S. and his mother to their hotel. They were not given any after-care instructions.

74. Approximately six months later, J.S. received two telephone calls from Medra inquiring as to whether he had experienced improvement. He said he had not. Medra personnel asked if he wanted to go back for another injection at no charge. J.S. declined.

75. Thereafter, J.S.'s mother began making vitriolic, disparaging entries against Respondent and people associated with him on a Topix.com board. She claimed she did it to "save other people." (P.S.'s statement.)

76. Dr. Duncan opined in general terms only. She did not address the standard of care with respect to J.S. specifically. She stated only that Respondent did not act as the physician for any patient, but that if he did, he had comported himself within the standard of care in all respects.

77. Dr. Kornblum opined that the physician-patient relationship between Respondent and J.S. was established by his recommendation for treatment. Even though Respondent was not present when the treatment was administered, he arranged for the treatment, and the treatment would not have taken place at all without his involvement in the case. It is analogous to a physician who arranges for his patient to undergo surgery by a surgeon but is not present during the surgery. Because Respondent was J.S.'s physician, he was obligated to properly evaluate J.S. before recommending fetal stem cell therapy. The evaluation would include "an understanding of the timing and mechanism of the injury" and "appropriate immunologic testing of the sample to be administered as well as the patient, depending on the type of sample, a knowledge of the general health of the patient to ensure that . . . they would be able to both get to the site of treatment as well as tolerate the treatment and potential side effects of the treatment." (Exhibit 33, AGO 01865.) In addition, a physical examination must be performed. Dr. Kornblum credibly opined that Respondent's failure to properly evaluate J.S. before recommending treatment was an extreme departure from the standard of care. That opinion is adopted as a factual finding herein.

78. Dr. Kornblum further opined that Respondent failed to provide concise, understandable and accurate information regarding the potential risks and benefits of the fetal stem cell therapy. He wrote:

> Part of any informed consent procedure includes a discussion of the risks of therapy. In numerous locations, including discussions between Dr. Rader and the patients' family, in materials from the Internet, in Dr. Rader's book statements are made to the effect that there are no side effects of treatment. This is untrue. Potential side effects from the treatments proposed range from minor

> side effects to major side effects and even death. First, the process of injection has potential side effects. Any introduction of a needle into the body can result in bleeding which is usually mild or self-limited as well as infection, which can also be very mild, but can also be life-threatening. The cells, themselves, or the fluids or vehicles used in treatment can also carry infection. Although there is assurance from Dr. Rader that the cells are tested by PCR for infections, it is not clear what these infections are and there is no documentation of such testing procedures provided or any documentation of certification of the accuracy of such tests. Furthermore, specific routes of administration can carry with them specific risks. Administration into the intrathecal space, a route suggested in the interview with Dr. Rader, for example, can introduce serious infections into the cerebrospinal fluid, resulting in meningitis. The misplacement of needles can also cause bleeding and even paralysis. The introduction of cells into the intravenous space can also cause more serious infections than simple introduction into the subcutaneous space. While standard precautions can be taken to minimize these risks, they cannot be eliminated completely. There is no discussion of such risks in any of the literature I have seen, nor in the statements provided by the families of Mr. C . . . and S. . . . Furthermore, there is no indication that the suppliers of the cells or the Rader group have standard operating procedures that would ensure the safety and purity of the cells. Another point on which there is false or misleading information provided to the patients is the issue of immunogenicity. There are several documents indicating that the cells cannot be rejected. All allogeneic (cells bearing genes different from the recipient) cells can give rise to an immune response. This is true now and there was no reason to believe the contrary in 2010. Rejection, if untreated will cause treatment failure. A most devastating potential complication, in the case of hematopoietic stem cell infusion is that of graft vs. host disease. Although it is very unlikely that any of the hematopoietic stem cells will achieve the targeted goal of engraftment, if such proves to be true, there is a likelihood that the immunocompetent cells produced from the stem cells would view the host as "other" and attack the host's cells. In its most severe case, graft vs. host disease can be lethal. In the least, it requires supportive management. Taken together, the failure of Dr. Rader or his staff to provide concise, understandable and accurate information of the potential risks and benefits of the proposed therapies represents an extreme departure of standard of care.

(Exhibit 33, AGO 01866-01867.)

79. Dr. Korblum's opinions and the reasons therefor are convincing. Further, Dr. Parkman opined that, because fetal stem cells are not anti-allogenic, Respondent's failure to administer immunosuppressive drugs constitutes an extreme departure from the standard of care. Respondent's decision not to administer immunosuppressive drugs to J.S. posed a risk he should have disclosed. Respondent's failure to provide concise, understandable and accurate information regarding the potential risks and benefits of the fetal stem cell therapy constitutes an extreme departure from the standard of care.

80. As with Patient J.D., Complainant alleged that Respondent committed gross

negligence and repeated negligent acts by recommending to J.S. that he undergo fetal stem cell treatment when there was "no medical evidence that such treatment could benefit patient J.S." (Accusation, page 9, para. 29A.) Complainant failed to prove that allegation for the same reasons set forth with respect to Patient J.D., above.

Patient H.C.

81. In 2010, H.C., then approximately 73 years old, became ill and comatose for two weeks. He emerged from the coma with an anoxic brain injury. His physicians told his family there was no hope for survival, and they recommended that his family consent to have him removed from life support. However, when they consented and life support was removed, H.C. continued to breathe on his own. After approximately one week, his wife and five daughters took him home where his daughter, I.T., acted as his caregiver with the assistance of hospice services. Although he was breathing on his own, H.C. was completely dependent on others for all other aspects and activities of daily living.

82. I.T. was "desperate" (I.T.'s term) to find a way to improve her father's health. She researched the Internet and wrote to television personality, Dr. Oz. (She received no response from him.) Her Internet search brought her to the Medra website where she read and viewed testimonials from individuals with a wide range of disorders, including brain injuries, who had experienced dramatic improvement through the use of fetal stem cell therapy. According to the website, Respondent had successfully treated 1,500 patients. He described his procedures on the website. I.T. was interested, and she sent an e-mail to Medra. She received a reply within five minutes. She subsequently spoke with John Brower at Medra, who told her H.C. was a "perfect candidate" (I.T.'s term) for stem cell therapy. Mr. Brower did not disclose that he was not a physician.

83. Within a few hours of I.T.'s initial e-mail, a conference call took place between Respondent, H.C.'s wife and daughters, and Mr. Brower. The family explained the nature of H.C.'s brain injury. Respondent told them that stem cells would go to the brain, "re-open" it (I.T.'s term) and re-grow healthy cells. The cells would be injected into the brain and arm at a cost of $30,000. H.C. would travel by helicopter (air ambulance) from his home in Mobile, Alabama to the Dominican Republic at a cost of $2,000.[18] Respondent stated the procedure had to be performed as quickly as possible. The family could not afford the price of treatment and transportation, so Respondent recommended that the treatment be performed in Mexico at a cost of $20,000. The family understood that Respondent would personally perform the procedure. He said nothing about physicians in Mexico. I.T. and her mother decided to accept that option. The remainder of their family was skeptical and did not approve of their father traveling from Mobile to Tijuana for fetal stem cell therapy. When the family was subsequently unable to raise the money for the trip and the treatment, Respondent's wife reduced the price of the treatment to $17,500, provided it was paid in cash.

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[18] Respondent's records indicate that transportation was to be by prop jet air ambulance at a cost of $22,000 or by "jet" (presumably fan jet) at a cost of $28,000. (Exhibit 18, AGO 01793.).

84. On February 11, 2010, Mr. Brower wrote two letters to "to whom it may concern" requesting expedited passports for I.T. and a friend who would be traveling with them. The letters were written under Respondent's/Medra, Inc.'s letterhead. The body of each letter began with the following language: "This letter is to confirm that Mr. H . . . C . . . is a patient of Dr. William C. Rader MD . . ."

85. The family was provided with a medical history form which they completed and signed on February 16, 2010. The family was not told the information would be shared with a physician in Mexico, and they were not asked to consent to it. The treatment was planned for February 20.

86. Instead of paying for an air ambulance, I.T. and her mother rented a recreational vehicle (RV) and, with a friend and one of I.T.'s sisters, began the trip to California where they would meet Respondent's employees who would escort them through the border without her father having a passport.

87. The trip began on February 17, 2010 with arrival planned for February 20. During the trip, H.C.'s blood pressure dramatically vacillated between 40/24 and 160/98. I.T. attempted to stabilize his blood pressure by medicating him through the tube that physicians had inserted in his abdomen. While driving through Texas, the problem became so intense that the family called 911. Paramedics were able to stabilize H.C. However, the problem returned four or five hours later. This time, I.T. telephoned Respondent and asked if he could help. Respondent asked if anyone on the RV had a Valium. When the family located one, Respondent instructed I.T. to give it to her father.

88. When the family arrived in San Diego on February 19, H.C.'s condition was so deteriorated that they were unable to go to the hotel. An ambulance transported H.C. to the Emergency Department at Scripps Mercy Hospital where he was initially seen by Clayton Whiting, M.D.

89. Dr. Whiting found H.C. chronically debilitated and ill and in a chronic vegetative state. H.C. was breathing on his own; he had a pulse; he was unable to communicate; he had contracted musculature, and his blood pressure was somewhat depressed. However, he was "essentially stable" (Dr. Whiting's term) and did not require immediate intervention. Dr. Whiting believed H.C. was at the end of life with an anticipated life expectancy of three to six months. Dr. Whiting called for a consult by Denise Waugh, M.D., a specialist in hospice and palliative medicine.

90. While providing the medical history, I.T. had informed Dr. Whiting that the family was enroute to Mexico for her father to receive stem cell treatment, and that Respondent was H.C.'s doctor. After Dr. Whiting called in Dr. Waugh, I.T. asked Dr. Whiting to speak with Respondent. Respondent then instructed Dr. Whiting to render no treatment other than to give the patient fluids, and to have the patient continue to Mexico with his family. Dr. Whiting declined that instruction.

91. Dr. Waugh examined H.C. after receiving his history from I.T. She found him

non-responsive and close to death. Sensory and motor functions were absent. Dr. Waugh went to the Medra website to verify what I.T. had said about Respondent. The family expressed the desire to have H.C. continue to live or to die comfortably. They were troubled about being estranged from the other family members, and they were open to the opinions of Drs. Whiting and Waugh. Dr. Waugh offered the family inpatient hospice at the hospital or elsewhere. She was concerned that H.C. would die in the RV if the family attempted to return him to Alabama. The only appropriate therapy at that point was supportive therapy, and to address the spiritual and psycho-social issues for the family. The family members wanted to re-unite the family, and they did not want to deny the other family members the possibility of seeing their father alive again. They chose to return home to Alabama.

92. Once enroute, I.T. and Respondent spoke by telephone. Respondent offered to perform the procedure for free if I.T. would turn around and bring her father to Tijuana for the treatment. I.T. declined the offer. H.C. survived the return trip to Alabama but died on March 15, 2010. Upon I.T.'s request, Respondent reimbursed her for the RV rental and gasoline. According to I.T.'s testimony, the reimbursement was conditioned on I.T.'s written promise not to tell anyone what had occurred. However, the letter the family sent to Respondent refers to the reimbursement and states, "We will not pursue any futher [*sic*] actions against you." (Exhibit 12, AGO 00067.) There is no reference to a promise not to disclose the events relating to H.C.

93. Respondent testified that, although he believes he had a telephone conversation with Dr. Whiting, he does not recall it. That testimony had little credibility. This was not the kind of conversation likely to skip one's mind. This was a call across an international border with an emergency department physician about a patient Respondent was waiting to arrive in an RV, but who was in a chronic vegetative state on the other side of the border. However, Respondent does remember offering to treat H.C. for free if I.T. would bring him to Tijuana.

94. Despite that recollection, Respondent testified that he had not been H.C.'s physician and that he had not approved H.C. to receive the stem cell treatment. However, Medra's chart for H.C. contains the two letters identifying Respondent as H.C.'s physician, a number of references to "Dr. Rader's evaluation," and statements from at least two Medra employees that H.C. would receive the treatment in the RV.

95. As stated above, Dr. Duncan took the position that Respondent did not serve in the capacity of physician for any patients, but if he did, he comported himself within the standard of care in all respects.

96. Dr. Kornblum's and Dr. Parkman's opinions were the same with respect to H.C. as they were in connection with J.D. and J.S. Their opinions and their underlying reasons are more persuasive than those of Dr. Duncan.

97. Respondent's failure to properly evaluate H.C. before recommending treatment, and his failure to provide concise, understandable and accurate information regarding the potential risks and benefits of the fetal stem cell therapy each constitute an extreme departure from the standard of care.

98. As with Patients J.D. and J.S., Complainant alleged that Respondent committed gross negligence and repeated negligent acts by recommending to H.C. (via his family) that he undergo fetal stem cell treatment when there was "no medical evidence that such treatment could benefit patient H.C." (Accusation, page 7, para. 21A.) Complainant failed to prove that allegation for the same reasons set forth with respect to Patients J.D. and J.S., above.

99. Dr. Kornblum also criticized Respondent for giving medical advice for H.C. without adequate training and knowledge to understand the situation and recommend a course of treatment, both with respect to recommending Valium belonging to someone else and in making treatment recommendations to the emergency department physician. Dr. Kornblum considered Respondent's conduct in that regard an extreme departure from the standard of care. He wrote:

> Dr. Rader recommended directly to the treating physicians that Mr. C . . . was to be given fluids and released, as demonstrated in the notes. In the setting of a critically ill elderly person, such recommendations would require careful evaluation by an experienced, appropriately trained physician. There is no evidence that Dr. Rader has such training or experience. The recommendation made by Dr. Rader would represent an extreme departure from the standard of care.

(Exhibit 33, AGO 01867-01868.)

100. Respondent's medical decision making with respect to his instruction to give the patient a Valium and his instructions to the emergency department physician constitutes an extreme departure from the standard of care.

Undercover Patient E.B.

101. Between February and November 2012, two investigators for the Board conducted an undercover operation in connection with Respondent's business. On February 18, 2012, the first investigator, using an assumed name (C.A.), sent a contact inquiry to the Medra.com website, claiming her friend, E.B., had suffered a spinal cord injury and was interested in stem cell therapy. A few days later, she was contacted by Ken Venisnik from Medra.

102. On March 15, 2012, a conference call was held between C.A., E.B., and Venisnik. Venisnik denied having any medical background. He claimed to be Respondent's assistant or secretary. He stated that Respondent had treated his son whose condition had improved with the treatment. He provided the undercover investigators with information about stem cell therapy and said the cost of treatment was $30,000. C.A. asked to speak with Respondent, and Venisnik agreed to forward the request to Respondent along with what he had learned about E.B.'s condition. Shortly after that conversation, C.A. received a link to Respondent's book.

103. On April 2, 2012, C.A. and E.B. participated in a conference call with Respondent. Respondent told them about fetal stem cell therapy, that he was the only physician in the world doing it, and that he had treated over 2,000 patients, more than 100 of whom had spinal cord injuries. Most of those patients had shown improvement. Respondent told them the

cells come from fetuses aborted in Eastern Europe, that the cells were harvested and tested at his laboratory in Germany and then sent to treatment sites in the Dominican Republic and Tijuana. He discussed his book stating that what he was doing was unavailable in the United States because "the powers that be" (C.A.'s term) were blocking its use. He believed fetal stem cell therapy would definitely benefit E.B. because E.B.'s spinal cord injury was incomplete. He stated the procedure would be a lumbar puncture or spinal tap performed by an anesthesiologist in Tijuana with Respondent present, and that his employees would follow up at three months. E.B. would be given Respondent's private e-mail address and cellular telephone number. Respondent further stated that no side effects were possible because of the nature of the fetal stem cells. He confirmed that the cost of the treatment was $30,000 and said E.B. might not notice any improvement for three to six months. E.B. asked if Respondent needed to see him before the procedure. Respondent stated that it would not be necessary. Following that conversation, a Medra staff member requested a recent MRI. The investigators did not provide one.

104. Respondent's records for April 2, 2012, indicate that Respondent would administer both an epidural and lumbar puncture.

105. C.A. read Respondent's book and found numerous references that led the reader to believe he was the treating physician for fetal stem cell patients. (See Factual Finding 146.)

106. C.A. contacted Medra again on October 12, 2012. By that time, the company name had changed to Stem Cell of America. On October 18, she informed Stem Cell of America personnel that she had raised $25,000 of the required $30,000. She did not request a discount. However, she was offered two different discounts according to certain payment dates. November 17, 2012 was scheduled for the day E.B. would undergo the treatment.

107. On October 26, 2012, C.A. and E.B. participated in another telephone conversation with Respondent. Respondent did not seem to remember them, and he reiterated the same things he told them during their first conversation. E.B. asked Respondent about informing his neurologist of the stem cell treatment. Respondent stated he usually discouraged patients from telling their doctors about it because the doctors disapprove of it, but that E.B. could tell his neurologist after the treatment was completed. However, Respondent predicted that the neurologist would attribute any progress to spontaneous improvement.

108. C.A. subsequently received information from Stem Cell of America regarding travel arrangements and instructions on how to wire funds to cover the fee. Neither C.A. nor E.B. ever wired any funds or submitted a medical history questionnaire. C.A. did, however, receive a confirmation on the November 17 treatment date. On November 1, 2012, C.A. sent an e-mail to Stem Cell of America informing them that E.B. could not keep his appointment. She received a reply stating that Respondent had not yet spoken directly with E.B., even though he had done so twice.

109. On February 13, 2013, the investigator who had posed as C.A. conducted an interview with Respondent. During that interview, Respondent stated he does not treat patients, but is more of a referral service who refers patients to foreign physicians who decide whether to treat the patient. He denied making recommendations for patients. These statements were

contrary to statements Respondent made during the undercover operation.

110. As stated above, Dr. Duncan took the position that Respondent did not serve in the capacity of physician for any patients, but if he did, he comported himself within the standard of care in all respects.

111. Dr. Kornblum's and Dr. Parkman's opinions and their bases were the same for E.B. as they were with respect to the other patients. Their opinions and their bases were credible and persuasive. Respondent's failure to properly evaluate E.B. before recommending treatment, and his failure to provide concise, understandable and accurate information regarding the potential risks and benefits of the fetal stem cell therapy each constitute an extreme departure from the standard of care.

112. However, as with the other patients, Complainant alleged that Respondent committed gross negligence and repeated negligent acts by recommending to E.B. that he undergo fetal stem cell treatment when there was "no medical evidence that such treatment could benefit patient E.B." (Accusation, page 7, para. 21A.) Complainant failed to prove that allegation for the same reasons set forth with respect to Patients J.D., J.S., and H.C., above.

The "Fact" Patients

113. Respondent offered the testimony of four "fact witnesses" (Respondent's term), individuals who had successfully undergone, or whose child had successfully undergone, fetal stem cell therapy through Respondent's companies.

S.F.

114. S.F. resides near Chicago. She is married to an ophthalmologist who specializes in stem cell therapy. She wanted to stay as young looking and feeling as possible. She was undergoing hormone replacement therapy when she asked her physician if there was anything else she could do. He referred her to Respondent.

115. Respondent did not offer S.F. any guarantees, but he told her he had successes in the anti-aging area. S.F. underwent her first treatment in the Dominican Republic in November 2002. She was treated in a hospital or clinic setting. She signed a consent form when she arrived at the clinic. She understood the treatment was experimental and that Respondent would not be her doctor. Respondent did not participate in the procedure. She paid $25,000 for the treatment.

116. Having experienced no benefit from the first treatment, S.F. returned three months later for a second. She was charged $2,500. Respondent told her that, if she felt no improvement that time, the stem cells were working on something of which she was unaware.

117. S.F. again had no benefit from the stem cells. She returned to the same facility for a third treatment, again with no results. Respondent told her to wait one year before returning.

118. S.F. continued to treat with her regular physician during the course of the three

treatments. At some point, she contracted chronic lymphocytic leukemia. She was told the disease was chronic, and there was no treatment available until it became acute. S.F. continued to get stem cells once per year. Each time, the number of atypical cells was reduced. S.F. believes the fetal stem cells saved her life. Her physician agrees.[19] However, at the hearing, S.F. had no documentation to establish the efficacy of the stem cell treatment.

