

COMMONWEALTH OF MASSACHUSETTS

Suffolk, SS.

Division of Administrative Law Appeals

Docket No. RM-15-137

Adjudicatory Case No. 2015-013

Board of Registration in Medicine,
Petitioner

v.

Edward Levitan, M.D.
Respondent

STIPULATION

Edward Levitan, M.D. (Respondent), Respondent's attorney, and Complaint Counsel agree that this Stipulation shall be filed with the Administrative Magistrate for the Division of Administrative Law Appeals (DALA), as a resolution of questions of material fact and law as set forth by the Statement of Allegations referenced above. The Respondent admits to the Findings of Fact described below and agrees that the Administrative Magistrate and the Board may make Conclusions of Law as set forth below.

FINDINGS OF FACT

1. The Respondent was born on June 7, 1975. He graduated from Boston University School of Medicine in 2003. He is certified by the American Board of Family Medicine. He has been licensed to practice medicine in Massachusetts under certificate number 222719 since 2004. He has privileges at Beth Israel Deaconess Hospital Needham.

2. At all times relevant to this matter, the Respondent owned Visions Medical Center, P.C. ("Visions"), a separate legal medical services entity with an office in Wellesley,

Massachusetts.

3. Patient A was a 61-year-old male when he first presented to the Respondent in May 2011 for treatment of his previously-diagnosed coronary artery disease (CAD).

4. Prior to seeking treatment with Respondent at Visions, Patient A had determined not to treat his CAD via conventional medical procedures such as surgery, but instead to address it with integrative medical methods, such as medications combined with lifestyle and/or dietary alterations, and a course of chelation therapy.

5. Chelation therapy, in conventional medicine, involves injecting a chelating agent – Ethylene Diamine Tetraacetic Acid (EDTA) – into the bloodstream to reduce levels of toxic metals or minerals in the bloodstream.

6. Chelation therapy, in integrative medicine, has been used in the treatment of CAD; the injected chelating agents are designed to bind molecules on the bloodstream, such as minerals, in order to ultimately remove them from the body.

7. The National Institute of Health (NIH) has estimated that by 2007, approximately 111,000 adults were undergoing chelation therapy for the treatment of coronary diseases despite the fact that no rigorous scientific study had yet been concluded to establish its safety or efficacy for that purpose.

8. In order to carefully evaluate the safety and efficacy of chelation therapy for the treatment of CAD, the NIH together with the National Center for Complementary and Alternative Medicine (now, the National Center for Complimentary and Integrative Health) jointly sponsored a study entitled “A Trial to Assess Chelation Therapy” generally known as the TACT trial.

9. The TACT trial was conducted over approximately ten years at 134 specifically

designated research sites in the United States and Canada. The TACT study enrolled more than 1,700 patients, of which 839 patients were randomized to be treated with chelating agents, while 869 patients received a placebo.

10. Prior to seeking chelation therapy treatment from the Respondent at Visions, Patient A had begun a course of EDTA therapy from another physician (Provider 1).

11. At all times relevant to this matter, Provider 1 and his medical practice were authorized participants in the TACT trial.

12. After Patient A had received 23 chelation treatments, Patient A decided to seek out a different provider to complete the recommended course of therapy, and he chose the Respondent for that specific purpose; the Respondent did not assume any role greater than the administration and oversight of chelation therapy, i.e., the Respondent did not assume the role of a primary care provider.

13. At all times relevant to this matter, neither the Respondent nor Visions were participants in the TACT trial. Prior to establishing the Visions practice, the Respondent was previously employed by the same medical practice as Provider 1.

14. At Patient A's first visit at Visions, the Respondent presented a document to Patient A that was entitled "Visions Medical Center Informed Consent Agreement Concerning Chelation Therapy" (Consent Form).

15. As a condition of commencing the remainder of Patient A's course of chelation treatments, Patient A was required to sign the Consent Form.

