

COMMONWEALTH OF KENTUCKY
BOARD OF MEDICAL LICENSURE
CASE NO. 1810

FILED OF RECORD

JUN 22 2018

K.B.M.L.

IN RE: THE LICENSE TO PRACTICE MEDICINE IN THE COMMONWEALTH OF KENTUCKY HELD BY ELIZABETH VEENEMAN BATES, M.D., LICENSE NO. 36808, 4211 SPRINGHURST BOULEVARD, SUITE 101, LOUISVILLE, KENTUCKY 40241

ORDER OF INDEFINITE RESTRICTION

At its June 21, 2018, meeting, the Kentucky Board of Medical Licensure (hereinafter "the Board"), acting by and through its Hearing Panel A, took up this case for final action. The members of Panel A reviewed the Complaint, filed of record August 10, 2017; the Hearing Officer's Findings of Fact, Conclusions of Law and Recommended Order, dated April 11, 2018; the licensee's exceptions, filed of record April 27, 2018; and an April 27, 2018, memorandum from the Board's counsel.

Having considered all the information available and being sufficiently advised, Hearing Panel A ACCEPTS the hearing officer's Findings of Fact and Conclusions of Law and ADOPTS those Findings of Fact and Conclusions of Law and INCORPORATES them BY REFERENCE into this Order. (Attachment) Hearing Panel A FURTHER ACCEPTS AND ADOPTS the hearing officer's recommended order and in accordance with that recommended order, Hearing Panel A ORDERS:

1. The license to practice medicine held by Elizabeth Veeneman Bates, M.D., SHALL BE RESTRICTED/LIMITED FOR AN INDEFINITE PERIOD OF TIME to begin immediately upon the date of filing of this Order of Indefinite Restriction and continuing until further order of the Board;
2. During the effective period of this Order of Indefinite Restriction, the licensee's Kentucky medical license SHALL BE SUBJECT TO THE FOLLOWING TERMS

AND CONDITIONS OF RESTRICTION/LIMITATION until further order of the

Board:

- a. The licensee SHALL NOT practice medicine in the context of hormone replacement and/or optimization therapy;
 - b. Pursuant to KRS 311.565(1)(v), the licensee SHALL REIMBURSE to the Board the costs of the proceedings in the amount of \$47,287.50 within five (5) years from entry of this Order; and
 - c. The licensee SHALL NOT violate any provision of KRS 311.595 and/or 311.597.
3. The Panel SHALL NOT consider a request by the licensee to resume the practice of hormone replacement and/or optimization therapy unless and until the Board has received an assessment report and educational or remediation plan (if recommended) following the licensee's completion of a clinical skills assessment in hormone replacement and/or optimization therapy at either:
- a. Center for Personalized Education for Professionals ("CPEP"), 720 South Colorado Boulevard, Suite 1100-N, Denver, Colorado 80246, Tel. (303) 577-3232 Fax: (303) 577-3241 or
 - b. LifeGuard, 777 East Park Drive, Harrisburg, Pennsylvania, 17111, Tel. (717) 909-2590;

SO ORDERED on this 22nd day of June, 2018.



C. WILLIAM BRISCOE, M.D.
CHAIR, HEARING PANEL A

CERTIFICATE OF SERVICE

I certify that the original of the foregoing Order of Indefinite Restriction was delivered to Mr. Michael S. Rodman, Executive Director, Kentucky Board of Medical Licensure, 310 Whittington Parkway, Suite 1B, Louisville, Kentucky 40222; a copy was mailed, first-class postage prepaid, to Thomas J. Hellmann, Esq., Hearing Officer, 810 Hickman Hill Road, Frankfort, Kentucky 40601; and copies were mailed via certified mail return-receipt requested to the licensee, Elizabeth Veeneman Bates, M.D., License No. 36808, 4211 Springhurst Boulevard, Suite 101, Louisville, Kentucky 40241, and to her counsel, Carole Christian, Esq., Wyatt, Tarrant & Combs, 500 West Jefferson Street, Suite 2800, Louisville, Kentucky 40202 on this 22nd day of June, 2018.



Sara Farmer
Assistant General Counsel
Kentucky Board of Medical Licensure
310 Whittington Parkway, Suite 1B
Louisville, Kentucky 40222
502/429-7150

EFFECTIVE DATE AND APPEAL RIGHTS

Pursuant to KRS 311.593(1) and 13B.120, the effective date of this Order will be thirty (30) days after this Order is received by the licensee or the licensee's attorney, whichever shall occur first.