W.G.

119. W.G. is a radiologist. His daughter was born on August 1, 2005. She developed mitochondrial disease. Although she manifested signs and symptoms of the disease as an infant, it was not diagnosed until age two or three. She became unable to walk, crawl, feed or speak.

120. W.G. read the literature on stem cell therapy and learned that it was not at the point where it could be utilized. Eventually he reached Respondent who provided him with information that led him to decide the benefits of the therapy outweighed any possible risks.

121. W.G's daughter underwent her first fetal stem cell treatment in October 2009. W.G. understood that Respondent would not perform the procedure, but that he would be there for "moral support." (W.G.'s term.) He also understood that the FDA did not approve the treatment. He signed a consent form indicating the treatment was experimental and might not work. W.G. felt fully informed when he consented to the treatment. Following the first treatment, W.G.'s daughter showed improvement. She was hospitalized less frequently, and she became more affectionate.

122. W.G. took his daughter for a second treatment in approximately February 2011. She showed more improvement after that treatment in that she was hospitalized for epilepsy less frequently, and she was able to walk 44 stairs. She started school at age five.

123. W.G.'s daughter underwent two subsequent treatments. Each time, her improvement rate increased, and she went from being unable to go outdoors to wanting to go out.

124. W.G.'s daughter died of arrhythmia shortly after the fourth stem cell treatment. W.G. believes her death was caused by complications from her disease. Nonetheless, he attributes her improvement to the fetal stem cell therapy. He believes there was no hope for his daughter without it, and that the therapy should not be kept from other children. W.G. has offered to help Respondent in the future by sharing his experiences regarding his daughter's treatment and

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[19] S.F.'s primary care physician, Walter R. Grobelny, M.D. submitted a declaration, signed under penalty of perjury, which was admitted as Exhibit VV. In it, Dr. Grobelny states that S.F. sought embryonic stem cell therapy outside the country against his instructions and without his support. S.F. disputed those statements claiming he had supported her decision to undergo the therapy. Further, S.F. testified that Dr. Grobelny only assumed the stem cells were embryonic as opposed to fetal. This discrepancy emphasizes the extant difficulties in using empirical evidence as a measure of treatment efficacy. Given the disparities between Dr. Grobelny's declaration and S.F.'s testimony, both of which were offered under penalty of perjury, both are given only limited weight.

improvement.

J.G.

125. J.G. is a retired nurse with a degree in counseling. She has 15 children. One of her daughters was a school football and basketball star who developed a swollen ankle and foot in 2009 that prevented her from walking well. J.G. sought traditional treatment for her daughter, but the condition worsened and she developed swelling in the wrist, headaches, fatigue, numbness in the fingers, and a rash around her face. She was eventually diagnosed with lupus and arthritis. Conventional medical treatment, including chemotherapy, did not help, and her condition continued to deteriorate.

126. In approximately April 2013, J.G. contacted Respondent after viewing his website. Respondent did not promise results, but J.G. decided that fetal stem cells were her last hope, and she took her daughter to Mexico for the treatment.

127. J.G. was given a consent form when she entered the office in Mexico. She read it and understood the treatment was experimental and that results were not guaranteed. She expected the nursing staff to perform the procedure.

128. The facility where the treatment took place was clean and well-staffed. J.G. and her daughter were taken to a room that looked like a treatment room in a physician's office. Respondent was present but did not participate in the procedure. Vitals were taken and an IV was established. Stem cells were delivered through the IV and abdominal injection.

129. Following the treatment, J.G. and her daughter were taken back to their hotel. Within two or three hours of the treatment, J.G.'s daughter was walking on the elliptical machine and the treadmill in the hotel. They returned home, and her daughter regained her energy. She subsequently underwent a second fetal stem cell treatment.

130. This year, J.G.'s daughter was named the most valuable player on her football team. J.G. attributes her daughter's improvement to the fetal stem cell treatment. She believes Respondent saved her daughter's life by giving her the opportunity to receive stem cell therapy. J.G. did not research whether the treatment was being offered elsewhere in Mexico.

131. Respondent was the only physician with whom J.G. spoke concerning her daughter's stem cell therapy. However, she did not consider Respondent to be the treating doctor.

132. At the hearing, J.G. did not have any documentation to establish the efficacy of the fetal stem cell therapy.

C.P.

133. C.P. has or had Parkinson's Disease. In addition, an accident she suffered in her youth left her hard of hearing.

134. C.P. first noticed symptoms of Parkinson's Disease in December 2011 when she developed hand tremors. Thinking they would resolve on their own, she postponed seeing her internist for one year. He then prescribed medication that was only partially effective. A neurologist agreed with the internist's diagnosis and kept C.P. on the same medication. However, within approximately two months, her condition deteriorated rapidly. A DaT scan showed a mild loss of dopamine in the brain but not enough to raise a concern about Alzheimer's Disease. Nonetheless, C.P. was suffering from tremors, her body was jerking, and she was unable to articulate words. She was repeatedly told there was no cure for her condition. She thought she was dying.

135. An online search about Parkinson's Disease led C.P. to the Stem Cell of America website. She spoke with a man at Stem Cell of America, and she obtained and read Respondent's book. She decided to try fetal stem cell therapy.

136. C.P. received a medical history form in the mail which she filled out and returned. She was told it would be reviewed, but she was not told who would review it. C.P. assumes Respondent reviewed the form. However, she does not consider Respondent to be her doctor.

137. C.P. traveled to Tijuana in April 2013. She was taken to a clean clinic where she was given a consent form which she read and understood. She understood the treatment was not guaranteed, that it was experimental, that Respondent would not perform the procedure, and that she would not hold anyone responsible. She was taken to a room where an IV was started. A man introduced himself to her saying he was a doctor. He said he would give her two injections. The second injection would withdraw spinal fluid and inject stem cells. Respondent was present at that time, but he did not participate.

138. Following the procedure, Respondent asked a lady at the front desk to give C.P. a telephone number to call if she had questions. The number she received was that for Respondent's cellular telephone.

139. Three days after the treatment, C.P. noticed she had stopped falling and she had her balance. She could speak without stuttering. A few days later, she experienced a "light body jerk" (C.P.'s term). She has had none since that time. At the hearing, C.P. stated, "I am a miracle." She attributes her improvement to the stem cell therapy.

140. C.P. continued to take her medication after receiving the stem cells. However, she discontinued the medicine she took at night, but did not tell her physician until a week before she testified at the hearing.

141. While doing her online search, C.P. found other clinics in Tijuana performing stem cell therapy, but she decided to use Respondent because she had read his book and considered him "legitimate." (C.P.'s term.)

142. The fetal stem cell therapy had no effect on C.P.'s hearing loss. She did not discuss her hearing loss with Respondent.

143. At the hearing, C.P. did not have any documentation establishing the efficacy of fetal stem cell therapy.

Respondent's Book and Advertising

144. Respondent published his book, Blocked in the USA The Stem Cell Miracle (book), in 2010. He wrote the book for the lay public rather than as a scientific treatise. Therefore, he eschewed references to authorities such as peer reviewed articles in medical journals in favor of magazine and newspaper articles and articles published on the Internet. He wrote the book in first person and included in it numerous anecdotes of his patients whose many disparate medical disorders had improved with his fetal stem cell treatment. He wrote that stem cell therapy was something of which the public was unaware but should be, and that it could be used in the most dire of circumstances. He claimed that patients were not given a choice of treatment in traditional medicine, but that fetal stem cell therapy offered them an option.

145. In the book, Respondent wrote that he had treated over 1,500 patients with fetal stem cell therapy. At the hearing, Respondent claimed that statement was not true, and that he wrote it to give potential patients a better understanding of what he was doing. He testified that the effect would have been "attenuated" (Respondent's term) if he wrote that he only referred patients to health care professionals practicing in foreign countries. Respondent also wrote that 96 percent of the 1,500 patients he treated had a positive outcome. At the hearing, he admitted that the figure was only a general statement and not the result of a statistical analysis.

146. When the Board investigator who posed as C.A. read Respondent's book, she found numerous references that would lead the reader to believe Respondent was the treating physician for patients who came to him for fetal stem cell treatment. Among those references were phrases such as "more than 1,500 of my patients," "I have the means to save his life, "a few of the cases I have treated," and "disease processes I have treated." In addition, in over 80 patient testimonials or summaries, Respondent refers to the stem cell recipients as his patients. Those representations are consistent with the first paragraph Respondent wrote in the section entitled "About the Author:"

> William C. Rader, M.D. is the only American physician involved in the actual clinical application of human fetal stem cells. Since 1995 he has successfully treated more than 1,500 patients.

(Exhibit 31, AGO 01701.)

147. The book contains a disclaimer which states that Respondent is not "rendering medical, health, or any other kind of personal and/or professional services in the book." (Exhibit 31, AGO 01337.) That statement is belied by numerous references in the book, as well as on Respondent's websites, and the evidence adduced at the hearing.

148. At the administrative hearing, Respondent continued to deny having ever treated anyone with fetal stem cell therapy, and he denied that he was the physician for any patient receiving the therapy. He claimed he only referred potential recipients to foreign physicians. In

so doing, he admitted the falsity of a great many statements in the book. For example, (1) he could not describe how many disease processes he had treated; (2) numerous references to patients he had successfully treated; (3) he was the only American doctor who had administered fetal stem cells; (4) references to "my" fetal stem cell patients; (5) references to "my therapy"; (6) numerous references to "my patients"; and (7) by the time a certain study had been published, he had been administering fetal stem cells to human patients for over five years.

149. Respondent also admitted to the falsity of other statements in the book. For example, he wrote that millions of children can be treated with the cells of only one fetus, and that fetal stem cells have no antigenicity.

150. Respondent read the book for accuracy before he published it. He was aware at that time that numerous statements were untrue. At the hearing, he admitted he wrote the falsehoods because he wanted people to believe he was a credible person, and because he was writing for lay people and it would be "too casual" (Respondent's term) to say he only observed the procedures. He admitted that a lay person reading the book would not know that he had only observed but not treated the myriad of patients he claimed were his own and whom he had treated. In light of those admissions, Respondent's testimony that he did not intend to mislead the public was not credible. He further testified that he could "easily and happily" (Respondent's term) correct the book's inaccuracies. According to Deputy Attorney General Kapur, Respondent had not done so as of the final day of the hearing.

151. Although Respondent testified that it was important to him that his website be accurate and not mislead the public, he wrote the same and similar untruths and misrepresentations on the Medra, Stem Cell of America, and his personal websites. Included with the statements referenced above were that Stem Cell of America is an international company; that Stem Cell of America has laboratories and employs scientists; and that he founded Stem Cell of America in 1995 dedicated to research. (Respondent testified that he wrote the last statement because "it makes sense to let people know what the future is." (Respondent's statement.)

152. Statements on Respondent's website such as "Dr. William Rader Continues Groundbreaking Stem Cell Therapy . . . " (Exhibit 43, AGO 02425), "Dr. William Rader's Stem Cell Therapy Holds Several Major Advantages . . ." (*ibid.*), and "Dr. William Rader's stem cell treatment remains the preferred treatment above any of the stem cell therapies currently available in the United States . . ." (*id.*) further evidence the falsity of his claims that he has never treated a patient and does not serve as the physician for potential and actual stem cell recipients. Those statements are credited over Respondent's denials at the hearing that he was not the physician of any patients because they are consistent with the overwhelming weight of the evidence that establishes the physician/patient relationship with all of the patients involved in this case, as is more fully set forth below.

153. For the reasons set forth in Factual Findings 38, 39, and 40, Drs. Kornblum and Parkman found that Respondent's claim in his book and on his websites that his stem cells are pluripotent was not true. Even Dr. Duncan, Respondent's expert, conceded that fetal stem cells are not pluripotent. However, she testified that they sometimes can appear to be. Dr. Kornblum also correctly pointed out Respondent's book and websites deny the existence of the many

potential negative side effects associated with stem cell therapy. Those side effects include but are not limited to graft vs. host disease and the known risks associated with spinal taps and lumbar punctures.

LEGAL CONCLUSIONS

1. Cause exists to discipline Respondent's certificate, pursuant to Business and Professions Code sections 2227 and 2234, subdivision (b), for gross negligence, as set forth in Findings 12 and 32 through 112.

2. Cause exists to discipline Respondent's certificate, pursuant to Business and Professions Code sections 2227 and 2234, subdivision (c), for repeated negligent acts, as set forth in Findings 12 and 32 through 112.

3. Cause exists to discipline Respondent's certificate, pursuant to Business and Professions Code sections 2227 and 2271, for false and/or misleading advertising, as set forth in Findings 36 through 41, and 144 through 153.

4. Cause exists to discipline Respondent's certificate, pursuant to Business and Professions Code section 651, subdivisions (a), (b)(1), (b)(2), (b)(3), and (b)(7), for disseminating false or misleading statements, as set forth in Findings 36 through 41, and 144 through 153.

5. Cause exists to discipline Respondent's certificate, pursuant to Business and Professions Code sections 2227 and 2234, subdivision (e), for dishonesty or corruption, as set forth in Findings 37 through 41, and 144 through 153.

6. Cause exists to discipline Respondent's certificate, pursuant to Business and Professions Code sections 2227 and 2234, for general unprofessional conduct, as set forth in Findings 12, 32 through 112, and 144 through 153.

7. Cause exists to discipline Respondent's certificate, pursuant to Business and Professions Code sections 2227 and 2234, for violation of provisions of the Medical Practice Act, as set forth in Findings 12, 32 through 112, and 144 through 153.

8. Cause does not exist to discipline Respondent's certificate, pursuant to Business and Professions Code sections 2227, 2234, subdivision (b), or 2234, subdivision (c), for gross negligence or repeated negligent acts, for recommending that patients undergo fetal stem cell treatment where there was no medical evidence that such treatment could benefit the patients. Although Respondent lacked evidence based on controlled studies, he based his decision on empirical evidence from his experience. Because the allegations refer to "no medical evidence," they fail for lack of specificity.

9. The law is clear that the standard of proof to be used in this proceeding is "clear and convincing." (*Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 856 [185 Cal.Rptr. 601].) This means the burden rests on Complainant to establish the charging allegations by

proof that is clear, explicit and unequivocal--so clear as to leave no substantial doubt, and sufficiently strong to command the unhesitating assent of every reasonable mind. (*In re Marriage of Weaver* (1990) 224 Cal.App.3d 478.) Complainant sustained her burden of proof.

10. Respondent is accused of having committed both gross negligence and repeated negligent acts. Gross negligence has been defined as an extreme departure from the ordinary standard of care or the "want of even scant care." (*Gore v. Board of Medical Quality Assurance* (1970) 110 Cal.App.3d 184, 195-198.) Only one extreme departure from the standard of care need be found for a licensee to have committed gross negligence. The statute permitting the Board to discipline a licensee for "repeated negligent acts" (Bus. & Prof. Code, § 2234, subd. (c)) may be invoked on basis of as few as two occurrences. (*Zabetian v. Medical Board of California* (2000) 80 Cal.App.4th 462, 468.)

11. In this case, Respondent is found to have committed numerous departures from the standard of care. Because each of them was an extreme departure, he committed gross negligence. Because of their number, they constitute repeated negligent acts.

Jurisdiction

12. Respondent argues that the Board lacks jurisdiction with respect to patients J.D. and J.S. because the treatment occurred out of the country. Respondent is incorrect. Jurisdiction in a disciplinary action runs with the license rather than the location of an alleged violation. (See *Windham v. Board of Medical Quality Assurance* (1980) 104 Cal.App.3d 461.) The agency determines whether the substance of the matter falls within its jurisdiction. (See *Mazda Motor, Inc. v. New Motor Vehicle Board* (2003) 110 Cal.App.4th 1451.) In *Hughes v. Board of Architectural Examiners* (1998) 17 Cal.4th 763, 792, the Court stated:

> [C]onduct occurring anywhere that falls within the statutory grounds for *denial* of a license, may provide the basis for such denial without offending jurisdictional principles. It is obvious that the statutory provisions affording a basis for denial of a license because of prior convictions, dishonest conduct, or certain other conduct for which a licensee would be subject to discipline, apply whether the conduct occurred in this state or in another jurisdiction. The mere circumstance that the act occurring within the boundaries of another state or locality is being scrutinized at a different stage of the Board's administrative authority over the subject—that is, following licensure—does not undermine the agency's authority to act based upon the out-of-state conduct.
>
> In this state and others, postlicensure disciplinary proceedings have been based upon acts that occurred prior to licensure and outside the state in which the individual was licensed. (See, e.g., *Windham v. Board of Medical Quality Assurance* (1980) 104 Cal.App.3d 461, 464 [163 Cal.Rptr. 566] [proceedings to revoke license of California physician following conviction based upon prelicensure filing of fraudulent tax returns in Mississippi]; *Office of Disciplinary Counsel v. Clark* (1988) 40 Ohio St.3d 81, 81 [531 N.E.2d 671] [disciplinary proceedings against attorney in Ohio following conviction based

> upon prelicensure trafficking in controlled substances in Virginia].) Although in these decisions, the disciplinary action was based upon the convictions that occurred following licensure, that circumstance did not affect the conclusion that the discipline meted out by one jurisdiction properly could be based upon conduct that occurred in another jurisdiction prior to licensure in the jurisdiction imposing that discipline. As we have discussed above, the decisional law has distinguished between the facts that in themselves, justify discipline, giving rise to a conviction, and the conviction itself, which as a matter of law may be expunged from the licensee's or applicant's record. (Emphasis in text.)

13. Further, the allegations against Respondent regarding those two patients address Respondent's conduct in California as well as elsewhere.

The Physician/Patient Relationship

14. Respondent contends that he is not subject to the standard of care because he was never the physician of any potential or actual fetal stem cell recipient and therefore, those individuals were not his patients. Respondent is incorrect.

15. Evidence Code section 991 states:

> As used in this article, "patient" means a person who consults a physician or submits to an examination by a physician for the purpose of securing a diagnosis or preventive, palliative, or curative treatment of his physical or mental or emotional condition.

16. It is indisputable that each of the patients referenced in this Decision consulted Respondent for the purpose of securing preventive, palliative, or curative fetal stem cell treatment of his/her physical condition. In fact, Respondent advertised for that very purpose.

17. The physician/patient relationship is established when the patient reasonably believes the physician he/she consults is the physician who will also diagnose or treat the condition. (Cf. *Kramer v. Policy Holders Life Ins. Assn.* (1935) 5 Cal.App.2d 380, 386-387.)

18. Civil Code section 56.05, subdivision (c), defines a "patient" as "any natural person, whether or not still living, who received health care services from a provider of health care and to whom medical information pertains."[20] In *Pettus v. Cole* (1996) 49 Cal.App.4th 402, a case decided under the CMIA, a psychiatrist performed a psychiatric evaluation on the appellant at the request and expense of the appellant's employer. The psychiatrist sent a full written report

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[20] The parties did not offer any legal authority in support of their respective positions on whether the physician/patient relationship existed between Respondent and his potential and/or actual fetal stem cell recipients. Civil Code section 56.05 is part of the Confidentiality of Medical Information Act (CMIA). Although that Act is not germane to this case, the definition provides guidance in resolving this issue.

to the appellant's managers without first obtaining from the appellant a written authorization for release of his medical records. The psychiatrist later claimed that, because he saw the appellant only once, provided no care or treatment to him, and performed the evaluation and wrote the report for the employer's benefit, no physician/patient relationship was formed, and the appellant was not his patient.

19. The court disagreed stating:

> It is undisputed that Dr. Cole's meeting with Pettus generated highly sensitive medical information which was subsequently reported to Du Pont. According to statutory definitions, "medical information" is information "derived from a provider of health care" and a patient is someone who has received health care services from a provider of health care and to whom medical information pertains. (Citation.) Unfortunately, the term "health care services" is not defined by the Act. However, logic dictates that in order for a health care provider to gather medical information about a person, the provider must have dealt with the person at some level and performed professional services of some type. By failing to include the term "health care services" in the list of definitions, the drafters failed to define the precise level of interaction between the provider and the subject necessary to constitute "health care services." It is, however, appropriate to construe the term in a manner which effectuates the purpose of the statute. (Citation.)