16. The Consent Form did not fully disclose the lack of efficacy or the potential adverse interactions of chelation therapy when used for CAD, and contained language styled as a release of legal liability for the Respondent's administration of chelation therapy to Patient A.

17. Between May 2011 and September 2011, Patient A completed an additional 27 chelation therapy treatments with Respondent at Visions. At the conclusion of that course of a total of 50 chelation treatments, the treatments were discontinued.

18. In March 2013, the results of the TACT trial were published in the Journal of the American Medical Association (TACT Report).

19. The TACT Report concluded, in part, that “chelation therapy can be safely administered when rigid quality control parameters are in place ... and under these conditions therapy has modest benefits.”

20. The TACT Report also concluded that further research is necessary before the treatment can be applied to routine clinical care for CAD.

MITIGATING FACTS

21. Once made aware of the Board’s concerns relative to the Consent Form, the Respondent revised the document to reflect the known benefits and risks of chelation therapy, and deleted language relating to a release of liability.

22. The Respondent has since completely discontinued the use of chelation therapy for the treatment of CAD and, based on the results of the TACT trial, has expressly acknowledged that he will not provide such therapy until and unless such use is approved by the NIH.

CONCLUSIONS OF LAW

A. The Respondent has engaged in conduct that undermines the public confidence in the integrity of the medical profession. *See Levy v. Board of Registration in Medicine*, 378 Mass. 519 (1979); *Raymond v. Board of Registration in Medicine*, 387 Mass. 708 (1982).

SANCTION

The Respondent, the Respondent's attorney and Complaint Counsel expressly acknowledge that the Board may impose sanctions against the Respondent based upon the above Findings of Fact and Conclusions of Law. The Respondent, the Respondent's attorney and Complaint Counsel jointly agree to recommend to the Board that it impose the sanction set forth below. The parties hereto understand that the recommended sanction is not binding on the Board, and that the Board may impose a different sanction on the Respondent.

At the time the Board considers this Stipulation, it will inform the parties of its inclination as to sanction. If the Board's sanction is different from the one recommended by the parties, the Respondent will be given an opportunity to either accept or reject the proposed sanction. If the Respondent rejects the proposed sanction, then the matter will continue through the adjudicatory process pursuant to General Laws chapter 30A and 801 CMR 1.00 et seq.

The parties jointly agree to recommend to the Board that the Respondent's license be reprimanded.

EXECUTION OF THIS STIPULATION

The parties agree that the approval of this Stipulation is left to the discretion of the Administrative Magistrate and the Board. As to any matter this Stipulation leaves to the discretion of the Administrative Magistrate or the Board, neither the Respondent nor anyone else acting on his behalf has received any promises or representations regarding the same.

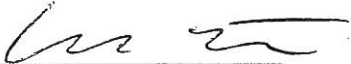
The signature of the Respondent, his attorney, and Complaint Counsel are expressly conditioned on the Administrative Magistrate and the Board accepting this Stipulation.

If the Administrative Magistrate rejects any provision contained in this Stipulation, the entire document shall be null and void and the matter will be scheduled for a hearing pursuant to

General Laws c. 30A and 801 CMR 1.00 et seq.

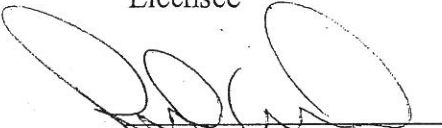
If the Board rejects any provision in this Stipulation or modifies the Sanction and said modification is rejected by the Respondent, the entire document shall be null and void and the matter will be recommitted to the Division of Administrative Law Appeals for a hearing pursuant to General Laws c. 30A and 801 CMR 1.00 et seq.

Neither of the parties nor anyone else may rely on the Stipulation in these proceedings or in any appeal there from.



Edward Levitan, M.D.
Licensee

3/31/16
Date



Paul Cirel, Esq.
Attorney for the Licensee

4/4/16
Date



John Costello
Complaint Counsel

4/5/16
Date