The licensee may appeal from this Order, pursuant to KRS 311.593 and 13B.140-.150, by filing a Petition for Judicial Review in Jefferson Circuit Court within thirty (30) days after this Order is mailed or delivered by personal service. Copies of the petition shall be served by the licensee upon the Board and its General Counsel or Assistant General Counsel. The Petition shall include the names and addresses of all parties to the proceeding and the agency involved, and a statement of the grounds on which the review is requested, along with a copy of this Order.

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IN RE: THE LICENSE TO PRACTICE MEDICINE IN THE COMMONWEALTH OF KENTUCKY HELD BY ELIZABETH VEENEMAN BATES, M.D., LICENSE NO. 36808, 4211 SPRINGHURST BOULEVARD, SUITE 101, LOUISVILLE, KENTUCKY 40241

**FINDINGS OF FACT, CONCLUSIONS
OF LAW, AND RECOMMENDED ORDER**

The Kentucky Board of Medical Licensure brought this action against the license of Dr. Elizabeth Veeneman Bates charging her with violating two statutes governing the practice of medicine in Kentucky. The administrative hearing was conducted on January 8-11, 2018. Hon. Sara Farmer represented the Kentucky Board of Medical Licensure, and Hon. Carole Christian represented Dr. Bates.

After considering the evidence admitted at the hearing and the arguments of counsel, the hearing officer finds Dr. Bates has violated two statutes governing the practice of medicine, and he recommends the Board take any appropriate action against her license for those violations. In support of his recommendation the hearing officer submits the following findings of fact, conclusions of law, and recommended order.

FINDINGS OF FACT

1. On August 10, 2017, the Board issued the *Complaint* against Dr. Bates charging her with violating KRS 311.595(9), as illustrated by KRS 311.597(3) and (4). Exhibit 50E, Tab 10. [Seventy exhibits were admitted into evidence at the hearing on the *Emergency Order of Restriction*, and those exhibits were also admitted into evidence at the hearing on the *Complaint*

at which twenty-six separately numbered exhibits were admitted into evidence. Therefore, in order to distinguish between the two groups of exhibits, all references in this recommendation to exhibits from the emergency hearing will include an "E" after the exhibit number, such as Exhibit 50E.].

2. Pursuant to KRS 311.597(3) and (4), respectively, a physician may be subject to discipline for conduct that constitutes "gross incompetence, gross ignorance, gross negligence, or malpractice," and for conduct that constitutes a "departure from, or failure to conform to the standards of acceptable and prevailing medical practice" in Kentucky.

3. The investigation of Dr. Bates' medical practice began after the Board received an anonymous grievance from a concerned pharmacist "who had seen a 'slew of prescriptions called in from Body Shapes Medical for Armour Thyroid 60mg (always for the same strength).' " Exhibit 50E, page 1.

4. The grievant "was concerned that Body Shapes Medical was using the medication to hyperstimulate the thyroid to promote weight loss in patients with normal thyroid activity." Id.

5. In response to those allegations the Board obtained fifteen randomly selected charts of patients who had been seen by Dr. Bates and prescribed Armour Thyroid between July 1, 2015, and July 31, 2015. DVD III, 9:03 a.m. [The administrative hearing on the *Emergency Order of Restriction* was conducted over two days, August 31 and September 1, 2017, and the hearing on the *Complaint* was conducted over four days, January 8-11, 2018. All citations to the record of the hearings will include a Roman numeral to reference the sequential day of the hearing, and references to the emergency will include an "E" after the Roman numeral.]

6. Two Board consultants, Dr. Ahsen Ali, who is board certified in Internal Medicine, and Dr. Sathya S. Krishnasamy, who is board certified in Endocrinology, reviewed the fifteen charts for the five male and ten female patients and issued reports to the Board. Exhibits 3-5, and 12-14.

7. Dr. Bates specializes in "hormone optimization" in which she prescribes Armour Thyroid, testosterone, and other hormones in response to the patients' complaints of fatigue, low energy, low libido, and other symptoms. Exhibit 51E.