(*Id.* at page 429-430.)

20. Using *Pettus* as a model, the evidence evinces a finding that Respondent served as the physician for those patients who came to him seeking fetal stem cell therapy. He discussed their cases with them by telephone. He made recommendations to them for the therapy. He had medical history forms sent to them which he reviewed upon their return. He decided whether to refer the patient to a foreign clinic. Although he did not perform the actual procedures on J.D. and J.S., he was present at one and spoke by telephone with the patient at another. It was his custom and practice to be present at all of the procedures performed through his companies. He met with the patients before and after the treatment and answered their questions, and he provided his own cellular telephone number to them with the invitation to call if they had additional questions. In other words, he performed professional services.

21. Respondent has demonstrated other indicia of the physician/patient relationship as well: He, exclusively, ordered and provided the stem cells for the recipients. He referred patients only to physicians he trained and employed. He received payment for the treatment. The consent form listed only his name and the name of his company. The patient was not asked to sign a consent form naming the foreign physicians or clinics. In his book and on his websites, Respondent described the recipients as his patients, and he claims to have performed the treatment approximately 2,000 times. In H.C.'s case, two letters written on his letterhead indicate that H.C. was his patient, and references in his chart indicate he would perform the therapy in the RV. In addition, Respondent instructed H.C.'s family to give him a Valium tablet to control his vacillating blood pressure, and he instructed an emergency room physician treating H.C. to give H.C. fluids and discharge him from care. In J.D.'s case, he directed the lumbar puncture.

Respondent told him: "I'm your doctor. You have to trust me."

22. Ultimately, while claiming to offer only a referral service, Respondent provided the medical evaluation, the medical advice, the materials, and the medical personnel necessary for the fetal stem cell treatment to take place.

23. The experts expressed disparate opinions regarding whether potential and actual stem cell recipients were Respondent's patients, with Drs. Kornblum and Parkman opining they were and Dr. Duncan opining they were not. Although the experts were competent to render those opinions, they offer little to resolve the issue because the determination of whether one is a "patient" is a question of law and not the proper subject of expert testimony. (*Pettus v. Cole, ante,* at page 431, footnote 20.) Nonetheless, were the issue to turn on the experts' opinions, those of Drs. Kornblum and Parkman would be the more convincing for the reasons set forth above.

The Standard of Care

24. In *Lawless v. Calaway* (1944) 24 Cal.2d 81, 86, the Court stated:

> The law demands only that a physician or surgeon have the degree of learning and skill ordinarily possessed by practitioners of the medical profession in the same locality and that he exercise ordinary care in applying such learning and skill to the treatment of his patient. [Citations.] The same degree of responsibility is imposed in the making of a diagnosis as in the prescribing and administering of treatment. [Citations.] Ordinarily, a doctor's failure to possess or exercise the requisite learning or skill can be established only by the testimony of experts. [Citations.] Where, however, negligence on the part of a doctor is demonstrated by facts which can be evaluated by resort to common knowledge, expert testimony is not required since scientific enlightenment is not essential for the determination of an obvious fact. [Citations.]

25. The fact that Respondent claims to be the only physician in America who has been and is infusing fetal stem cells into humans virtually per se means he is operating outside of the standard of care.

26. In his report, Dr. Kornblum offered specific criteria necessary to meet the standard of care with respect to each of the four medical issues he addressed:

a. Recommendation to patients to receive stem cell therapy: "Standard of care and standard of ethical practice is to recommend (or agree to provide) and provide treatments that are safe and potentially effective." (Exhibit 33, AGO 01864.)

b. Proper evaluation prior to institution of therapy: "Standard of Care is to appropriately evaluate a patient's condition to determine whether a proposed treatment is going to be safe and effective for that treatment." (*id.* at AGO 01865.)

c. The providing of information to patients regarding risks and benefits of the therapy: "Standard of Care is to provide accurate information to the patient with respect to the potential risks and benefits of a therapy prior to administration of the therapy, and to ensure that the patient or their representatives understand these risks and benefits." (*id.* at AGO 01866.)

d. Involvement in medical decision-making in the absence of appropriate information or expertise: "Standard of Care: Medical advice to patients or physicians should be provided that is based on sound medical principles, based on adequate training and knowledge of the therapy or course of action being advised as well as the specific situation for which it is being advised." (*id.* at AGO 01867.)

27. At the hearing, Dr. Kornblum accurately articulated the standard of care consistent with California law. His more specific definitions do not reflect ignorance of the legal definition, and they do not change the outcome of this action.

28. A physician accused of deviating from the standard of care must be judged in light of the standard of care as it existed at the time of the alleged deviation and not what it should have been at that time.

> Under existing law, testimony, including expert testimony, is not admissible to show the standard of care should have been different; an expert is not permitted to "second-guess an entire profession"' as to what the standard of care should have been. (Citation.)

(*N.N.V. v. American Assn. of Blood Banks* (1999) 75 Cal.App.4th 1358, 1385 [89 Cal.Rptr.2d 885].)

29. Dr. Duncan did not address the standard of care in her report. (Exhibit FF.) In fact, she wrote: "I refrain from addressing here in detail the Respondent's alleged departures from standard medical practice as outlined by the California Health Board and opined by Harley Kornblum and Robertson Parkman." (Exhibit FF, page 4.) Dr. Duncan did not state her reason(s) for declining to address the standard of care in her report. Although she touched on it briefly in her testimony, she made no attempt to define it. Therefore, one cannot know the criteria on which she based her opinion that, if Respondent were to be deemed the physician of the patients who came to him for fetal stem cell therapy (which she disputes), he practiced within the standard of care at all times.

30. Dr. Duncan's knowledge and opinions were based almost entirely on hearsay from the articles she read, Respondent's book and websites, an intra-testimony conversation with an unidentified physician in Ukraine, and conversations with Respondent. Both Dr. Duncan and Respondent had difficulty recalling the subject matter of their conversations.

31. The gravamen of Dr. Duncan's report and testimony centered on the safety, efficacy and need for fetal stem cell therapy. This is an issue only tangential to the allegations in this case. It need not be, should not be, and is not adjudicated here. It is noteworthy, however, that in a medical practice that would seemingly lend itself well to trials of stem cell therapy (sports, pain, and rehabilitation medicine), Dr. Duncan has referred only one patient for that

treatment. Were the safety, efficacy and need for fetal stem cell therapy at issue in this case, that fact would lead one to question the sincerity of Dr. Duncan's opinions.

32. Respondent committed multiple extreme departures from the standard of care as more fully set forth above, in connection with his care and treatment of patients J.D., J.S., H.C., and undercover "patient" E.B. Those extreme departures were in connection with his failure to properly evaluate the patients prior to recommending treatment, and his failure to provide concise, understandable and accurate information regarding the potential risks and benefits of fetal stem cell therapy. Included in the several risks of which Respondent failed to advise his patients is the fact that professional opinions vary regarding whether fetal stem cells are immuno-privileged and that the cells express HLA over time as they mature into somatic cells. Therefore, Respondent's decision to decline typing donors and recipients for histocompatibility and, if necessary, administering immunosuppressant drugs, poses a risk of rejection, host vs. graft disease and graft vs. host disease.

33. It was not proven that there was anything improper or insufficient in the testing and freezing of the cells Respondent used on his patients.

34. The "fact" patients' testimony was interesting and encouraging, but it was not dispositive. Their stories of improvement are unconfirmed by scientific methods. Therefore, it cannot be ascertained whether the extraordinary results Respondent claims to have achieved are due to fetal stem cell therapy, other methods of treatment, placebo effect, a different causative factor, or some combination of factors.

False Statements in the Book and on the Websites

35. Respondent wrote or is responsible for the writing of a great many untruths, misrepresentations, and inaccuracies in his book and on his and his companies' websites. He was aware the statements were untrue, and he wrote them deliberately for the purpose of making himself, his companies, and his stem cell therapy appear more important, authoritative, credible and desirable to the lay public. At the time he wrote them, he was also aware that the lay public would have no method of determining the falsity of the statements.

Conclusion/Consideration of Penalty

36. The vast majority of Respondent's training in stem cells to which he testified came from his "fellowship" in Ukraine. Much of his testimony relating to statements made to him by physicians/scientists in Ukraine was hearsay. None of it was corroborated by any literature or other evidence that could establish the reliability of that information other than Respondent's testimony and the testimony of the four "fact" witnesses. That testimony, while encouraging as anecdotal/empirical evidence, remains unconfirmed by more traditional scientific means.

37. It is possible that Respondent is completely correct in his assessment of the efficacy and future of fetal stem cell therapy. If he is, neither science nor the standard of care has caught up with him. If he is not, he poses an unacceptable risk to the health, safety, welfare and interest of the public. Either way, he is operating outside of the standard of care, and the Board

cannot stand idly by or put its stamp of approval on his conduct.

38. Respondent has misunderstood and abused his role in the process. By taking a medical history and offering medical advice regarding the efficacy and propriety of the use of fetal stem cell therapy in each patient's particular case, he became the physician on whom each patient relied for his/her safety and recovery. "There is no other profession in which one passes so completely within the power and control of another as does the medical patient." *Shea v. Board of Medical Examiners* (1978) 81 Cal.App.3d 564, 578 [146 Cal.Rptr. 653.] Through his actions Respondent has purposefully dealt with patients in a dishonest way by enticing them into treatment based on false and misleading information.

39. Respondent has shown no remorse for his actions. In fact, he remains convinced of the correctness, legitimacy, and timeliness of the use of fetal stem cells and of his role in the process. His only concession is his willingness to change the representations in his book to more accurately reflect his position, and not for the benefit of the public. Respondent's recalcitrance justifies the revocation of his certificate.

40. Business and Professions Code section 2229 states:

(a) Protection of the public shall be the highest priority for the Division of Medical Quality, the California Board of Podiatric Medicine, and administrative law judges of the Medical Quality Hearing Panel in exercising their disciplinary authority.
(b) In exercising his or her disciplinary authority an administrative law judge of the Medical Quality Hearing Panel, the division, or the California Board of Podiatric Medicine, shall, wherever possible, take action that is calculated to aid in the rehabilitation of the licensee, or where, due to a lack of continuing education or other reasons, restriction on scope of practice is indicated, to order restrictions as are indicated by the evidence.
(c) It is the intent of the Legislature that the division, The California Board of Podiatric Medicine, and the enforcement program shall seek out those licensees who have demonstrated deficiencies in competency and then take those actions as are indicated, with priority given to those measures, including further education, restrictions from practice, or other means, that will remove those deficiencies. Where rehabilitation and protection are inconsistent, protection shall be paramount.

41. Rehabilitation and protection of the public are inconsistent in this case because Respondent's conduct, statements during the administrative hearing and during oral arguments continue to demonstrate that he is unrepentant, takes no responsibility for his actions, and has no intention of truly changing his behavior. The dishonest way with which he dealt with patients was evident throughout the record. That each patient thought he was their doctor speaks volumes. His dishonesty permeates every aspect of his business and practices. He referred and facilitated for his patients treatment for which there is no proof of efficacy, and under conditions which fall below the standard of care. His resolve to disavow the physician/patient relationship

after luring the patients to him with false information highlights the futility of rehabilitation efforts.

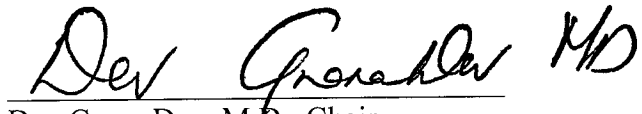
42. Respondent's dishonest conduct can only be described as self-serving, showing poor character, a lack of integrity, and an unwillingness to follow the law. As so eloquently pointed out in *Griffith v. Superior Court* (2002) 98 Cal.App.4th 757; 772, citing *Golde v. Fox* (1979) 98 Cal.App.3d 167, 176, "[T]here is more to being a licensed professional than mere knowledge and ability. Honesty and integrity are deeply and daily involved in various aspects of the practice." This statement is even more critical in reference to the practice of medicine where a patient's life, health and welfare depend on the representations of physicians, and where almost every aspect of the profession calls for honesty and integrity. The Board has reviewed the disciplinary guidelines, and can find no term or condition that could aid Respondent's rehabilitation and still provide protection to the public. Under these circumstances, protection of the public trumps rehabilitation efforts and the Board finds that Respondent's physician and surgeon certificate must be revoked.

ORDER

Certificate No. A22848 issued to Respondent, William C. Rader, M.D., is revoked.

This Decision shall become effective on: November 5, 2014.

It is so ORDERED: October 6, 2014.



Dev GnanaDev, M.D., Chair
Panel B

BEFORE THE
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of Accusation Against:	)	
	)	
WILLIAM C. RADER, M.D.	)	
	)	Case No.: 20-2010-205857
Physician's & Surgeon's	)	
Certificate No: A 22848	)	OAH No.: 2013040837
	)	
Respondent	)	
	)	
	)	

ORDER OF NON-ADOPTION
OF PROPOSED DECISION

The Proposed Decision of the Administrative Law Judge in the above-entitled matter has been **non-adopted.** A panel of the Medical Board of California (Board) will decide the case upon the record, including the transcript and exhibits of the hearing, and upon such written argument as the parties may wish to submit directed to the question of whether the proposed penalty should be modified. The parties will be notified of the date for submission of such argument when the transcript of the above-mentioned hearing becomes available.

To order a copy of the transcript, please contact Kennedy Court Reporting , 920 West 17th Street, Second Floor, Santa Ana, CA 92706 . The telephone number is 714.835.0366

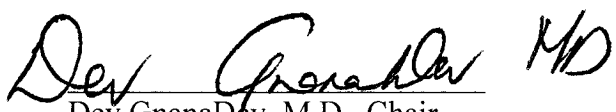
To order a copy of the exhibits, please submit a written request to this Board.

In addition, oral argument will only be scheduled if a party files a request for oral argument with the Board within 20 days from the date of this notice. If a timely request is filed, the Board will serve all parties with written notice of the time, date and place for oral argument. Oral argument shall be directed only to the question of whether the proposed penalty should be modified. Please do not attach to your written argument any documents that are not part of the record as they cannot be considered by the Panel. The Board directs the parties attention to Title 16 of the California Code of Regulations, sections 1364.30 and 1364.32 for additional requirements regarding the submission of oral and written argument.

Please remember to serve the opposing party with a copy of your written argument and any other papers you might file with the Board. The mailing address of the Board is as follows:

MEDICAL BOARD OF CALIFORNIA
2005 Evergreen Street, Suite 1200
Sacramento, CA 95815-3831
916.263.2451
Attention: Teresa Schaeffer

Date: May 6, 2014



Dev GnanaDev, M.D., Chair
Panel B

BEFORE THE
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against:	
WILLIAM C. RADER, M.D.,	Case No. 20-2010-205857
Physician's and Surgeon's Certificate No. A22848,	OAH No. 2013040837
Respondent.	

PROPOSED DECISION

This matter came on regularly for hearing on February 18, 19, 20, 21, 25, 26, and 28, and March 6, 7, 10, 11, and 12, 2014, in Los Angeles, California, before H. Stuart Waxman, Administrative Law Judge, Office of Administrative Hearings, State of California.

Harinder K. Kapur, Deputy Attorney General, represented Complainant, Linda K. Whitney (Complainant), Executive Director of the Medical Board of California (Board).

Respondent was present on each day of the hearing and was represented by Robert L. Shapiro, Fred D. Heather, and Alexander M. Kargher, Attorneys at Law.

Oral and documentary evidence was received. The record was closed on March 12, 2014, and the matter was submitted for decision.

Complainant has alleged seven causes for discipline against Respondent for gross negligence (Bus. & Prof. Code[1] § 2234, subd. (b)), repeated negligent acts (§ 2234, subd. (c)), false and/or misleading advertising (§ 2271), disseminating false or misleading statements (§ 651, subd. (a), (b)(1), (b)(2), (b)(3), and (b)(7)), dishonesty or corruption (§ 2234, subd. (e)), general unprofessional conduct (§ 2234), and violation of a provision or provisions of the Medical Practice Act (§ 2234, subd. (a)). The allegations were made in connection with Respondent's advertising for, recommending, and or participating in the use of fetal stem cell therapy on human beings.

[1] All statutory references are to the Business and Professions Code unless otherwise indicated.

FACTUAL FINDINGS

1. On June 25, 1968, the Board issued Physician's and Surgeon's Certificate Number A22848 to Respondent. The license was in full force and effect at all relevant times. It will expire on March 31, 2014, unless renewed. The license bears no history of discipline.

Respondent's Background and Present Work

2. Respondent graduated from Lafayette College with a Bachelor of Science Degree in business administration in 1959. Dissatisfied with his participation in his family's wholesale drug company, he took prerequisite courses and then enrolled in medical school at State University of New York at Buffalo, graduating with honors in 1967. Following an internship and psychiatric residency at the University of Southern California/County of Los Angeles Medical Center, he served in the United States Navy as a Chief Medical Officer, earning a Naval Commendation in 1973 for work in the alcohol addiction program. Respondent entered the private practice of psychiatry in 1974.

3. During his professional career, Respondent established programs in alcoholism and eating disorders at San Pedro Hospital and Redondo Beach Hospital, a rape survivor program, a program to assist hemodialysis patients obtain more appropriate personal treatment, and an HIV program in Mexico. He has made numerous television appearances in his professional capacity, and he co-hosted and produced his own television show.

4. In 1995, having become interested in stem cells, Respondent traveled to Ukraine to serve a one-year "fellowship" (Respondent's term) with a group of physicians and scientists experienced in the field. The fellowship involved his observing all aspects of stem cell therapy, including harvesting, separating, analyzing, freezing, and delivery. However, Respondent denies having actually participated in any of those activities. He testified that the Ukrainian physicians had been performing this work for 20 years, had injected 20,000 patients with stem cells, and had published 1,700 studies.[2] Yet, despite that body of work, they were frustrated because "no one in the West would listen to them." (Respondent's testimony.)[3] The cells being used were neuronal and hematopoietic CD 34+ cells originating in the liver. They were fetal stem cells, meaning they were harvested from aborted fetuses at 8-12 weeks gestation. Respondent explained that neuronal cells were capable of becoming any of the four cell types found in the brain, and that hematopoietic CD 34+ cells were capable of becoming any of the 200 cell types occurring within the body. Respondent was not awarded a certificate at the completion of the Ukrainian fellowship because, as he stated, it was not "that formal." He was "just there to observe." (Respondent's testimony.)

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[2] None of those studies was offered in evidence at the administrative hearing.

[3] Much of Respondent's testimony regarding his time in Ukraine consisted of statements made to him by other physicians and scientists. Those hearsay statements are not accepted for the truth of the matter asserted.

5. While in Ukraine, Respondent became acquainted with and later associated with other physicians in the country of Georgia who were engaged in the same work. He was more comfortable with the physicians and equipment there than with those in Ukraine. He now obtains the stem cells used by his company from Georgia.

6. Respondent testified that he sent an emissary to China to go through "all the medical libraries" to learn of the research being done with fetal stem cells in that country. Respondent did not identify the emissary or explain the extent or result of his/her work.

7. Since returning to the United States, Respondent has been an advocate for the use of fetal stem cell therapy in human patients to which end he has, among other things, formed three companies (Dulcinea Institute, Medra, Inc., and Stem Cell of America, Inc.), published a book (Rader, Blocked in the U.S.A. The Stem Cell Miracle (2010)), and maintained three websites. He opened offshore clinics to enable people he hired to perform stem cell transplants on patients who came to him in the United States. His first clinic was located in Nassau, Bahamas. He moved his clinic to the Dominican Republic after Bahamas officials requested he perform double-blind studies on stem cell therapy. In 2007, after changing locations twice in the Dominican Republic, he moved his operation to Tijuana, Mexico. The clinic in the Dominican Republic remained open a brief time after Respondent opened his clinic in Tijuana.

8. During the time Respondent's company was operating under the name Medra, Inc., a number of people began posting negative reviews of Respondent and his stem cell therapy on Internet chat lines. Thereafter, the television show 60 Minutes aired a segment on "con men" (Respondent's term). During that segment, Medra, Inc.'s name was shown on the screen. It was then that Respondent closed Medra and opened Stem Cell of America in its stead. The change required only the updating of the website. The operation and the marketing strategy remained the same.

9. Respondent explained that all three of his organizations operated in the same manner with only two differences. (1) Initially, potential stem cell recipients paid for the treatment in advance by sending payment via wire transfer to the Bahamas. Now they pay in advance by sending the payment to a bank in the United States. (2) The price for a treatment was initially $25,000, but it is now $30,000.

10. Respondent denies serving as the physician of any patient who expresses an interest in or receives stem cell therapy. He denies ever having performed a stem cell transplant on any patient. Instead, he trains physicians outside of the United States (presently in Mexico) in the theory and procedures of fetal stem cell therapy. The training he provides lasts approximately one week. It consists of a "long lecture" (Respondent's term), followed by questions and answers. He then observes the foreign physicians perform the treatment. He will intervene in their treatment if necessary. Respondent provided the physicians with his book and paperwork similar to that provided to potential stem cell recipients.

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11. Respondent views his role in his organization as the owner who chooses the employees, searches for physicians who practice outside of the United States, and gets information to the public. He does not view himself as the physician to the patients who seek fetal stem cell therapy from his company. Therefore, he does not request medical records from the patients' other physicians, and he does not perform a good faith physical examination before recommending the therapy he espouses. He does not speak with patients' other physicians because he believes those physicians would react negatively, if they chose to speak with him at all. In his testimony, Respondent did not mention any patient he considered unfit for fetal stem cell therapy except for those with complete spinal cord injuries.[4]

12. Respondent operates an office in Malibu, California. Individuals interested in stem cell therapy almost never go to that office. Generally, they become aware of his service through either the company's website or Respondent's own website. They telephone the number on the website and speak with a staff member who provides information about the therapy and offers to send the individual Respondent's book. Either then or in a subsequent call, the individual may request to speak with Respondent personally, and Respondent takes or returns the call, answering all questions posed to him, including whether Respondent believes, based on his experience and the information provided by the individual, that the individual might be a good candidate for stem cell therapy. If the individual wishes to undergo the treatment, he/she is asked to fill out and return the company's nine-page medical history questionnaire form. Respondent's criteria for referring the individual to Mexico[5] for treatment are (1) the individual must have exhausted all traditional and alternative forms of treatment, and (2) there is no remaining hope of recovery. However, Respondent does not request medical records from the individual's treating physician(s) to determine the nature or extent of the condition, which treatment approaches have been tried, what the current treatment is and its efficacy, or any other pertinent information. He does not see the individual before the day of the treatment. He does not perform a good faith physical examination on the individual because he does not believe it is necessary since the individual has already been diagnosed, and because, as a psychiatrist, he could not add anything to the diagnosis. As a result, Respondent does not know whether the information the individual provides to him is factually/medically accurate or even if the individual is lying to him.[6]

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[4] He testified that incomplete spinal cord injuries are very treatable with fetal stem cell therapy but that complete spinal cord injuries (fully-severed spinal cord) are not.

[5] Respondent presently operates only one clinic which is located in Tijuana, Mexico.

[6] At the administrative hearing, Respondent testified that he would be untroubled by such a lie. That testimony is inconsistent with his two purported criteria for referral of patients to Mexico.

13. According to Respondent, once his threshold criteria have been satisfied, he sends his chart[7] and the medical history questionnaire to his physicians in Mexico to determine whether the individual is an appropriate candidate for stem cell therapy. The patient is not given the option of choosing a physician in Mexico. Despite the fact that the Medical History Form contains the word, "Confidential" in its title, Respondent does not ask the individual to complete an authorization for release of medical records, and he does not inform the individual that the medical history questionnaire is being sent to another physician, or that he is referring the individual to a physician Respondent hired and pays. Nor is the patient informed of who is making the decision regarding whether he/she will be accepted for treatment. However, aside from Respondent's testimony, there was no evidence offered to show that documents are sent to the physicians in Mexico to decide whether to accept the patient, and some evidence indicated that it did not and does not occur. Respondent believes there are no contraindications to the treatment other than possible effects of medication the patient is taking (e.g., heparin may cause bleeding). Therefore, it is difficult to understand why Respondent does not make the decision whether the patient is an appropriate candidate for the therapy.

14. The patient pays the entire fee in advance. The fee is presently $30,000. The fee can be adjusted downward on what Respondent referred to as a sliding scale. Fee reductions must be approved by Respondent's wife. Additional treatments are given at a reduced rate. The fee covers the treatment, the stem cells, information from Stem Cell of America, assistance with travel arrangements, on-site transportation, overhead, and Respondent's "expertise." (Respondent's term.)

15. The patient may make travel arrangements independently, or Respondent's staff assists the individual with travel arrangements through a specific travel agency the staff uses exclusively. The treatments are delivered one day per month, usually on a Saturday. The individual travels to San Diego where he/she is picked up by a van operated by and/or paid for by Respondent and/or his company (presently Stem Cell of America) and taken across the border to the clinic. The treatments are administered by a physician or by non-physician medical personnel.

16. The stem cells transplanted into the patient belong to Respondent and/or his company. Respondent orders the stem cells from the laboratory in Georgia, and they are flown to Mexico, frozen in liquid nitrogen, at his company's expense. Only CD34+ hematopoietic cells are used. Respondent insists that only the stem cells he orders may be used on the patient. If one of the hired physicians chooses to obtain stem cells from another source, Respondent will no longer refer patients to that physician. If the patient desires to obtain stem cells from another source, Respondent will not refer that patient to his physicians in Mexico.

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[7] According to Respondent, the chart consists of notes on the initial discussion with the prospective recipient, the medical history questionnaire, and any other ancillary information.

17. As stated above, the physicians in Mexico have been trained in the theory and procedure of stem cell transplantation by Respondent over the course of approximately one week. Respondent hires and pays the physicians who perform their duties as independent contractors. Aside from those physicians, the clinic hires medical and non-medical staff. Respondent has the authority to fire the physicians and the staff members should he so desire.

18. After the patient has paid for the treatment and traveled to the clinic in Tijuana, he/she is presented with a consent form. The form is on Stem Cell of America letterhead (or the Medra or Dulcinea Institute letterhead for earlier uses). The form was composed by an attorney at Respondent's direction. Among other things, the consent form contains the following language:

> I understand that Dr. Rader has [a] financial interest in the (FCTP) [Fetal Cell Therapy Program]. I further understand that Dr. Rader will not administer or participate in the application of any medical treatment or other aspect of the (FCTP). I will be treated solely by doctors in the Mexico [*sic*]. I also agree that I will not disclose any information; including but not limited to, an individual or public (media, web site or posting) basis, any facts regarding my own or any other patients['] treatment pertaining to Fetal Stem Cell therapy, or any other knowledge that I have acquired from Medra [or Dulcinea Institute or Stem Cell of America], its staff, any of its affiliates or associates, without the express consent of a corporate officer of Medra [or Dulcinea Institute or Stem Cell of America].

(Exhibit 7, AGO 02156.)

19. The consent form also contains the following language: "Dr. Rader or his assistant has answered all of my questions and I understand the (FCTP) therapy including the possibility of adverse reactions, which might result from the therapy, and possible damage, which might be caused, [sic] by the therapy." That language is contrary to that in Respondent's book and on his websites to the effect that fetal stem cell therapy carries no risk of negative effects. No specific risks, such as those associated with a spinal tap or lumbar puncture, are addressed in the consent form. The form also informs the patient that the treatment is experimental and that Respondent is willing to speak with the patient's treating physician. Since the patient has already paid the fee and traveled to the clinic in Mexico before seeing the consent form, he/she sometimes feels that there is little choice but to sign the form and go forward with the treatment, even if the information on the form is disconcerting or even unacceptable.

20. Respondent's name is the only name that appears on the consent form other than the name of his company. The patient is not asked to sign a consent form naming the physicians or staff in Mexico.

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21. Respondent is present in the clinic when the patient undergoes the treatment. He meets with the patient after the patient signs the consent form and answers questions about the consent form at that time. Among other things, he tells the patient the method of delivery and that the procedure is not painful. He does not discuss with them the potential for a placebo effect.[8]

22. As part of the preparation for the treatment, the physicians or staff in Mexico take the patient's vital signs including his/her oxygen saturation.[9] Thirty million cells are transplanted for each patient. Delivery is made subcutaneously, intravenously, or intra-thecally (epidural). The physicians do not perform a good-faith physical examination on the patient. Respondent does not believe it would serve any purpose since one was performed by the patient's primary physician.

23. Respondent meets with the patient again immediately following the treatment. He asks how the procedure went and how the patient is feeling, and he answers any questions the patient has. He then hugs the patient and wishes him/her a good trip back. The van then returns the patient to San Diego. Before the patient leaves, he/she is given a telephone number to call if a problem arises. That number is Respondent's cellular telephone number.

24. Respondent testified that the physicians in Mexico maintain their own records, but that he has never seen them. That testimony was not credible. No such records were offered in the administrative hearing, and no patient testified to any such records. Respondent did not testify as to the basis of his knowledge that such records are kept. Further, it is difficult to understand how Respondent would not see any documentation during the many procedures he has observed, especially in light of the fact that he trained the doctors in Mexico, that he pays them, and that he has the authority to fire them. Since Respondent disavows being the physician to any patient undergoing fetal stem cell therapy, one would expect that he would be eager to see documentation that could serve as indicia for the absence of the physician/patient relationship on his part and the establishment of the physician/patient relationship between the patient and the physician in Mexico.

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[8] The placebo effect would itself be a negative and even dangerous effect in that it could cause a patient to postpone other, possibly efficacious, treatment simply because he/she feels better, even though the disease process progresses unabated.

[9] Respondent testified that he does not know why they choose to do so and that he did not teach them to take vital signs as part of the pre-treatment procedure. He also stated that the physicians have not told him why they decided to do it, and he has not asked them why. That testimony was not credible in light of the tight controls he maintains over his business, the importance he places on making the procedure appear completely risk-free, and the fact that he trained, hired, and pays the physicians and can fire them at will if he is dissatisfied with their work.

25. Respondent maintains a follow-up department in his business that contacts the patients two weeks post-treatment and every three months thereafter to find out how the patient is doing and to inquire as to whether the patient has noticed any improvement. Although Respondent testified that the purpose of that contact is to ensure customer satisfaction, as part of the follow-up, he makes himself available to speak with the patients and answer their questions, and he decides whether additional treatments could be beneficial and are indicated for the patient. He is therefore performing a medical, rather than a customer service function.

26. Respondent requires his patients not to speak to others about the treatment or Stem Cell of America because he feels that the patients and he would be unsafe from hostile anti-abortion advocates. When asked how he reconciles that with the great emphasis he places on informing people of the benefits of fetal stem cell therapy in his book and on his websites, he testified that a balance must be struck. In his doing so, it is difficult to determine where Respondent places the fulcrum. The evidence adduced at the hearing leads to the inference that he places it between his statements and those of his patients unless those patients are offering testimonials about Respondent and/or his stem cell therapy for his websites.

The Experts

27. Complainant offered the expert testimony of Harley Ian Kornblum, M.D., Ph.D. Dr. Kornblum is a Professor of Psychiatry,[10] Molecular and Medical Pharmacology and Pediatrics at the David Geffen School of Medicine at the University of California, Los Angeles (UCLA), and is the Director of the UCLA Neural Stem Cell Research Center. He is a diplomate of the American Board of Psychiatry and Neurology with Special Competence in Child Neurology. He has won numerous honors and awards. He is the past and present holder of numerous research grants. His work has been published more than 100 times. In addition to his extensive research in stem cell science, Dr. Kornblum sees both adult[11] and pediatric patients. Dr. Kornblum has never before served as an expert witness in a litigated matter.

28. Complainant also offered the expert testimony of Robertson Parkman, M.D. Dr. Parkman is a Professor of Pediatrics and Microbiology at the Keck School of Medicine, University of Southern California. He is a former Associate Professor of Pediatrics at the Harvard Medical School. He is certified by the American Board of Pediatrics and the American Board of Allergy and Immunology. He has extensive research and clinical experience. He has over 200 publications to his credit. Dr. Parkman has never before served as an expert witness in a litigated matter.

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[10] Dr. Kornblum's psychiatry professorship is an administrative position. He does not practice psychiatry.

[11] Dr. Kornblum's adult patients comprise between one and five percent of his clinical practice.

29. Respondent offered the expert testimony of Susana G. Duncan, M.D., ABPM&R, FAAPM&R. Dr. Duncan is a practitioner specializing in sports, pain and rehabilitation medicine in New York, New York. She is a diplomate of the American Board of Physical Medicine & Rehabilitation and the National Board of Medical Examiners, Part 3. She has engaged in five research projects, including residency research, the most recent ending in 1997. Between 1972 and 1982, she was a contributing editor and then senior editor of New York Magazine in which she published articles on science, medicine, psychology and sociology. She has four medical publications to her credit. Like Drs. Kornblum and Parkman, Dr. Duncan has never before served as an expert witness in a litigated matter.

30. Dr. Duncan has not practiced in California, and she does not profess knowledge of the standard of care for physicians and surgeons in California. However, she was not challenged on that issue, and no claim was made that the standard of care with respect to stem cell therapy differs between California and New York. Her opinions are therefore welcome in this proceeding. However, she lacks first-hand research and clinical experience with stem cells. The basis of her expertise is limited, for the most part, to 250 hours spent reading journal articles, reading Respondent's book, and discussing the issues with Respondent.

31. On balance, based on their education, training and experience, both as researchers and clinicians, coupled with their thoughtful and authoritative reasoning, the opinions of Drs. Kornblum and Parkman are more convincing than those of Dr. Duncan.

A Word About Medical Evidence

32. Clinical trials such as double-blind studies derive evidence from planned experiments based on methodologies designed to rule out as many variables as possible. Some use human subjects. Others use animals lower on the evolutionary ladder. The results are subject to statistical analysis. Because the methodologies are established, the experiments can be replicated to determine the reliability of the data.

33. Empirical evidence is based on observation. It is less structured than clinical trials, but consistent results do have value. However, because variables are, for the most part, not controlled, cause and effect can be difficult to establish. Therefore, results based on empirical evidence should be subject to replication in a controlled setting. Dr. Parkman credibly opined that, for such evidence to be reliable, there must be biological evidence of change rather than an expression by the patient that he/she feels better.

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34. In his book and on his websites, Respondent claims to have successfully treated 2,000 patients with fetal stem cell therapy.[12] However, in the absence of controlled studies replicating those results, too many variables exist to extrapolate those results to the general population.

Basic Information About Stem Cells

35. A great amount of time was spent during the administrative hearing discussing the complex science of stem cell research and therapy. However, not all of the information need be addressed in this Decision. The main issues in this case are whether Respondent deviated from the standard of care in his dealings with potential and actual stem cell recipients, whether he engaged in false or misleading advertising, and whether he committed dishonest or corrupt acts. Although a certain amount of knowledge regarding stem cell science is necessary to determine at least some, if not all, of those issues, the summary below covers the information necessary to make those determinations.

36. Depending on the gestational stage, stem cells may be embryonic (up to approximately six weeks), fetal (six to twelve weeks), or somatic or adult (beginning at approximately 13 weeks. Somatic cells are not at issue in this matter.

37. Respondent claims he uses only neuronal fetal stem cells for stem cell therapy. He does so because they are "pluripotent," meaning they are capable of differentiating into any of the more than 200 cell types in the human body, and because they are "anti-allogenic," meaning that they are not susceptible to rejection by the host, host vs. graft disease, a condition in which the recipient's immune system attacks the new cells and prevents a graft from occurring, or to graft vs. host disease, a condition in which the immunologically-incompatible cells attack the host upon their introduction into the body.[13] He bases his opinion regarding the characteristics of fetal stem cells on his training in Ukraine and his experience with over 2,000 patient treatment histories. During the hearing, his expert witness, Dr. Duncan, contradicted Respondent to a certain extent, when she explained that, unlike embryonic stem cells, fetal stem cells are not pluripotent, but they occasionally act as if they are.

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[12] His testimony at the hearing was essentially the same except that he denied ever treating any patient, and claimed he only referred patients to other physicians out of the United States, whom he trained, hired and paid.

[13] Graft vs. host disease makes the patient extremely ill and can be life-threatening.

38. Dr. Kornblum disagrees with Respondent. On his website, www.medra.com, Respondent claimed "Fetal Stem Cells are the cellular building blocks of the 220 cell types within the body. The Fetal Stem Cells are used by Medra remain in an undifferentiated state and therefore are capable of becoming any tissue, organ or cell type within the body." (Exhibit 35, AGO 02406.) Dr. Kornblum wrote in response to that statement:

> Only embryonic stem cells, which are derived from a blastocyst and expanded in culture and induced plu[ri]potent stem cells are pluripotent. Although Dr. Rader likely knew about induced pluripotent stem cells and embryonic stem cells in 2010, there is no indication that the cells used were either induced pluripotent or embryonic stem cells. In fact, Dr. Rader's literature specifically states that the cells were not cultured. Thus, there are no known pluripotent cells that are isolatable from the human fetus. If the stem cells provided were either truly "neuronal" or "hematopoietic", the state of the art in 2010 would indicate that the only cell types derived from these cells would be of neural or hematopoietic linages. Another point that Dr. Rader makes in the information provided is that the cells will home in to damaged areas, repair damage where needed as well as proliferate in the body. In the treatment paradigms provided, these events are highly unlikely to happen. There is some evidence that stem cells can home in on regions of acute damage in experimental animals, but this has never been shown to be true in human clinical studies of chronic brain anoxia or chronic spinal cord injury. Furthermore, intravenous or subcutaneous administration of the cells would make such "homing" of cells highly unlikely.

(Exhibit 33, AGO 01866.)

39. Dr. Parkman disagreed with Respondent regarding the claimed lack of allogenicity in fetal stem cells, and Respondent's claim that fetal stem cells are "immuno-privileged" meaning that there is no risk of rejection, host vs. graft disease or graft vs. host disease. Dr. Parkman wrote:

> Human cells express human leukocyte antigens (HLA), and therefore, the transplantation of allogeneic tissues or cells requires the testing of both donors and recipients to ensure the persistence of the donor cells and to determine if immunosuppressive drugs are required. Therefore, the Standard of Care is to HLA type the donor and recipient and, if histocompatibility differences exist, to give immunosuppressant drugs post-transplantation.

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Analysis

Erythroid and myeloid cells in the fetal yolk sac first have HLA Class I (A, B) and Class II (DR) histocompatibility antigens detected at six weeks post-conception. The cells then migrate to the fetal liver where the hematopoietic cells continue to express both Class I and Class II histocompatibility antigens with 50% of adult expression by 10 weeks post-conception. Thus, the hematopoietic stem cells and hematopoietic progenitors (CD34+) present in the fetal liver at 9-12 weeks post-conception express both Class 1 (HLA-A and –B) and Class 2 (HLA-DR) antigens.

Fetal spinal cord cells express both Class I HLA and Class II HLA histocompatibility antigens as early as six weeks of gestational age, although the frequency of Class I expressing cells is greater than that of Class II expressing antigens. The cerebral cortex anlage has lower levels of HLA expression than spinal cord cells.

Conclusion

Dr. Rader's statements that the fetal stem cells are not antigenic, i.e. do not express HLA antigens at the time the fetal stem cells are obtained at 8-12 weeks of post-conception, are not true. Therefore, the statements in his book as well as in his interview are inaccurate and represent a lack of knowledge.

[¶] . . . [¶]

The transplantation of allogeneic cells or tissues requires the administration of immunosuppressive drugs such as cyclosporine, anti-thymocyte globulin, or corticosteroids for their intermediate or long-term persistence.

Analysis

Although immunosuppressive drugs are not necessary after the transplantation of autologous or syngeneic cells (either tissues or cells), immunosuppression is required for the prolonged persistence of allogeneic cells expressing histocompatibility antigens. Since both fetal liver and spinal cord cells expressed histocompatibility antigens and their long-term persistence is expected, the lack of administration of immunosuppressant drugs will result in their rejection by the immunocompetent patient.

(Exhibit 49, pages 2-3.)