8. Dr. Bates described hormone optimization as "a different type of medicine" in which the physician treats the patient based upon a patient's symptoms in conjunction with a review of the results from the patients' blood work. DVD IIE, 9:12 a.m.

9. Dr. Bates also described hormone optimization as not always being "cut and dry" but as being "very fluid," with treatment having to be individualized for each patient, which requires the physician to think beyond "cookie cutter" type medicine that medical specialists may fall into when treating certain types of conditions. DVD I, 10:08 a.m.

10. Thus, Dr. Bates described as one of her attractions to the field of hormone optimization the fact that the treatment of a patient's symptoms was like trying to solve a puzzle. DVD I, 10:07 a.m.

11. Dr. Bates also offers weight loss services in conjunction with the hormone replacement therapy. Exhibit 50E, page 3.

12. In his report Dr. Ali considered Dr. Bates's medical practice to be a weight loss clinic and asserted she was "extremely unethical" to prescribe the medication to patients in spite

of normal thyroid function tests and in an effort to increase the patients' metabolism "for the sole reason to make the patient lose weight." Exhibit 4, marked page 22.

13. In support of his opinion that Dr. Bates operated a weight loss clinic Dr. Ali noted the patient records did not show any consultations by dietitians or exercise plans by physical therapists to assist the patients in their efforts to lose weight. Id.

14. Based upon Dr. Ali's reports the Board alleged in the *Complaint* that Dr. Bates "departed from or failed to conform to acceptable and prevailing medical practices" in her prescription practices for Armour Thyroid. Exhibit 50E, Paragraph 6, page 129.

15. Dr. Krishnasamy stated in her reports several concerns related to Dr. Bates' prescribing thyroid hormone and testosterone to both the male and female patients, including failing to perform physical examinations, prescribing hormones for patients with normal hormone levels, increasing patient hormones to high levels, and prescribing Armour Thyroid medication rather than the standard thyroid medication. Exhibit 13.

16. Based upon Dr. Krishnasamy's reports the Board alleged that Dr. Bates departed from or failed to conform to the standards of acceptable and prevailing medical practice in Kentucky in her diagnosis for seven patients, in her treatment of eleven patients, and in her overall care of five, while being borderline in her care for nine patients. Exhibits 13 and 50E, Paragraph 7, page 129.

17. At the same time that the *Complaint* was issued the Board issued an *Emergency Order of Restriction* that prohibited Dr. Bates "from practicing medicine in the context of hormone replacement therapy until resolution of the Complaint" Exhibit 50E, pages 143-149.

18. After conducting the administrative hearing on the emergency order on August 31 and September 1, 2017, the hearing officer affirmed the Board's order. *Final Order Affirming the Emergency Order of Restriction*, dated September 11, 2017.

19. In this action Dr. Bates raises several defenses to the allegations in the *Complaint*. She asserts that the Board's consultants did not understand the nature of her medical practice or the standards of acceptable and prevailing medical practice that should be applied to her hormone optimization practice. She further asserts that her specialty of hormone optimization is fundamentally different from the traditional or conventional practice of medicine and from endocrinology, and therefore, her medical practice cannot be evaluated using the usual medical standards for assessing thyroid function and hormone deficiencies. She asserts that in her medical practice she strives to adjust patients' thyroid hormones to an "optimal" level in order to provide the patients with improved energy, function, mood, sleep, and overall well-being, which the traditional practice of medicine has failed to provide for her patients. She asserts that her expert witnesses and her own patients who testified on her behalf at the administrative hearing on the emergency order have shown that her medical practice conforms to the standards of acceptable and prevailing medical practice for hormone optimization, and that contrary to the assertions in Dr. Ali's report, she does not, and never has, operated a weight loss clinic. Therefore, she asserts the charges against her must be dismissed.

20. The resolution of the issues in this action turns largely on an understanding of the nature of Dr. Bates's medical practice and on the credibility and trustworthiness of the opinions of parties' expert witnesses regarding her practice. The hearing officer found the Board's experts to be more credible and trustworthy than Dr. Bates's and that the preponderance of the evidence

supports the opinions of the Board's experts. Therefore, the hearing officer finds Dr. Bates's defenses to the Board's charges to be without merit and finds that she has violated KRS 311.595(9), as illustrated by KRS 311.597(3) and (4).