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40. The gravamen of Dr. Parkman's position is that, as a stem cell develops from the embryonic stage to the somatic stage, it begins as non-allogeneic, but acquires Class HLA-I and later the HLA-II antigens as fetal stem cells. Fetal stem cells begin to express HLA-I at six to seven weeks. Therefore, unless the cells to be infused are autologous (from the patient's own body) or are to be exchanged between identical twins, immunosuppressant drugs must be used to prevent rejection, host vs. graft disease or graft vs. host disease.

41. Dr. Duncan conceded that fetal stem cells do carry the HLA I antigen, but not to the degree that rejection, host vs. graft disease, or graft vs. host disease will occur. She pointed out that immuno-suppressant drugs are, themselves, dangerous in that they inhibit the immune system, placing the patient at risk of infection or disease he/she could otherwise have avoided. That point emphasizes what Complainant's experts explained—that science has not yet reached the point at which fetal stem cell therapy can be safely used in the treatment of human injury and disease. Respondent's claim that over 2,000 patients received fetal stem cell therapy without rejection or negative side effects is not supported by the overwhelming weight of the medical evidence.

The Patients Referenced in the Accusation

Patient J.D.[14]

42. In 1995, J.D. underwent a routine dental cleaning that resulted in a staph infection in his blood. His condition deteriorated until he was near death. Following a magnetic resonance imaging scan (MRI), he underwent an unsuccessful decompressive laminectomy at the C4-7 levels.[15] He was told his condition was irreversible and that he would probably never walk again or use his hands and arms normally. Rehabilitation efforts were unsuccessful. In 1996, through his own work-outs, J.D. was able to regain the ability to walk. However, the condition left him in constant, excruciating pain. In 2006, after trying various treatment forms including but not limited to pain management and 92 hyperbaric treatments, J.D. heard about stem cell science on television. Additional online research led him to Respondent.

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[14] The initials of the patients and those of their relatives are used in lieu of their names in order to protect their privacy.

[15] There was some testimony at the hearing that J.D. had been suffering from spinal meningitis. Dr. Kornblum testified that J.D. had contracted transverse myelitis, an inflammation of the spinal cord, but he explained that this was not necessarily his diagnosis. Other than his own records, which do not indicate any attempt at diagnosing J.D.'s, condition, Respondent's chart contains only an incomplete operative report without a reported diagnosis.

43. After viewing some videos of testimonials on the Medra website, and Respondent's statement that he had successfully treated 1,500 patients, J.D. contacted Respondent. Respondent told him he had treated seven to nine spinal cord injuries with fetal stem cells and arranged for J.D. to speak with R.K., a former spinal cord injury patient he had successfully treated. J.D. offered to forward his medical records to Respondent. Respondent stated it would not be necessary to do so and that he felt certain he could help J.D. with stem cells. Respondent said that one million stem cells would be transplanted, that there was no risk of disease from the transplant, and that the treatment would cost $25,000.

44. When asked, Respondent told J.D. the treatment was performed outside of the United States because it was not approved by the Food and Drug Administration (FDA). However, he had applied to have it approved, and he anticipated its approval very soon. However, he did not tell J.D. that another physician would administer the treatment. J.D. assumed Respondent was his doctor.

45. J.D. and Respondent spoke again in March 2007. Respondent was encouraging, but J.D. was reluctant to undergo the treatment because of all he had been through.

46. In or around July 2007, Respondent contacted R.K. R.K. told him she had suffered a spinal cord injury which Respondent had treated with some success over three treatments three months apart. R.K. stated that the treatment had been painful, that it felt as if she was "being taken over by some entity" (J.D.'s statement), and that she lost sensation in her legs, but that it came back some time later. R.K. encouraged J.D. to undergo the therapy.

47. J.D. decided to undergo the treatment. After a number of telephone conversations with Medra personnel, he was instructed to fill out a medical history form and return it, and to wire $25,000[16] to the Dulcinea Institute via the First Caribbean International Bank, which he did after securing a loan from his bank. J.D. did not discuss the matter with his regular physicians because Respondent instructed him not to discuss the treatment with anyone, and that he would let J.D. know when it was alright to talk about it.

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[16] The $25,000 was for the treatment only. It did not include airfare or lodging.

48. The day after J.D. arrived in the Dominican Republic, two locals wearing jeans and t-shirts picked him up in a van and took him down a dirt road to a small house in the center of a plowed field. J.D. was surprised at this because he had anticipated being taken to a medical facility. A woman standing in front of the house introduced herself as Deborah Huff-Rader, Respondent's wife. Mrs. Huff-Rader escorted J.D. to a bedroom in the house that appeared to be a normal residential bedroom as opposed to a medical treatment room. Two Spanish-speaking women were in the room. They were not wearing clothing representative of medical professionals. They did not speak to J.D. Mrs. Huff-Rader told J.D. to make himself comfortable on the bed. Respondent telephoned and said he would arrive shortly. One of the women established an IV but did not state its purpose. In 10 to 15 minutes, Respondent arrived with a vial containing a yellow liquid and told J.D., "These are your stem cells." Respondent handed the vial to one of the women and she picked up a syringe. He told J.D. to unbutton his shirt. He then placed a piece of paper on J.D.'s lap.

49. The document was a consent form. J.D. scanned it without reading it carefully. However, he was concerned about it because he had not been made aware that the treatment was experimental or that Respondent would not be performing the procedure. Nor had he been aware of the possibility of adverse reactions or possible danger as referenced in the consent form. The consent form required that he not disclose any information regarding his or anyone else's treatment or any knowledge he had acquired from Medra and/or its staff absent the express consent of a Medra corporate officer. J.D. was hesitant to sign the consent form, but he had already paid for the treatment and traveled to the Dominican Republic, so he decided to proceed with the treatment. Respondent did not discuss any risks or benefits of fetal stem cell therapy with J.D. before J.D. signed the consent form.

50. After J.D. signed the consent form, Respondent instructed the woman to give J.D. three injections in the abdomen and to place some of the liquid in the IV. Respondent gave J.D. a card stating that it bore his personal telephone number, and he instructed J.D. to call him if a problem arose. Five minutes later, the IV was disconnected and J.D. was taken back to his hotel. He returned home the next day.

51. Beginning three months after the treatment, Medra personnel telephoned J.D. occasionally to ask how the procedure had gone and how he was doing. At six months, there still had been no improvement in his condition. J.D. spoke with Respondent in February 2009. Respondent said, "You'll be normal again, I promise. I just don't know when." He told J.D. that patients occasionally required additional treatment and suggested that he go to Tijuana for another treatment. Respondent offered the second treatment at no cost to J.D.

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52. J.D. decided to undergo a second stem cell treatment. The procedure in Tijuana was the same as it had been in the Dominican Republic. He had not been told his medical information would be shared with anyone outside of Medra, and he had not signed an authorization for release of his medical records. The day after his arrival he was taken to a facility next door to a mall and was directed to a cubicle containing a leather-covered lounge chair. Respondent and a local woman were present in the cubicle. Respondent's wife and another woman were outside the cubicle. No one wore medical uniforms. The woman in the cubicle established an IV. Respondent handed a consent form to J.D. and said he had to sign it or they could not proceed. He did not discuss any risks or benefits of the therapy with J.D. J.D. signed the form, and the woman placed the entire vial into the IV. At that time, J.D.'s pain spiked and he was unable to hold still. Respondent was "hovering" (J.D.'s term) over him saying he must stay still. They finally got the IV into J.D.'s vein. Respondent then said he knew what needed to be done: J.D. had to return to the Dominican Republic the next month for an epidural, and that he thought he knew a woman who could do it. J.D. is certain Respondent said "woman," not "doctor." A few minutes later, Respondent had received the entire contents of the vial. He was returned by van across the border.

53. No one from Mexico followed up with J.D. In April 2009, he received a telephone call from Terrie at Medra. He told her he still had no relief. He was undecided about returning to the Dominican Republic for a third treatment, but eventually decided to go. In July, Respondent offered the epidural at no charge.

54. Upon arriving in the Dominican Republic, J.D. was taken to a small house near the ocean. It appeared to be a private home. J.D. noticed a bar to his right when he entered. He was taken to a large room which housed a regular residential bed. Respondent instructed him to lie down on it, and he gave J.D. another consent form which J.D. signed. Respondent instructed J.D. to face the wall and lower his pants to expose his back. Respondent did not discuss the risks or potential side effects of an epidural.

55. Two Dominican women and Respondent's wife were present. One of the women told the other to swab alcohol on J.D.'s back. Respondent then helped her identify the precise location for insertion of the syringe. The woman gave J.D. the injection. Respondent left the room, returned with two men who were dressed in jeans and t-shirts, and instructed the men to lift the end of the bed, which they did. Respondent told J.D. he had instructed them to do so to help the stem cells migrate to the area of damage. J.D. returned home the following day.

56. J.D. experienced no benefit from any of the three treatments. A subsequent open MRI showed no changes. He remains in extraordinary, constant pain today for which he takes multiple doses of MS Contin (morphine sulfate). His new neurologist explained that the science of stem cells had not progressed to the point at which stem cells could be made into the type of cells that could help him, and that there was no way the stem cell treatments J.D. received could have helped him. Shortly thereafter, J.D. viewed the 60 Minutes television show about doctors injecting stem cells for large fees with no results. He saw Medra's logo in the center of the screen.

57. A couple of months after the third treatment, J.D. developed "horrible headaches" (J.D.'s term) that lasted for hours. The evidence did not establish a nexus between the stem cell treatments and the headaches.

58. At one time during the course of their relationship, Respondent said to J.D. "I'm your doctor. You have to trust me." However, during the course of the entire relationship, over three stem cell treatments, Respondent made no effort to determine the cause of J.D.'s excruciating pain.

59. Dr. Duncan took the position that Respondent was not J.D.'s physician. Therefore, he would not be subject to the standard of care. Dr. Duncan explained that Respondent is a psychiatrist and is not in a position to evaluate an individual's physical condition or attempt to add to the diagnosis. She did not acknowledge that a physician's specialty does not limit his/her ability to practice in other areas of general or specialized medicine. She also testified that no physician-patient relationship is established absent a specific agreement between the physician and the patient. Because Respondent never specifically agreed to serve as the physician for any of the patients involved in this case, he was not the physician of any of them. However, even if he were their physician, his conduct had been within the standard of care in all respects. Dr. Duncan did not address Respondent's conduct with respect to any particular patient.

60. Dr. Kornblum opined that Respondent acted as J.D.'s physician by evaluating and recommending a specific course of treatment which was then undertaken. The evaluation was a discussion between J.D., Respondent, and Respondent's staff. It was important for Respondent to obtain J.D.'s medical records so he could better understand J.D.'s condition. Because the transplantation of stem cells was an invasive procedure, it was incumbent upon Respondent to evaluate J.D.'s medical records and to evaluate J.D. in person. As stated above, the opinions and reasoning of Dr. Kornblum and Dr. Parker are more convincing than those of Dr. Duncan.

61. Based on Dr. Kornblum's opinion and the reasons supporting it, Respondent was J.D.'s physician, and he failed to properly evaluate J.D. That failure constitutes an extreme departure from the standard of care.

62. Dr. Kornblum also opined that Respondent failed to discuss the risks and benefits of fetal stem cell therapy with J.D. That opinion is consistent with Respondent's testimony and steadfast position that he does not discuss them with the patient because there are no risks associated with the treatment. Dr. Parkman opined that, because fetal stem cells are not anti-allogenic, Respondent's failure to administer immunosuppressive drugs constitutes an extreme departure from the standard of care. (Exhibit 9, AGO 02247.) Respondent's decision against administering immunosuppressive drugs to J.D. posed a risk he should have disclosed. Respondent's failure to discuss with J.D. the risks and benefits of the treatment he received constitutes an extreme departure from the standard of care.

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63. Complainant also alleged with respect to Patient J.D. that Respondent deviated from the standard of care by "recommending that patient J.D. undergo a fetal stem cell treatment when there was no medical evidence that such treatment could benefit patient J.D." (Accusation, p. 10, para. 36A.) Complainant did not sustain her burden of proof on that issue. Although there was no evidence in the form of clinical studies to support Respondent's position, Respondent relied on empirical evidence in making his recommendation. Both Drs. Kornblum and Parker conceded that empirical evidence can be of value in certain situations. Thus, there was not a complete absence of evidence, only a lack of formal evidence.

Pt. J.S.

64. J.S. is a 35-year-old man who was involved in a motorcycle accident on April 15, 2006. He suffered a C6-7 crush injury in the accident that left him paralyzed from the chest down. He is confined to a wheelchair. Following the accident, his mother became his primary caregiver. J.S.'s injury is considered an incomplete spinal cord injury meaning that some signals to and from the brain are still able to traverse the damaged spinal cord.

65. Over time, through occupational therapy and physical therapy, J.S. gradually gained strength and was eventually able to drive a handicap van. However, physical therapy was expensive, and it eventually stopped yielding its earlier benefits.

66. J.S.'s mother, P.S., began researching alternate therapies for her son and became interested in stem cell therapy. She contacted a neurosurgeon who told her the research had not yet progressed to the point that stem cells could help J.S. However, P. S. continued to research the issue, and an Internet search led her to the Medra website. After watching the videos on the website, she discussed the possibility of stem cell treatment with her son who expressed an interest. P.S. then e-mailed Medra on his behalf and was contacted by Medra personnel. Following a few telephone conversations, they sent P.S. a patient information form to be filled out and returned.

67. In June 2008, P.S. spoke with Respondent who told her he had treated approximately 35 spinal cord injury patients and all had improved although not all were walking. He explained that he did not treat individuals with complete spinal cord injuries. He stated he was the only one in the world performing the stem cell transplantation procedure, that his stem cells proliferated forever, and that they were never rejected. He told her that her son was certain to improve with his treatment because of his age and physical condition. However, another employee at Medra had told P.S. that there were no guarantees of improvement.

68. On another occasion, Respondent spoke directly with J.S. Respondent told J.S. that stem cells would work well with an incomplete spinal cord injury such as his. He did not further discuss the risks or benefits of the treatment, and he did not tell J.S. how the cells would be injected. J.S. asked if Respondent wanted to speak with his physicians. Respondent said it would not be necessary.

69. J.S. and his mother agreed that he should undergo the procedure. P.S wired $30,000 to the Dulcinea Institute in the Bahamas with the understanding that Respondent was J.S.'s doctor. The $30,000 was to cover the treatment only, exclusive of travel expenses. P.S. was not told that J.S.'s medical information would be shared with others. She and her son then flew to the Dominican Republic.

70. No one appeared to greet them upon their arrival. They took a shuttle bus to their hotel, but it did not have a ramp. Two men lifted J.S. from his wheelchair and put him on a seat without a seat belt. The following day, they were picked up by a van to go to the treatment site. Two men pushed J.S. up a makeshift wooden ramp into the van. He was not strapped in. They were taken to an area of new residential construction where they entered a completed house. They were greeted by a man and a woman, who identified herself as Deborah Rader. She told J.S. and his mother that Respondent had a prior engagement in the United States and was unable to attend the procedure. That surprised J.S. because Respondent had informed him by telephone that he would be present and would perform the procedure himself.

71. J.S. was taken to a bedroom of the house that was furnished with a residential bed and nightstand. It had an adjacent bathroom. J.S. chose to stay in his wheelchair and did not transfer to the bed. A woman established an IV and took a small blood sample. She left and returned approximately 10 minutes later with a container. While J.S. and P.S. were waiting for her to return, they were given two forms. The first was a consent form. The second was a form according to which they were to promise not to disclose any information. P.S. signed the consent form on her son's behalf. However, she wanted to tell everyone about their experience, so she refused to sign the second form. Shortly thereafter, Respondent's wife brought a telephone to P.S. and told her Respondent was on the line. Respondent explained that the pharmaceutical companies would attempt to shut him down if they learned what he was doing.

72. P.S. signed the consent form after discussing it with J.S. She signed it even though she had not been told Respondent would not be there and that other doctors would be involved. She thought Respondent would perform the procedure. She had not been advised of the possibility of an adverse reaction. She had not been told the treatment was experimental. She had been told only that there was no guarantee of improvement and that the treatment was not legal in the United States.

73. Once both forms had been signed, the woman gave J.S. two injections in his abdomen and placed the remainder of the material in the IV. This was done in the absence of a physical examination or the taking of J.S.'s vital signs. Following the treatment, Respondent's wife told J.S. that Respondent wanted to speak with him. In a brief telephone conversation, Respondent asked J.S. how the treatment went, and that he was sorry he had been unable to be there. A few minutes later, another van came to return J.S. and his mother to their hotel. They were not given any after-care instructions.

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74. Approximately six months later, J.S. received two telephone calls from Medra inquiring as to whether he had experienced improvement. He said he had not. Medra personnel asked if he wanted to go back for another injection at no charge. J.S. declined.

75. Thereafter, J.S.'s mother began making vitriolic, disparaging entries against Respondent and people associated with him on a Topix.com board. She claimed she did it to "save other people." (P.S.'s statement.)

76. Dr. Duncan opined in general terms only. She did not address the standard of care with respect to J.S. specifically. She stated only that Respondent did not act as the physician for any patient, but that if he did, he had comported himself within the standard of care in all respects.

77. Dr. Kornblum opined that the physician-patient relationship between Respondent and J.S. was established by his recommendation for treatment. Even though Respondent was not present when the treatment was administered, he arranged for the treatment, and the treatment would not have taken place at all without his involvement in the case. It is analogous to a physician who arranges for his patient to undergo surgery by a surgeon but is not present during the surgery. Because Respondent was J.S.'s physician, he was obligated to properly evaluate J.S. before recommending fetal stem cell therapy. The evaluation would include "an understanding of the timing and mechanism of the injury" and "appropriate immunologic testing of the sample to be administered as well as the patient, depending on the type of sample, a knowledge of the general health of the patient to ensure that . . . they would be able to both get to the site of treatment as well as tolerate the treatment and potential side effects of the treatment." (Exhibit 33, AGO 01865.) In addition, a physical examination must be performed. Dr. Kornblum credibly opined that Respondent's failure to properly evaluate J.S. before recommending treatment was an extreme departure from the standard of care. That opinion is adopted as a factual finding herein.

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78. Dr. Kornblum further opined that Respondent failed to provide concise, understandable and accurate information regarding the potential risks and benefits of the fetal stem cell therapy. He wrote:

> Part of any informed consent procedure includes a discussion of the risks of therapy. In numerous locations, including discussions between Dr. Rader and the patients' family, in materials from the Internet, in Dr. Rader's book statements are made to the effect that there are no side effects of treatment. This is untrue. Potential side effects from the treatments proposed range from minor side effects to major side effects and even death. First, the process of injection has potential side effects. Any introduction of a needle into the body can result in bleeding which is usually mild or self-limited as well as infection, which can also be very mild, but can also be life-threatening. The cells, themselves, or the fluids or vehicles used in treatment can also carry infection. Although there is assurance from Dr. Rader that the cells are tested by PCR for infections, it is not clear what these infections are and there is no documentation of such testing procedures provided or any documentation of certification of the accuracy of such tests. Furthermore, specific routes of administration can carry with them specific risks. Administration into the intrathecal space, a route suggested in the interview with Dr. Rader, for example, can introduce serious infections into the cerebrospinal fluid, resulting in meningitis. The misplacement of needles can also cause bleeding and even paralysis. The introduction of cells into the intravenous space can also cause more serious infections than simple introduction into the subcutaneous space. While standard precautions can be taken to minimize these risks, they cannot be eliminated completely. There is no discussion of such risks in any of the literature I have seen, nor in the statements provided by the families of Mr. C . . . and S. . . . Furthermore, there is no indication that the suppliers of the cells or the Rader group have standard operating procedures that would ensure the safety and purity of the cells. Another point on which there is false or misleading information provided to the patients is the issue of immunogenicity. There are several documents indicating that the cells cannot be rejected. All allogeneic (cells bearing genes different from the recipient) cells can give rise to an immune response. This is true now and there was no reason to believe the contrary in 2010. Rejection, if untreated will cause treatment failure. A most devastating potential complication, in the case of hematopoietic stem cell infusion is that of graft vs. host disease. Although it is very unlikely that any of the hematopoietic stem cells will achieve the targeted goal of engraftment, if such proves to be true, there is a likelihood that the immunocompetent cells produced from the stem cells would view the host as "other" and attack the host's cells. In its most severe case, graft vs. host disease can be lethal. In the least, it requires supportive management.

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> Taken together, the failure of Dr. Rader or his staff to provide concise, understandable and accurate information of the potential risks and benefits of the proposed therapies represents an extreme departure of standard of care.

(Exhibit 33, AGO 01866-01867.)

79. Dr. Korblum's opinions and the reasons therefor are convincing. Further, Dr. Parkman opined that, because fetal stem cells are not anti-allogenic, Respondent's failure to administer immunosuppressive drugs constitutes an extreme departure from the standard of care. Respondent's decision not to administer immunosuppressive drugs to J.S. posed a risk he should have disclosed. Respondent's failure to provide concise, understandable and accurate information regarding the potential risks and benefits of the fetal stem cell therapy constitutes an extreme departure from the standard of care.

80. As with Patient J.D., Complainant alleged that Respondent committed gross negligence and repeated negligent acts by recommending to J.S. that he undergo fetal stem cell treatment when there was "no medical evidence that such treatment could benefit patient J.S." (Accusation, page 9, para. 29A.) Complainant failed to prove that allegation for the same reasons set forth with respect to Patient J.D., above.

Patient H.C.

81. In 2010, H.C., then approximately 73 years old, became ill and comatose for two weeks. He emerged from the coma with an anoxic brain injury. His physicians told his family there was no hope for survival, and they recommended that his family consent to have him removed from life support. However, when they consented and life support was removed, H.C. continued to breathe on his own. After approximately one week, his wife and five daughters took him home where his daughter, I.T., acted as his caregiver with the assistance of hospice services. Although he was breathing on his own, H.C. was completely dependent on others for all other aspects and activities of daily living.

82. I.T. was "desperate" (I.T.'s term) to find a way to improve her father's health. She researched the Internet and wrote to television personality, Dr. Oz. (She received no response from him.) Her Internet search brought her to the Medra website where she read and viewed testimonials from individuals with a wide range of disorders, including brain injuries, who had experienced dramatic improvement through the use of fetal stem cell therapy. According to the website, Respondent had successfully treated 1,500 patients. He described his procedures on the website. I.T. was interested, and she sent an e-mail to Medra. She received a reply within five minutes. She subsequently spoke with John Brower at Medra, who told her H.C. was a "perfect candidate" (I.T.'s term) for stem cell therapy. Mr. Brower did not disclose that he was not a physician.

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83. Within a few hours of I.T.'s initial e-mail, a conference call took place between Respondent, H.C.'s wife and daughters, and Mr. Brower. The family explained the nature of H.C.'s brain injury. Respondent told them that stem cells would go to the brain, "re-open" it (I.T.'s term) and re-grow healthy cells. The cells would be injected into the brain and arm at a cost of $30,000. H.C. would travel by helicopter (air ambulance) from his home in Mobile, Alabama to the Dominican Republic at a cost of $2,000.[17] Respondent stated the procedure had to be performed as quickly as possible. The family could not afford the price of treatment and transportation, so Respondent recommended that the treatment be performed in Mexico at a cost of $20,000. The family understood that Respondent would personally perform the procedure. He said nothing about physicians in Mexico. I.T. and her mother decided to accept that option. The remainder of their family was skeptical and did not approve of their father traveling from Mobile to Tijuana for fetal stem cell therapy. When the family was subsequently unable to raise the money for the trip and the treatment, Respondent's wife reduced the price of the treatment to $17,500, provided it was paid in cash.

84. On February 11, 2010, Mr. Brower wrote two letters to "to whom it may concern" requesting expedited passports for I.T. and a friend who would be traveling with them. The letters were written under Respondent's/Medra, Inc.'s letterhead. The body of each letter began with the following language: "This letter is to confirm that Mr. H . . . C . . . is a patient of Dr. William C. Rader MD . . ."

85. The family was provided with a medical history form which they completed and signed on February 16, 2010. The family was not told the information would be shared with a physician in Mexico, and they were not asked to consent to it. The treatment was planned for February 20.

86. Instead of paying for an air ambulance, I.T. and her mother rented a recreational vehicle (RV) and, with a friend and one of I.T.'s sisters, began the trip to California where they would meet Respondent's employees who would escort them through the border without her father having a passport.

87. The trip began on February 17, 2010 with arrival planned for February 20. During the trip, H.C.'s blood pressure dramatically vacillated between 40/24 and 160/98. I.T. attempted to stabilize his blood pressure by medicating him through the tube that physicians had inserted in his abdomen. While driving through Texas, the problem became so intense that the family called 911. Paramedics were able to stabilize H.C. However, the problem returned four or five hours later. This time, I.T. telephoned Respondent and asked if he could help. Respondent asked if anyone on the RV had a Valium. When the family located one, Respondent instructed I.T. to give it to her father.

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[17] Respondent's records indicate that transportation was to be by prop jet air ambulance at a cost of $22,000 or by "jet" (presumably fan jet) at a cost of $28,000. (Exhibit 18, AGO 01793.).

88. When the family arrived in San Diego on February 19, H.C.'s condition was so deteriorated that they were unable to go to the hotel. An ambulance transported H.C. to the Emergency Department at Scripps Mercy Hospital where he was initially seen by Clayton Whiting, M.D.

89. Dr. Whiting found H.C. chronically debilitated and ill and in a chronic vegetative state. H.C. was breathing on his own; he had a pulse; he was unable to communicate; he had contracted musculature, and his blood pressure was somewhat depressed. However, he was "essentially stable" (Dr. Whiting's term) and did not require immediate intervention. Dr. Whiting believed H.C. was at the end of life with an anticipated life expectancy of three to six months. Dr. Whiting called for a consult by Denise Waugh, M.D., a specialist in hospice and palliative medicine.

90. While providing the medical history, I.T. had informed Dr. Whiting that the family was enroute to Mexico for her father to receive stem cell treatment, and that Respondent was H.C.'s doctor. After Dr. Whiting called in Dr. Waugh, I.T. asked Dr. Whiting to speak with Respondent. Respondent then instructed Dr. Whiting to render no treatment other than to give the patient fluids, and to have the patient continue to Mexico with his family. Dr. Whiting declined that instruction.

91. Dr. Waugh examined H.C. after receiving his history from I.T. She found him non-responsive and close to death. Sensory and motor functions were absent. Dr. Waugh went to the Medra website to verify what I.T. had said about Respondent. The family expressed the desire to have H.C. continue to live or to die comfortably. They were troubled about being estranged from the other family members, and they were open to the opinions of Drs. Whiting and Waugh. Dr. Waugh offered the family inpatient hospice at the hospital or elsewhere. She was concerned that H.C. would die in the RV if the family attempted to return him to Alabama. The only appropriate therapy at that point was supportive therapy, and to address the spiritual and psycho-social issues for the family. The family members wanted to re-unite the family, and they did not want to deny the other family members the possibility of seeing their father alive again. They chose to return home to Alabama.

92. Once enroute, I.T. and Respondent spoke by telephone. Respondent offered to perform the procedure for free if I.T. would turn around and bring her father to Tijuana for the treatment. I.T. declined the offer. H.C. survived the return trip to Alabama but died on March 15, 2010. Upon I.T.'s request, Respondent reimbursed her for the RV rental and gasoline. According to I.T.'s testimony, the reimbursement was conditioned on I.T.'s written promise not to tell anyone what had occurred. However, the letter the family sent to Respondent refers to the reimbursement and states, "We will not pursue any futher [*sic*] actions against you." (Exhibit 12, AGO 00067.) There is no reference to a promise not to disclose the events relating to H.C.

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93. Respondent testified that, although he believes he had a telephone conversation with Dr. Whiting, he does not recall it. That testimony had little credibility. This was not the kind of conversation likely to skip one's mind. This was a call across an international border with an emergency department physician about a patient Respondent was waiting to arrive in an RV, but who was in a chronic vegetative state on the other side of the border. However, Respondent does remember offering to treat H.C. for free if I.T. would bring him to Tijuana.

94. Despite that recollection, Respondent testified that he had not been H.C.'s physician and that he had not approved H.C. to receive the stem cell treatment. However, Medra's chart for H.C. contains the two letters identifying Respondent as H.C.'s physician, a number of references to "Dr. Rader's evaluation," and statements from at least two Medra employees that H.C. would receive the treatment in the RV.

95. As stated above, Dr. Duncan took the position that Respondent did not serve in the capacity of physician for any patients, but if he did, he comported himself within the standard of care in all respects.

96. Dr. Kornblum's and Dr. Parkman's opinions were the same with respect to H.C. as they were in connection with J.D. and J.S. Their opinions and their underlying reasons are more persuasive than those of Dr. Duncan.

97. Respondent's failure to properly evaluate H.C. before recommending treatment, and his failure to provide concise, understandable and accurate information regarding the potential risks and benefits of the fetal stem cell therapy each constitute an extreme departure from the standard of care.

98. As with Patients J.D. and J.S., Complainant alleged that Respondent committed gross negligence and repeated negligent acts by recommending to H.C. (via his family) that he undergo fetal stem cell treatment when there was "no medical evidence that such treatment could benefit patient H.C." (Accusation, page 7, para. 21A.) Complainant failed to prove that allegation for the same reasons set forth with respect to Patients J.D. and J.S., above.

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99. Dr. Kornblum also criticized Respondent for giving medical advice for H.C. without adequate training and knowledge to understand the situation and recommend a course of treatment, both with respect to recommending Valium belonging to someone else and in making treatment recommendations to the emergency department physician. Dr. Kornblum considered Respondent's conduct in that regard an extreme departure from the standard of care. He wrote:

> Dr. Rader recommended directly to the treating physicians that Mr. C . . . was to be given fluids and released, as demonstrated in the notes. In the setting of a critically ill elderly person, such recommendations would require careful evaluation by an experienced, appropriately trained physician. There is no evidence that Dr. Rader has such training or experience. The recommendation made by Dr. Rader would represent an extreme departure from the standard of care.

(Exhibit 33, AGO 01867-01868.)

100. Respondent's medical decision making with respect to his instruction to give the patient a Valium and his instructions to the emergency department physician constitutes an extreme departure from the standard of care.

Undercover Patient E.B.

101. Between February and November 2012, two investigators for the Board conducted an undercover operation in connection with Respondent's business. On February 18, 2012, the first investigator, using an assumed name (C.A.), sent a contact inquiry to the Medra.com website, claiming her friend, E.B., had suffered a spinal cord injury and was interested in stem cell therapy. A few days later, she was contacted by Ken Venisnik from Medra.

102. On March 15, 2012, a conference call was held between C.A., E.B., and Venisnik. Venisnik denied having any medical background. He claimed to be Respondent's assistant or secretary. He stated that Respondent had treated his son whose condition had improved with the treatment. He provided the undercover investigators with information about stem cell therapy and said the cost of treatment was $30,000. C.A. asked to speak with Respondent, and Venisnik agreed to forward the request to Respondent along with what he had learned about E.B.'s condition. Shortly after that conversation, C.A. received a link to Respondent's book.

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103. On April 2, 2012, C.A. and E.B. participated in a conference call with Respondent. Respondent told them about fetal stem cell therapy, that he was the only physician in the world doing it, and that he had treated over 2,000 patients, more than 100 of whom had spinal cord injuries. Most of those patients had shown improvement. Respondent told them the cells come from fetuses aborted in Eastern Europe, that the cells were harvested and tested at his laboratory in Germany and then sent to treatment sites in the Dominican Republic and Tijuana. He discussed his book stating that what he was doing was unavailable in the United States because "the powers that be" (C.A.'s term) were blocking its use. He believed fetal stem cell therapy would definitely benefit E.B. because E.B.'s spinal cord injury was incomplete. He stated the procedure would be a lumbar puncture or spinal tap performed by an anesthesiologist in Tijuana with Respondent present, and that his employees would follow up at three months. E.B. would be given Respondent's private e-mail address and cellular telephone number. Respondent further stated that no side effects were possible because of the nature of the fetal stem cells. He confirmed that the cost of the treatment was $30,000 and said E.B. might not notice any improvement for three to six months. E.B. asked if Respondent needed to see him before the procedure. Respondent stated that it would not be necessary. Following that conversation, a Medra staff member requested a recent MRI. The investigators did not provide one.

104. Respondent's records for April 2, 2012, indicate that Respondent would administer both an epidural and lumbar puncture.

105. C.A. read Respondent's book and found numerous references that led the reader to believe he was the treating physician for fetal stem cell patients. (See Factual Finding 146.)

106. C.A. contacted Medra again on October 12, 2012. By that time, the company name had changed to Stem Cell of America. On October 18, she informed Stem Cell of America personnel that she had raised $25,000 of the required $30,000. She did not request a discount. However, she was offered two different discounts according to certain payment dates. November 17, 2012 was scheduled for the day E.B. would undergo the treatment.

107. On October 26, 2012, C.A. and E.B. participated in another telephone conversation with Respondent. Respondent did not seem to remember them, and he reiterated the same things he told them during their first conversation. E.B. asked Respondent about informing his neurologist of the stem cell treatment. Respondent stated he usually discouraged patients from telling their doctors about it because the doctors disapprove of it, but that E.B. could tell his neurologist after the treatment was completed. However, Respondent predicted that the neurologist would attribute any progress to spontaneous improvement.

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108. C.A. subsequently received information from Stem Cell of America regarding travel arrangements and instructions on how to wire funds to cover the fee. Neither C.A. nor E.B. ever wired any funds or submitted a medical history questionnaire. C.A. did, however, receive a confirmation on the November 17 treatment date. On November 1, 2012, C.A. sent an e-mail to Stem Cell of America informing them that E.B. could not keep his appointment. She received a reply stating that Respondent had not yet spoken directly with E.B., even though he had done so twice.

109. On February 13, 2013, the investigator who had posed as C.A. conducted an interview with Respondent. During that interview, Respondent stated he does not treat patients, but is more of a referral service who refers patients to foreign physicians who decide whether to treat the patient. He denied making recommendations for patients. These statements were contrary to statements Respondent made during the undercover operation.

110. As stated above, Dr. Duncan took the position that Respondent did not serve in the capacity of physician for any patients, but if he did, he comported himself within the standard of care in all respects.

111. Dr. Kornblum's and Dr. Parkman's opinions and their bases were the same for E.B. as they were with respect to the other patients. Their opinions and their bases were credible and persuasive. Respondent's failure to properly evaluate E.B. before recommending treatment, and his failure to provide concise, understandable and accurate information regarding the potential risks and benefits of the fetal stem cell therapy each constitute an extreme departure from the standard of care.

112. However, as with the other patients, Complainant alleged that Respondent committed gross negligence and repeated negligent acts by recommending to E.B. that he undergo fetal stem cell treatment when there was "no medical evidence that such treatment could benefit patient E.B." (Accusation, page 7, para. 21A.) Complainant failed to prove that allegation for the same reasons set forth with respect to Patients J.D., J.S., and H.C., above.

The "Fact" Patients

113. Respondent offered the testimony of four "fact witnesses" (Respondent's term), individuals who had successfully undergone, or whose child had successfully undergone, fetal stem cell therapy through Respondent's companies.

<u>S.F.</u>

114. S.F. resides near Chicago. She is married to an ophthalmologist who specializes in stem cell therapy. She wanted to stay as young looking and feeling as possible. She was undergoing hormone replacement therapy when she asked her physician if there was anything else she could do. He referred her to Respondent.

115. Respondent did not offer S.F. any guarantees, but he told her he had successes in the anti-aging area. S.F. underwent her first treatment in the Dominican Republic in November 2002. She was treated in a hospital or clinic setting. She signed a consent form when she arrived at the clinic. She understood the treatment was experimental and that Respondent would not be her doctor. Respondent did not participate in the procedure. She paid $25,000 for the treatment.

116. Having experienced no benefit from the first treatment, S.F. returned three months later for a second. She was charged $2,500. Respondent told her that, if she felt no improvement that time, the stem cells were working on something of which she was unaware.

117. S.F. again had no benefit from the stem cells. She returned to the same facility for a third treatment, again with no results. Respondent told her to wait one year before returning.

118. S.F. continued to treat with her regular physician during the course of the three treatments. At some point, she contracted chronic lymphocytic leukemia. She was told the disease was chronic, and there was no treatment available until it became acute. S.F. continued to get stem cells once per year. Each time, the number of atypical cells was reduced. S.F. believes the fetal stem cells saved her life. Her physician agrees.[18] However, at the hearing, S.F. had no documentation to establish the efficacy of the stem cell treatment.

W.G.

119. W.G. is a radiologist. His daughter was born on August 1, 2005. She developed mitochondrial disease. Although she manifested signs and symptoms of the disease as an infant, it was not diagnosed until age two or three. She became unable to walk, crawl, feed or speak.

120. W.G. read the literature on stem cell therapy and learned that it was not at the point where it could be utilized. Eventually he reached Respondent who provided him with information that led him to decide the benefits of the therapy outweighed any possible risks.

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[18] S.F.'s primary care physician, Walter R. Grobelny, M.D. submitted a declaration, signed under penalty of perjury, which was admitted as Exhibit VV. In it, Dr. Grobelny states that S.F. sought embryonic stem cell therapy outside the country against his instructions and without his support. S.F. disputed those statements claiming he had supported her decision to undergo the therapy. Further, S.F. testified that Dr. Grobelny only assumed the stem cells were embryonic as opposed to fetal. This discrepancy emphasizes the extant difficulties in using empirical evidence as a measure of treatment efficacy. Given the disparities between Dr. Grobelny's declaration and S.F.'s testimony, both of which were offered under penalty of perjury, both are given only limited weight.

121. W.G's daughter underwent her first fetal stem cell treatment in October 2009. W.G. understood that Respondent would not perform the procedure, but that he would be there for "moral support." (W.G.'s term.) He also understood that the FDA did not approve the treatment. He signed a consent form indicating the treatment was experimental and might not work. W.G. felt fully informed when he consented to the treatment. Following the first treatment, W.G.'s daughter showed improvement. She was hospitalized less frequently, and she became more affectionate.

122. W.G. took his daughter for a second treatment in approximately February 2011. She showed more improvement after that treatment in that she was hospitalized for epilepsy less frequently, and she was able to walk 44 stairs. She started school at age five.

123. W.G.'s daughter underwent two subsequent treatments. Each time, her improvement rate increased, and she went from being unable to go outdoors to wanting to go out.

124. W.G.'s daughter died of arrhythmia shortly after the fourth stem cell treatment. W.G. believes her death was caused by complications from her disease. Nonetheless, he attributes her improvement to the fetal stem cell therapy. He believes there was no hope for his daughter without it, and that the therapy should not be kept from other children. W.G. has offered to help Respondent in the future by sharing his experiences regarding his daughter's treatment and improvement.

J.G.

125. J.G. is a retired nurse with a degree in counseling. She has 15 children. One of her daughters was a school football and basketball star who developed a swollen ankle and foot in 2009 that prevented her from walking well. J.G. sought traditional treatment for her daughter, but the condition worsened and she developed swelling in the wrist, headaches, fatigue, numbness in the fingers, and a rash around her face. She was eventually diagnosed with lupus and arthritis. Conventional medical treatment, including chemotherapy, did not help, and her condition continued to deteriorate.

126. In approximately April 2013, J.G. contacted Respondent after viewing his website. Respondent did not promise results, but J.G. decided that fetal stem cells were her last hope, and she took her daughter to Mexico for the treatment.

127. J.G. was given a consent form when she entered the office in Mexico. She read it and understood the treatment was experimental and that results were not guaranteed. She expected the nursing staff to perform the procedure.

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128. The facility where the treatment took place was clean and well-staffed. J.G. and her daughter were taken to a room that looked like a treatment room in a physician's office. Respondent was present but did not participate in the procedure. Vitals were taken and an IV was established. Stem cells were delivered through the IV and abdominal injection.

129. Following the treatment, J.G. and her daughter were taken back to their hotel. Within two or three hours of the treatment, J.G.'s daughter was walking on the elliptical machine and the treadmill in the hotel. They returned home, and her daughter regained her energy. She subsequently underwent a second fetal stem cell treatment.