21. Endocrinology is the science and study of hormones and hormone systems as they relate both to health and to disease and involves the study of how hormone secretions interact with target organs and impact the overall health of the patient. DVD II, 9:06 a.m.

22. Although Dr. Bates prescribed various hormones, including Armour Thyroid and Testosterone to the fifteen patients at issue in this action, she asserts that she does not practice endocrinology and should not be held to the standards of that medical specialty because as a specialist in hormone optimization she is not practicing "conventional medicine." DVD IIE, 10:50-10:52 a.m. and 2:05-2:07 p.m.

23. Dr. Bates asserts that in contrast to her specialty of hormone optimization, conventional medicine, such as endocrinology, has residency programs and subspecialties and treats "diseases," whereas she treats "dysfunctions." DVD IIE, 2:05 p.m. and 2:09-2:10 p.m.

24. Dr. Bates described a dysfunction as "a grey zone" that exists "between healthy and having a disease process." DVD IIE, 9:23 a.m.

25. In an effort to further contrast her medical practice to the practice of endocrinology, Dr. Bates asserts she does not treat patients with hormone disorders resulting from hormones being above or below a "normal" range. Instead, she treats patients whose hormone levels may be within the "normal" range, but based upon a patient's complaints and symptoms, those levels are not in the optimal range for the patient. DVD IIE 9:23 a.m. and 9:43 a.m.

26. Therefore, she asserted that the standards and guidelines applicable to the practice of endocrinology do not apply to her medical practice of hormone optimization. DVD IIE, 2:05-2:07 p.m.

27. Dr. Bates asserts that a fellow hormone replacement specialist is the appropriate person to evaluate her medical practice, but in light of the fact that hormone optimization is not a recognized medical specialty, the hearing officer finds Dr. Bates's assertion to be without merit. DVD IV, 12:17-12:18 p.m.

28. Despite Dr. Bates' assertions to the contrary, her medical practice clearly relates to and involves the practice of endocrinology, and her medical practice will be evaluated under standards of acceptable and prevailing medical practice in Kentucky as they relate to the prescribing of hormones.

29. Dr. Bates does not have a medical background in endocrinology. Exhibit 50E, page 12.

30. She was trained in Internal Medicine and worked in private practice from 2001 until 2014, when she began working as the Medical Director of Body Shapes Medical. Exhibit 50E, page 12.

31. Dr. Bates began to feel overwhelmed by the demands of her private practice, which was the reason for joining the new practice. DVD I, 9:51-9:52 a.m.

32. Originally, the medical practice advertised itself as "Body Shapes Medical, Hormone Experts/Optimal Aging," but as the result of "rebranding" the practice is currently named "25 Again, by Body Shapes Medical." DVD I, 9:47 a.m. and 9:54 a.m.; Exhibit 50E, page 108.

33. The name "25 Again" refers to the age at which Dr. Bates believes a person has optimized levels of hormones, and since hormone levels begin to decline at an age in the late 30s to early 40s, Dr. Bates asserted that data shows people will become healthy when hormones are restored to the "optimal level" that existed when they were younger. DVD I, 9:47-9:49 a.m.

34. The forms that a patient completes at the initial appointment provides insight into the general nature of Dr. Bates's medical practice and the extent to which it involves the practice of endocrinology. Exhibits 51E-54E.

35. The patients are asked to answer several categories of questions related to the patient's symptoms that may suggest deficiencies in various hormones, including testosterone and thyroid hormones. Exhibit 51E.

36. The form asks the patients to respond to a list of "Signs and Symptoms" of a particular hormone deficiency and are graded to determine whether they have a deficiency and need additional hormones. Exhibit 51E.

37. Consistent with the restorative component of hormone optimization, Dr. Bates accepts patients into her practice who are thirty-five years of age and older, except in unusual circumstances. DVD IIE, 1:08 p.m.

38. Dr. Bates testified that she has had only "a handful of people" who have had a "perfect" level of thyroid hormone and haven't needed treatment. DVD IIE, 2:23 p.m.

39. She has, however, turned down many young people who have sought testosterone hormones from the clinic. DVD IIE, 2:22 p.m.

40. As medical director of the clinic Dr. Bates's duties include collaborating with the practice's nurse practitioners by reviewing patient charts, answering questions, consulting on

difficult patients, developing the clinic's medical practices, and navigating company policies.