130. This year, J.G.'s daughter was named the most valuable player on her football team. J.G. attributes her daughter's improvement to the fetal stem cell treatment. She believes Respondent saved her daughter's life by giving her the opportunity to receive stem cell therapy. J.G. did not research whether the treatment was being offered elsewhere in Mexico.

131. Respondent was the only physician with whom J.G. spoke concerning her daughter's stem cell therapy. However, she did not consider Respondent to be the treating doctor.

132. At the hearing, J.G. did not have any documentation to establish the efficacy of the fetal stem cell therapy.

C.P.

133. C.P. has or had Parkinson's Disease. In addition, an accident she suffered in her youth left her hard of hearing.

134. C.P. first noticed symptoms of Parkinson's Disease in December 2011 when she developed hand tremors. Thinking they would resolve on their own, she postponed seeing her internist for one year. He then prescribed medication that was only partially effective. A neurologist agreed with the internist's diagnosis and kept C.P. on the same medication. However, within approximately two months, her condition deteriorated rapidly. A DaT scan showed a mild loss of dopamine in the brain but not enough to raise a concern about Alzheimer's Disease. Nonetheless, C.P. was suffering from tremors, her body was jerking, and she was unable to articulate words. She was repeatedly told there was no cure for her condition. She thought she was dying.

135. An online search about Parkinson's Disease led C.P. to the Stem Cell of America website. She spoke with a man at Stem Cell of America, and she obtained and read Respondent's book. She decided to try fetal stem cell therapy.

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136. C.P. received a medical history form in the mail which she filled out and returned. She was told it would be reviewed, but she was not told who would review it. C.P. assumes Respondent reviewed the form. However, she does not consider Respondent to be her doctor.

137. C.P. traveled to Tijuana in April 2013. She was taken to a clean clinic where she was given a consent form which she read and understood. She understood the treatment was not guaranteed, that it was experimental, that Respondent would not perform the procedure, and that she would not hold anyone responsible. She was taken to a room where an IV was started. A man introduced himself to her saying he was a doctor. He said he would give her two injections. The second injection would withdraw spinal fluid and inject stem cells. Respondent was present at that time, but he did not participate.

138. Following the procedure, Respondent asked a lady at the front desk to give C.P. a telephone number to call if she had questions. The number she received was that for Respondent's cellular telephone.

139. Three days after the treatment, C.P. noticed she had stopped falling and she had her balance. She could speak without stuttering. A few days later, she experienced a "light body jerk" (C.P.'s term). She has had none since that time. At the hearing, C.P. stated, "I am a miracle." She attributes her improvement to the stem cell therapy.

140. C.P. continued to take her medication after receiving the stem cells. However, she discontinued the medicine she took at night, but did not tell her physician until a week before she testified at the hearing.

141. While doing her online search, C.P. found other clinics in Tijuana performing stem cell therapy, but she decided to use Respondent because she had read his book and considered him "legitimate." (C.P.'s term.)

142. The fetal stem cell therapy had no effect on C.P.'s hearing loss. She did not discuss her hearing loss with Respondent.

143. At the hearing, C.P. did not have any documentation establishing the efficacy of fetal stem cell therapy.

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Respondent's Book and Advertising

144. Respondent published his book, Blocked in the USA The Stem Cell Miracle (book), in 2010. He wrote the book for the lay public rather than as a scientific treatise. Therefore, he eschewed references to authorities such as peer reviewed articles in medical journals in favor of magazine and newspaper articles and articles published on the Internet. He wrote the book in first person and included in it numerous anecdotes of his patients whose many disparate medical disorders had improved with his fetal stem cell treatment. He wrote that stem cell therapy was something of which the public was unaware but should be, and that it could be used in the most dire of circumstances. He claimed that patients were not given a choice of treatment in traditional medicine, but that fetal stem cell therapy offered them an option.

145. In the book, Respondent wrote that he had treated over 1,500 patients with fetal stem cell therapy. At the hearing, Respondent claimed that statement was not true, and that he wrote it to give potential patients a better understanding of what he was doing. He testified that the effect would have been "attenuated" (Respondent's term) if he wrote that he only referred patients to health care professionals practicing in foreign countries. Respondent also wrote that 96 percent of the 1,500 patients he treated had a positive outcome. At the hearing, he admitted that the figure was only a general statement and not the result of a statistical analysis.

146. When the Board investigator who posed as C.A. read Respondent's book, she found numerous references that would lead the reader to believe Respondent was the treating physician for patients who came to him for fetal stem cell treatment. Among those references were phrases such as "more than 1,500 of my patients," "I have the means to save his life, "a few of the cases I have treated," and "disease processes I have treated." In addition, in over 80 patient testimonials or summaries, Respondent refers to the stem cell recipients as his patients. Those representations are consistent with the first paragraph Respondent wrote in the section entitled "About the Author:"

> William C. Rader, M.D. is the only American physician involved in the actual clinical application of human fetal stem cells. Since 1995 he has successfully treated more than 1,500 patients.

(Exhibit 31, AGO 01701.)

147. The book contains a disclaimer which states that Respondent is not "rendering medical, health, or any other kind of personal and/or professional services in the book." (Exhibit 31, AGO 01337.) That statement is belied by numerous references in the book, as well as on Respondent's websites, and the evidence adduced at the hearing.

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148. At the administrative hearing, Respondent continued to deny having ever treated anyone with fetal stem cell therapy, and he denied that he was the physician for any patient receiving the therapy. He claimed he only referred potential recipients to foreign physicians. In so doing, he admitted the falsity of a great many statements in the book. For example, (1) he could not describe how many disease processes he had treated; (2) numerous references to patients he had successfully treated; (3) he was the only American doctor who had administered fetal stem cells; (4) references to "my" fetal stem cell patients; (5) references to "my therapy"; (6) numerous references to "my patients"; and (7) by the time a certain study had been published, he had been administering fetal stem cells to human patients for over five years.

149. Respondent also admitted to the falsity of other statements in the book. For example, he wrote that millions of children can be treated with the cells of only one fetus, and that fetal stem cells have no antigenicity.

150. Respondent read the book for accuracy before he published it. He was aware at that time that numerous statements were untrue. At the hearing, he admitted he wrote the falsehoods because he wanted people to believe he was a credible person, and because he was writing for lay people and it would be "too casual" (Respondent's term) to say he only observed the procedures. He admitted that a lay person reading the book would not know that he had only observed but not treated the myriad of patients he claimed were his own and whom he had treated. In light of those admissions, Respondent's testimony that he did not intend to mislead the public was not credible. He further testified that he could "easily and happily" (Respondent's term) correct the book's inaccuracies. According to Deputy Attorney General Kapur, Respondent had not done so as of the final day of the hearing.

151. Although Respondent testified that it was important to him that his website be accurate and not mislead the public, he wrote the same and similar untruths and misrepresentations on the Medra, Stem Cell of America, and his personal websites. Included with the statements referenced above were that Stem Cell of America is an international company; that Stem Cell of America has laboratories and employs scientists; and that he founded Stem Cell of America in 1995 dedicated to research. (Respondent testified that he wrote the last statement because "it makes sense to let people know what the future is." (Respondent's statement.)

152. Statements on Respondent's website such as "Dr. William Rader Continues Groundbreaking Stem Cell Therapy . . . " (Exhibit 43, AGO 02425), "Dr. William Rader's Stem Cell Therapy Holds Several Major Advantages . . ." (*ibid.*), and "Dr. William Rader's stem cell treatment remains the preferred treatment above any of the stem cell therapies currently available in the United States . . ." (*id.*) further evidence the falsity of his claims that he has never treated a patient and does not serve as the physician for potential and actual stem cell recipients. Those statements are credited over Respondent's denials at the hearing that he was not the physician of any patients because they are consistent with the overwhelming weight of the evidence that establishes the physician/patient relationship with all of the patients involved in this case, as is more fully set forth below.

153. For the reasons set forth in Factual Findings 38, 39, and 40, Drs. Kornblum and Parkman found that Respondent's claim in his book and on his websites that his stem cells are pluripotent was not true. Even Dr. Duncan, Respondent's expert, conceded that fetal stem cells are not pluripotent. However, she testified that they sometime can appear to be. Dr. Kornblum also correctly pointed out Respondent's book and websites deny the existence of the many potential negative side effects associated with stem cell therapy. Those side effects include but are not limited to graft vs. host disease and the known risks associated with spinal taps and lumbar punctures.

LEGAL CONCLUSIONS

1. Cause exists to discipline Respondent's certificate, pursuant to Business and Professions Code sections 2227 and 2234, subdivision (b), for gross negligence, as set forth in Findings 12 and 32 through 112.

2. Cause exists to discipline Respondent's certificate, pursuant to Business and Professions Code sections 2227 and 2234, subdivision (c), for repeated negligent acts, as set forth in Findings 12 and 32 through 112.

3. Cause exists to discipline Respondent's certificate, pursuant to Business and Professions Code sections 2227 and 2271, for false and/or misleading advertising, as set forth in Findings 36 through 41, and 144 through 153.

4. Cause exists to discipline Respondent's certificate, pursuant to Business and Professions Code section 651, subdivisions (a), (b)(1), (b)(2), (b)(3), and (b)(7), for disseminating false or misleading statements, as set forth in Findings 36 through 41, and 144 through 153.

5. Cause exists to discipline Respondent's certificate, pursuant to Business and Professions Code sections 2227 and 2234, subdivision (e), for dishonesty or corruption, as set forth in Findings 37 through 41, and 144 through 153.

6. Cause exists to discipline Respondent's certificate, pursuant to Business and Professions Code sections 2227 and 2234, for general unprofessional conduct, as set forth in Findings 12, 32 through 112, and 144 through 153.

7. Cause exists to discipline Respondent's certificate, pursuant to Business and Professions Code sections 2227 and 2234, for violation of provisions of the Medical Practice Act, as set forth in Findings 12, 32 through 112, and 144 through 153.

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8. Cause does not exist to discipline Respondent's certificate, pursuant to Business and Professions Code sections 2227, 2234, subdivision (b), or 2234, subdivision (c), for gross negligence or repeated negligent acts, for recommending that patients undergo fetal stem cell treatment where there was no medical evidence that such treatment could benefit the patients. Although Respondent lacked evidence based on controlled studies, he based his decision on empirical evidence from his experience. Because the allegations refer to "no medical evidence," they fail for lack of specificity.

9. The law is clear that the standard of proof to be used in this proceeding is "clear and convincing." (*Ettinger v. Board of Medical Quality Assurance* (1982) 135 Cal.App.3d 853, 856 [185 Cal.Rptr. 601].) This means the burden rests on Complainant to establish the charging allegations by proof that is clear, explicit and unequivocal--so clear as to leave no substantial doubt, and sufficiently strong to command the unhesitating assent of every reasonable mind. (*In re Marriage of Weaver* (1990) 224 Cal.App.3d 478.) Complainant sustained her burden of proof.

10. Respondent is accused of having committed both gross negligence and repeated negligent acts. Gross negligence has been defined as an extreme departure from the ordinary standard of care or the "want of even scant care." (*Gore v. Board of Medical Quality Assurance* (1970) 110 Cal.App.3d 184, 195-198.) Only one extreme departure from the standard of care need be found for a licensee to have committed gross negligence. The statute permitting the Board to discipline a licensee for "repeated negligent acts" (Bus. & Prof. Code, § 2234, subd. (c)) may be invoked on basis of as few as two occurrences. (*Zabetian v. Medical Board of California* (2000) 80 Cal.App.4th 462, 468.)

11. In this case, Respondent is found to have committed numerous departures from the standard of care. Because each of them was an extreme departure, he committed gross negligence. Because of their number, they constitute repeated negligent acts.

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Jurisdiction

12. Respondent argues that the Board lacks jurisdiction with respect to patients J.D. and J.S. because the treatment occurred out of the country. Respondent is incorrect. Jurisdiction in a disciplinary action runs with the license rather than the location of an alleged violation. (See *Windham v. Board of Medical Quality Assurance* (1980) 104 Cal.App.3d 461.) The agency determines whether the substance of the matter falls within its jurisdiction. (See *Mazda Motor, Inc. v. New Motor Vehicle Board* (2003) 110 Cal.App.4th 1451.) In *Hughes v. Board of Architectural Examiners* (1998) 17 Cal.4th 763, 792, the Court stated:

> [C]onduct occurring anywhere that falls within the statutory grounds for *denial* of a license, may provide the basis for such denial without offending jurisdictional principles. It is obvious that the statutory provisions affording a basis for denial of a license because of prior convictions, dishonest conduct, or certain other conduct for which a licensee would be subject to discipline, apply whether the conduct occurred in this state or in another jurisdiction. The mere circumstance that the act occurring within the boundaries of another state or locality is being scrutinized at a different stage of the Board's administrative authority over the subject—that is, following licensure—does not undermine the agency's authority to act based upon the out-of-state conduct.
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> In this state and others, postlicensure disciplinary proceedings have been based upon acts that occurred prior to licensure and outside the state in which the individual was licensed. (See, e.g., *Windham v. Board of Medical Quality Assurance* (1980) 104 Cal.App.3d 461, 464 [163 Cal.Rptr. 566] [proceedings to revoke license of California physician following conviction based upon prelicensure filing of fraudulent tax returns in Mississippi]; *Office of Disciplinary Counsel v. Clark* (1988) 40 Ohio St.3d 81, 81 [531 N.E.2d 671] [disciplinary proceedings against attorney in Ohio following conviction based upon prelicensure trafficking in controlled substances in Virginia].) Although in these decisions, the disciplinary action was based upon the convictions that occurred following licensure, that circumstance did not affect the conclusion that the discipline meted out by one jurisdiction properly could be based upon conduct that occurred in another jurisdiction prior to licensure in the jurisdiction imposing that discipline. As we have discussed above, the decisional law has distinguished between the facts that in themselves, justify discipline, giving rise to a conviction, and the conviction itself, which as a matter of law may be expunged from the licensee's or applicant's record. (Emphasis in text.)

13. Further, the allegations against Respondent regarding those two patients address Respondent's conduct in the California as well as elsewhere.

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The Physician/Patient Relationship

14. Respondent contends that he is not subject to the standard of care because he was never the physician of any potential or actual fetal stem cell recipient and therefore, those individuals were not his patients. Respondent is incorrect.

15. Evidence Code section 991 states:

> As used in this article, "patient" means a person who consults a physician or submits to an examination by a physician for the purpose of securing a diagnosis or preventive, palliative, or curative treatment of his physical or mental or emotional condition.

16. It is indisputable that each of the patients referenced in this Decision consulted Respondent for the purpose of securing preventive, palliative, or curative fetal stem cell treatment of his/her physical condition. In fact, Respondent advertised for that very purpose.

17. The physician/patient relationship is established when the patient reasonably believes the physician he/she consults is the physician will also diagnose or treat the condition. (Cf. *Kramer v. Policy Holders Life Ins. Assn.* (1935) 5 Cal.App.2d 380, 386-387.)

18. Civil Code section 56.05, subdivision (c), defines a "patient" as "any natural person, whether or not still living, who received health care services from a provider of health care and to whom medical information pertains."[19] In *Pettus v. Cole* (1996) 49 Cal.App.4th 402, a case decided under the CMIA, a psychiatrist performed a psychiatric evaluation on the appellant at the request and expense of the appellant's employer. The psychiatrist sent a full written report to the appellant's managers without first obtaining from the appellant a written authorization for release of his medical records. The psychiatrist later claimed that, because he saw the appellant only once, provided no care or treatment to him, and performed the evaluation and wrote the report for the employer's benefit, no physician/patient relationship was formed, and the appellant was not his patient.

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[19] The parties did not offer any legal authority in support of their respective positions on whether the physician/patient relationship existed between Respondent and his potential and/or actual fetal stem cell recipients. Civil Code section 56.05 is part of the Confidentiality of Medical Information Act (CMIA). Although that Act is not germane to this case, the definition provides guidance in resolving this issue.

19. The court disagreed stating:

> It is undisputed that Dr. Cole's meeting with Pettus generated highly sensitive medical information which was subsequently reported to Du Pont. According to statutory definitions, "medical information" is information "derived from a provider of health care" and a patient is someone who has received health care services from a provider of health care and to whom medical information pertains. (Citation.) Unfortunately, the term "health care services" is not defined by the Act. However, logic dictates that in order for a health care provider to gather medical information about a person, the provider must have dealt with the person at some level and performed professional services of some type. By failing to include the term "health care services" in the list of definitions, the drafters failed to define the precise level of interaction between the provider and the subject necessary to constitute "health care services." It is, however, appropriate to construe the term in a manner which effectuates the purpose of the statute. (Citation.)

(*Id.* at page 429-430.)

20. Using *Pettus* as a model, the evidence evinces a finding that Respondent served as the physician for those patients who came to him seeking fetal stem cell therapy. He discussed their cases with them by telephone. He made recommendations to them for the therapy. He had medical history forms sent to them which he reviewed upon their return. He decided whether to refer the patient to a foreign clinic. Although he did not perform the actual procedures on J.D. and J.S., he was present at one and spoke by telephone with the patient at another. It was his custom and practice to be present at all of the procedures performed through his companies. He met with the patients before and after the treatment and answered their questions, and he provided his own cellular telephone number to them with the invitation to call if they had additional questions. In other words, he performed professional services.

21. Respondent has demonstrated other indicia of the physician/patient relationship as well: He, exclusively, ordered and provided the stem cells for the recipients. He referred patients only to physicians he trained and employed. He received payment for the treatment. The consent form listed only his name and the name of his company. The patient was not asked to sign a consent form naming the foreign physicians or clinics. In his book and on his websites, Respondent described the recipients as his patients, and he claims to have performed the treatment approximately 2,000 times. In H.C.'s case, two letters written on his letterhead indicate that H.C. was his patient, and references in his chart indicate he would perform the therapy in the RV. In addition, Respondent instructed H.C.'s family to give him a Valium tablet to control his vacillating blood pressure, and he instructed an emergency room physician treating H.C. to give H.C. fluids and discharge him from care. In J.D.'s case, he directed the lumbar puncture. Respondent told him: "I'm your doctor. You have to trust me."

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22. Ultimately, while claiming to offer only a referral service, Respondent provided the medical evaluation, the medical advice, the materials, and the medical personnel necessary for the fetal stem cell treatment to take place.

23. The experts expressed disparate opinions regarding whether potential and actual stem cell recipients were Respondent's patients, with Drs. Kornblum and Parkman opining they were and Dr. Duncan opining they were not. Although the experts were competent to render those opinions, they offer little to resolve the issue because the determination of whether one is a "patient" is a question of law and not the proper subject of expert testimony. (*Pettus v. Cole, ante,* at page 431, footnote 20.) Nonetheless, were the issue to turn on the experts' opinions, those of Drs. Kornblum and Parkman would be the more convincing for the reasons set forth above.

The Standard of Care

24. In *Lawless v. Calaway* (1944) 24 Cal.2d 81, 86, the Court stated:

> The law demands only that a physician or surgeon have the degree of learning and skill ordinarily possessed by practitioners of the medical profession in the same locality and that he exercise ordinary care in applying such learning and skill to the treatment of his patient. [Citations.] The same degree of responsibility is imposed in the making of a diagnosis as in the prescribing and administering of treatment. [Citations.] Ordinarily, a doctor's failure to possess or exercise the requisite learning or skill can be established only by the testimony of experts. [Citations.] Where, however, negligence on the part of a doctor is demonstrated by facts which can be evaluated by resort to common knowledge, expert testimony is not required since scientific enlightenment is not essential for the determination of an obvious fact. [Citations.]

25. The fact that Respondent claims to be the only physician in America who has been and is infusing fetal stem cells into humans virtually per se means he is operating outside of the standard of care.

26. In his report, Dr. Kornblum offered specific criteria necessary to meet the standard of care with respect to each of the four medical issues he addressed:

a. Recommendation to patients to receive stem cell therapy: "Standard of care and standard of ethical practice is to recommend (or agree to provide) and provide treatments that are safe and potentially effective." (Exhibit 33, AGO 01864.)

b. Proper evaluation prior to institution of therapy: "Standard of Care is to appropriately evaluate a patient's condition to determine whether a proposed treatment is going to be safe and effective for that treatment." (*id.* at AGO 01865.)

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c. The providing of information to patients regarding risks and benefits of the therapy: "Standard of Care is to provide accurate information to the patient with respect to the potential risks and benefits of a therapy prior to administration of the therapy, and to ensure that the patient or their representatives understand these risks and benefits." (*id.* at AGO 01866.)

d. Involvement in medical decision-making in the absence of appropriate information or expertise: "Standard of Care: Medical advice to patients or physicians should be provided that is based on sound medical principles, based on adequate training and knowledge of the therapy or course of action being advised as well as the specific situation for which it is being advised." (*id.* at AGO 01867.)

27. At the hearing, Dr. Kornblum accurately articulated the standard of care consistent with California law. His more specific definitions do not reflect ignorance of the legal definition, and they do not change the outcome of this action.

28. A physician accused of deviating from the standard of care must be judged in light of the standard of care as it existed at the time of the alleged deviation and not what it should have been at that time.

> Under existing law, testimony, including expert testimony, is not admissible to show the standard of care should have been different; an expert is not permitted to "second-guess an entire profession"' as to what the standard of care should have been. (Citation.)

(*N.N.V. v. American Assn. of Blood Banks* (1999) 75 Cal.App.4th 1358, 1385 [89 Cal.Rptr.2d 885].)

29. Dr. Duncan did not address the standard of care in her report. (Exhibit FF.) In fact, she wrote: "I refrain from addressing here in detail the Respondent's alleged departures from standard medical practice as outlined by the California Health Board and opined by Harley Kornblum and Robertson Parkman." (Exhibit FF, page 4.) Dr. Duncan did not state her reason(s) for declining to address the standard of care in her report. Although she touched on it briefly in her testimony, she made no attempt to define it. Therefore, one cannot know the criteria on which she based her opinion that, if Respondent were to be deemed the physician of the patients who came to him for fetal stem cell therapy (which she disputes), he practiced within the standard of care at all times.

30. Dr. Duncan's knowledge and opinions were based almost entirely on hearsay from the articles she read, Respondent's book and websites, an intra-testimony conversation with an unidentified physician in Ukraine, and conversations with Respondent. Both Dr. Duncan and Respondent had difficulty recalling the subject matter of their conversations.

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31. The gravamen of Dr. Duncan's report and testimony centered on the safety, efficacy and need for fetal stem cell therapy. This is an issue only tangential to the allegations in this case. It need not be, should not be, and is not adjudicated here. It is noteworthy, however, that in a medical practice that would seemingly lend itself well to trials of stem cell therapy (sports, pain, and rehabilitation medicine), Dr. Duncan has referred only one patient for that treatment. Were the safety, efficacy and need for fetal stem cell therapy at issue in this case, that fact would lead one to question the sincerity of Dr. Duncan's opinions.

32. Respondent committed multiple extreme departures from the standard of care as more fully set forth above, in connection with his care and treatment of patients J.D., J.S., H.C., and undercover "patient" E.B. Those extreme departures were in connection with his failure to properly evaluate the patients prior to recommending treatment, and his failure to provide concise, understandable and accurate information regarding the potential risks and benefits of fetal stem cell therapy. Included in the several risks of which Respondent failed to advise his patients is the fact that professional opinions vary regarding whether fetal stem cells are immuno-privileged and that the cells express HLA over time as they mature into somatic cells. Therefore, Respondent's decision to decline typing donors and recipients for histocompatibility and, if necessary, administering immunosuppressant drugs, poses a risk of rejection, host vs. graft disease and graft vs. host disease.

33. It was not proven that there was anything improper or insufficient in the testing and freezing of the cells Respondent used on his patients.

34. The "fact" patients' testimony was interesting and encouraging, but it was not dispositive. Their stories of improvement are unconfirmed by scientific methods. Therefore, it cannot be ascertained whether the extraordinary results Respondent claims to have achieved are due to fetal stem cell therapy, other methods of treatment, placebo effect, a different causative factor, or some combination of factors.

False Statements in the Book and on the Websites

35. Respondent wrote or is responsible for the writing of a great many untruths, misrepresentations, and inaccuracies in his book and on his and his companies' websites. He was aware the statements were untrue, and he wrote them deliberately for the purpose of making himself, his companies, and his stem cell therapy appear more important, authoritative, credible and desirable to the lay public. At the time he wrote them, he was also aware that the lay public would have no method of determining the falsity of the statements.

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Conclusion

36. The vast majority of Respondent's training in stem cells to which he testified came from his "fellowship" in Ukraine. Much of his testimony relating to statements made to him by physicians/scientists in Ukraine was hearsay. None of it was corroborated by any literature or other evidence that could establish the reliability of that information other than Respondent's testimony and the testimony of the four "fact" witnesses. That testimony, while encouraging as anecdotal/empirical evidence, remains unconfirmed by more traditional scientific means.

37. It is possible that Respondent is completely correct in his assessment of the efficacy and future of fetal stem cell therapy. If he is, neither science nor the standard of care has caught up with him. If he is not, he poses an unacceptable risk to the health, safety, welfare and interest of the public. Either way, he is operating outside of the standard of care.

38. Respondent has misunderstood his role in the process. By taking a medical history and offering medical advice regarding the efficacy and propriety of the use of fetal stem cell therapy in each patient's particular case, he became the physician on whom each patient relied for his/her safety and recovery. "There is no other profession in which one passes so completely within the power and control of another as does the medical patient." *Shea v. Board of Medical Examiners* (1978) 81 Cal.App.3d 564, 578 [146 Cal.Rptr. 653.]

39. Respondent has shown no remorse for his actions. In fact, he remains convinced of the correctness, legitimacy, and timeliness of the use of fetal stem cells and of his role in the process. His only concession is his willingness to change the representations in his book to more accurately reflect his position. Respondent's recalcitrance could justify the revocation of his certificate. However, Business and Professions Code section 2229, subdivision (b) states:

> In exercising his or her disciplinary authority an administrative law judge of the Medical Quality Hearing Panel, the division, or the California Board of Podiatric Medicine, shall, wherever possible, take action that is calculated to aid in the rehabilitation of the licensee, or where, due to a lack of continuing education or other reasons, restriction on scope of practice is indicated, to order restrictions as are indicated by the evidence.

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40. In light of the priorities set forth in Business and Professions Code section 2229, subdivision (b), Respondent shall be permitted to continue practicing medicine with a properly-conditioned probationary license. The conditions shall include a period of suspension to give him the opportunity to correct the false statements in his book and on his and his companies' websites concerning his practice. Because he believes that, as a psychiatrist, he cannot or should not perform physical examinations on his patients who come for stem cell therapy, he will receive assistance in that area through a clinical training program and a practice monitor. This will enable him to determine whether, in his professional opinion, a patient is a proper candidate for fetal stem cell therapy before referring the patient to a foreign country for treatment. This will be important in light of the finding that the patients who come to Respondent as potential fetal stem cell patients are Respondent's patients at least until they come under the care of another physician. They will remain his patients if Respondent attends the procedure, offers pre-treatment and/or post-treatment consultation (in person or by telephone), and/or offers, either personally or through his company, post-treatment follow-up services.

41. The Board's model terms (Medical Board of California Manual of Model Disciplinary Orders and Disciplinary Guidelines, 11th ed. 2011) set forth specific commencement times for various terms and conditions of probation. The requirement that Respondent's certificate be suspended for the first six months of probation renders some of those commencement times ineffective. Those dates so affected will be postponed to commence an appropriate number of days after termination of suspension.

ORDER

Certificate No. A22848 issued to Respondent, William C. Rader, M.D., is revoked pursuant to Legal Conclusions 1, 2, 3, 4, 5, 6, and 7, separately and for all of them. However, the revocation is stayed and Respondent is placed on probation for seven years upon the following terms and conditions.

1. Actual Suspension

As part of probation, Respondent is suspended from the practice of medicine for 180 days beginning the 16th day after the effective date of this Decision.

2. Correction of Falsities

Within 180 days of the effective date of this Decision, Respondent shall correct all untruths, misrepresentations, and inaccuracies referred to in this Decision in his book(s), website(s), and other media over which he has control, so as to minimize the risk of misleading the public.

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3. Education Course

Within 60 calendar days of the effective date of this Decision, and on an annual basis thereafter, Respondent shall submit to the Board or its designee for its prior approval educational program(s) or course(s) which shall not be less than 40 hours per year, for each year of probation. The educational program(s) or course(s) shall be aimed at correcting any areas of deficient practice or knowledge and shall be Category I certified. The educational program(s) or course(s) shall be at Respondent's expense and shall be in addition to the Continuing Medical Education (CME) requirements for renewal of licensure. Following the completion of each course, the Board or its designee may administer an examination to test Respondent's knowledge of the course. Respondent shall provide proof of attendance for 65 hours of CME of which 40 hours were in satisfaction of this condition.

4. Professionalism Program (Ethics Course)

Within 60 calendar days of the effective date of this Decision, Respondent shall enroll in a professionalism program, that meets the requirements of Title 16, California Code of Regulations (CCR), section 1358. Respondent shall participate in and successfully complete that program. Respondent shall provide any information and documents that the program may deem pertinent. Respondent shall successfully complete the classroom component of the program not later than six months after Respondent's initial enrollment, and the longitudinal component of the program not later than the time specified by the program, but no later than one year after attending the classroom component. The professionalism program shall be at Respondent's expense and shall be in addition to the Continuing Medical Education (CME) requirements for renewal of licensure.

A professionalism program taken after the acts that gave rise to the charges in the Accusation, but prior to the effective date of the Decision may, in the sole discretion of the Board or its designee, be accepted towards the fulfillment of this condition if the program would have been approved by the Board or its designee had the program been taken after the effective date of this Decision.

Respondent shall submit a certification of successful completion to the Board or its designee not later than 15 calendar days after successfully completing the program or not later than 15 calendar days after the effective date of the Decision, whichever is later.

5. Clinical Training Program

Within 60 calendar days of the termination of suspension, Respondent shall enroll in a clinical training or educational program equivalent to the Physician Assessment and Clinical Education Program (PACE) offered at the University of California - San Diego School of Medicine (program). Respondent shall successfully complete the program not later than six months after Respondent's initial enrollment unless the Board or its designee agrees in writing to an extension of that time.

The program shall consist of a Comprehensive Assessment program comprised of a two-day assessment of Respondent's physical and mental health; basic clinical and communication skills common to all clinicians; and medical knowledge, skill and judgment pertaining to Respondent's area of practice in which Respondent was alleged to be deficient, and at minimum, a 40 hour program of clinical education in the area of practice in which Respondent was alleged to be deficient and which takes into account data obtained from the assessment, Decision(s), Accusation(s), and any other information that the Board or its designee deems relevant. Respondent shall pay all expenses associated with the clinical training program.

Based on Respondent's performance and test results in the assessment and clinical education, the program will advise the Board or its designee of its recommendation(s) for the scope and length of any additional educational or clinical training, treatment for any medical condition, treatment for any psychological condition, or anything else affecting Respondent's practice of medicine. Respondent shall comply with program recommendations.

At the completion of any additional educational or clinical training, Respondent shall submit to and pass an examination. Determination as to whether Respondent successfully completed the examination or successfully completed the program is solely within the program's jurisdiction.

If Respondent fails to enroll, participate in, or successfully complete the clinical training program within the designated time period, Respondent shall receive a notification from the Board or its designee to cease the practice of medicine within three calendar days after being so notified. Respondent shall not resume the practice of medicine until enrollment or participation in the outstanding portions of the clinical training program has been completed. If Respondent did not successfully complete the clinical training program, Respondent shall not resume the practice of medicine until a final decision has been rendered on the accusation and/or a petition to revoke probation. The cessation of practice shall not apply to the reduction of the probationary time period.

Within 60 days after Respondent successfully completes the clinical training program, Respondent shall participate in a professional enhancement program equivalent to the one offered by the Physician Assessment and Clinical Education Program at the University of California, San Diego School of Medicine, which shall include quarterly chart review, semi-annual practice assessment, and semi-annual review of professional growth and education. Respondent shall participate in the professional enhancement program at Respondent's expense during the term of probation, or until the Board or its designee determines that further participation is no longer necessary.

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6. Practice Monitoring

Within 30 calendar days of the effective date of this Decision, Respondent shall submit to the Board or its designee for prior approval as a practice monitor, the name and qualifications of one or more licensed physicians and surgeons whose licenses are valid and in good standing, and who are preferably American Board of Medical Specialties (ABMS) certified. A monitor shall have no prior or current business or personal relationship with Respondent, or other relationship that could reasonably be expected to compromise the ability of the monitor to render fair and unbiased reports to the Board, including but not limited to any form of bartering, shall be in Respondent's field of practice, and must agree to serve as Respondent's monitor. Respondent shall pay all monitoring costs.

The Board or its designee shall provide the approved monitor with copies of the Decision(s) and Accusation(s), and a proposed monitoring plan. Within 15 calendar days of receipt of the Decision(s), Accusation(s), and proposed monitoring plan, the monitor shall submit a signed statement that the monitor has read the Decision(s) and Accusation(s), fully understands the role of a monitor, and agrees or disagrees with the proposed monitoring plan. If the monitor disagrees with the proposed monitoring plan, the monitor shall submit a revised monitoring plan with the signed statement for approval by the Board or its designee.

Within 60 calendar days of the termination of suspension, and continuing throughout probation, Respondent's practice shall be monitored by the approved monitor. Respondent shall make all records available for immediate inspection and copying on the premises by the monitor at all times during business hours and shall retain the records for the entire term of probation.

If Respondent fails to obtain approval of a monitor within 60 calendar days of the effective date of this Decision, Respondent shall receive a notification from the Board or its designee to cease the practice of medicine within three calendar days after being so notified. Respondent shall cease the practice of medicine until a monitor is approved to provide monitoring responsibility.

The monitor(s) shall submit a quarterly written report to the Board or its designee which includes an evaluation of Respondent's performance, indicating whether Respondent's practices are within the standards of practice of medicine, and whether Respondent is practicing medicine safely. It shall be the sole responsibility of Respondent to ensure that the monitor submits the quarterly written reports to the Board or its designee within 10 calendar days after the end of the preceding quarter.

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If the monitor resigns or is no longer available, Respondent shall, within five calendar days of such resignation or unavailability, submit to the Board or its designee, for prior approval, the name and qualifications of a replacement monitor who will be assuming that responsibility within 15 calendar days. If Respondent fails to obtain approval of a replacement monitor within 60 calendar days of the resignation or unavailability of the monitor, Respondent shall receive a notification from the Board or its designee to cease the practice of medicine within three calendar days. After being so notified, Respondent shall cease the practice of medicine until a replacement monitor is approved and assumes monitoring responsibility.

In lieu of a monitor, Respondent may participate in a professional enhancement program equivalent to the one offered by the Physician Assessment and Clinical Education Program at the University of California, San Diego School of Medicine, that includes, at minimum, quarterly chart review, semi-annual practice assessment, and semi-annual review of professional growth and education. Respondent shall participate in the professional enhancement program at Respondent's expense during the term of probation.

7. Notification

Within seven days of the effective date of this Decision, Respondent shall provide a true copy of this Decision and Accusation to the Chief of Staff or the Chief Executive Officer at every hospital where privileges or membership are extended to Respondent, at any other facility where Respondent engages in the practice of medicine, including all physician and locum tenens registries or other similar agencies, and to the Chief Executive Officer at every insurance carrier which extends malpractice insurance coverage to Respondent. Respondent shall submit proof of compliance to the Board or its designee within 15 calendar days.

This condition shall apply to any change(s) in hospitals, other facilities or insurance carrier.

8. Supervision of Physician Assistants

During probation, Respondent is prohibited from supervising physician assistants.

9. Obey All Laws

Respondent shall obey all federal, state and local laws, all rules governing the practice of medicine in California and remain in full compliance with any court ordered criminal probation, payments, and other orders.

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10. Quarterly Declarations

Respondent shall submit quarterly declarations under penalty of perjury on forms provided by the Board, stating whether there has been compliance with all the conditions of probation.

Respondent shall submit quarterly declarations not later than 10 calendar days after the end of the preceding quarter.

11. General Probation Requirements

Compliance with Probation Unit

Respondent shall comply with the Board's probation unit and all terms and conditions of this Decision.

Address Changes

Respondent shall, at all times, keep the Board informed of Respondent's business and residence addresses, email address (if available), and telephone number. Changes of such addresses shall be immediately communicated in writing to the Board or its designee. Under no circumstances shall a post office box serve as an address of record, except as allowed by Business and Professions Code section 2021, subdivision (b).

Place of Practice

Respondent shall not engage in the practice of medicine in Respondent's or patient's place of residence, unless the patient resides in a skilled nursing facility or other similar licensed facility.

License Renewal

Respondent shall maintain a current and renewed California physician's and surgeon's license.

Travel or Residence Outside California

Respondent shall immediately inform the Board or its designee, in writing, of travel to any areas outside the jurisdiction of California which lasts, or is contemplated to last, more than 30 calendar days.

In the event Respondent should leave the State of California to reside or to practice, Respondent shall notify the Board or its designee in writing 30 calendar days prior to the dates of departure and return.

12. Interview with the Board or its Designee

Respondent shall be available in person upon request for interviews either at Respondent's place of business or at the probation unit office, with or without prior notice throughout the term of probation.

13. Non-practice While on Probation

Respondent shall notify the Board or its designee in writing within 15 calendar days of any periods of non-practice lasting more than 30 calendar days and within 15 calendar days of Respondent's return to practice. Non-practice is defined as any period of time Respondent is not practicing medicine in California as defined in Business and Professions Code sections 2051 and 2052 for at least 40 hours in a calendar month in direct patient care, clinical activity or teaching, or other activity as approved by the Board. All time spent in an intensive training program which has been approved by the Board or its designee shall not be considered non-practice. Practicing medicine in another state of the United States or Federal jurisdiction while on probation with the medical licensing authority of that state or jurisdiction shall not be considered non-practice. A Board-ordered suspension of practice shall not be considered as a period of non-practice.

In the event Respondent's period of non-practice while on probation exceeds 18 calendar months, Respondent shall successfully complete a clinical training program that meets the criteria of Condition 18 of the current version of the Board's "Manual of Model Disciplinary Orders and Disciplinary Guidelines" prior to resuming the practice of medicine.

Respondent's period of non-practice while on probation shall not exceed two years.

Periods of non-practice will not apply to the reduction of the probationary term.

Periods of non-practice will relieve Respondent of the responsibility to comply with the probationary terms and conditions with the exception of this condition and the following terms and conditions of probation: Obey All Laws; and General Probation Requirements.

14. Violation of Probation

Failure to fully comply with any term or condition of probation is a violation of probation. If Respondent violates probation in any respect, the Board, after giving Respondent notice and the opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If an Accusation, or Petition to Revoke Probation, or an Interim Suspension Order is filed against Respondent during probation, the Board shall have continuing jurisdiction until the matter is final, and the period of probation shall be extended until the matter is final.

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15. License Surrender

Following the effective date of this Decision, if Respondent ceases practicing due to retirement or health reasons or is otherwise unable to satisfy the terms and conditions of probation, Respondent may request to surrender his license. The Board reserves the right to evaluate Respondent's request and to exercise its discretion in determining whether or not to grant the request, or to take any other action deemed appropriate and reasonable under the circumstances. Upon formal acceptance of the surrender, Respondent shall, within 15 calendar days, deliver Respondent's wallet and wall certificate to the Board or its designee and Respondent shall no longer practice medicine. Respondent will no longer be subject to the terms and conditions of probation. If Respondent re-applies for a medical license, the application shall be treated as a petition for reinstatement of a revoked certificate.

16. Probation Monitoring Costs

Respondent shall pay the costs associated with probation monitoring each and every year of probation, as designated by the Board, which may be adjusted on an annual basis. Such costs shall be payable to the Medical Board of California and delivered to the Board or its designee no later than January 31 of each calendar year.

17. Completion of Probation

Respondent shall comply with all financial obligations (e.g., restitution, probation costs) not later than 120 calendar days prior to the completion of probation. Upon successful completion of probation, Respondent's certificate shall be fully restored.

Dated: March 27, 2014

H. STUART WAXMAN
Administrative Law Judge
Office of Administrative Hearings