DVD I, 9:49 a.m.

41. In addition, Dr. Bates has approximately 380 patients for whom she is their healthcare provider. DVD I, 9:50 a.m.

42. Body Shapes Medical does not accept Medicaid or Medicare patients and does not accept health insurance. DVD I, 10:15 a.m. and 10:17 a.m.

43. Dr. Bates distinguished her hormone optimization practice from the "traditional" or "conventional" practice of medicine due to her willingness to look at patients as individuals and not to rely simply upon lab results or practice guidelines for every patient. DVD I, 10:10 a.m.

44. She explained further that instead of having a cookie cutter approach to her patients, she takes the time to consider what is really happening with them, and she relies more on a patient's symptoms to determine why the patient doesn't feel well and will not stop searching for an answer simply because the lab results are normal. DVD I, 10:11 a.m.

45. In her practice Dr. Bates typically meets with the patients for at least thirty minutes every eight to ten weeks, although she imposes no limitation on the frequency of the patients' office visits. DVD IIE, 9:30-9:31 a.m.

46. Patients are scheduled to meet with Dr. Bates on a regular basis because their hormone levels fluctuate, which requires more frequent monitoring. DVD IIE, 9:14 a.m.

47. Dr. Bates asserts there are numerous health benefits from hormone optimization, including decreases in body weight, in bowel difficulties, and in depression, and increases in energy, metabolism, and concentration. Exhibit 50E, page 2.

48. In the order issued after the administrative hearing on the *Emergency Order of Restriction*, the hearing officer found that Dr. Bates is a dedicated, conscientious, and professional physician who provides treatment for her patients in a sincere effort to improve their health and well-being. *Final Order Affirming Emergency Order of Restriction*, page 11.

49. After considering the additional evidence admitted at the hearing on the *Complaint*, however, the hearing officer finds the preponderance of the evidence supports the conclusion that although Dr. Bates may be sincere and well-meaning regarding the care and treatment of her patients, her hormone optimization practice does not meet the standards of acceptable and prevailing medical practice in Kentucky as they relate to the treatment of patients with hormone medications such as testosterone and Armour Thyroid.

50. Because Dr. Bates no longer practices Internal Medicine, she has let that board certification expire. DVD 1, 10:12 a.m.

51. She currently does not have any certification recognized by the American Board of Medical Specialties. Id.

52. Dr. Bates had no formal training in hormone optimization prior to starting at Body Shapes Medical in March 2014, and as a result, Dr. Bates followed the nurse practitioners for a period of time as they provided treatment to the patients. DVD 1, 10:09-10:10 a.m.

53. Much of her training in hormone optimization was provided by Dr. Robert N. Rouzier, whom Dr. Bates described as a pioneer in the field of hormone replacement therapy. DVD 1E, 9:25 a.m.; Exhibit 50E, page 25.

54. Dr. Rouzier testified on behalf of Dr. Bates at the administrative hearing, and he was qualified as an expert in hormone replacement therapy. DVD 1E, 11:10 a.m.

55. An essential feature of hormone optimization as advocated by Dr. Rouzier is the manipulation of a patient's T3, T4, and testosterone levels. DVD IE, 11:16-11:18 a.m.

56. There was no disagreement among the expert witnesses at the administrative hearing regarding the negative feedback loop between the pituitary and thyroid glands in which the pituitary gland produces Thyroid Stimulating Hormone (hereinafter, "TSH"), which stimulates the thyroid to produce the hormones T3 and T4, and as a result of that feedback loop, there's an inverse relationship between the TSH level and the levels of T3 and T4. DVD IE, 11:12-11:15 a.m.; DVD II, 9:28 a.m.

57. If a patient's TSH level is up, the hormones must be low, and the TSH will stimulate the production of the hormones. Id.

58. Dr. Rouzier asserted, however, that the focus in determining adequate thyroid hormone levels should not be on TSH but on the patient's T3 level. DVD IE, 11:40-11:42 a.m.; Exhibit 2E.

59. The stated goal of the hormone therapy for thyroid optimization is be to raise the T3 level to the upper end of the normal range rather than simply to have the level withing the range for an "average population." DVD IE, 11:17-11:18 a.m.

60. While acknowledging the Board's consultants' opinions may be consistent with the current standards of care of the professional medical societies for hormone replacement therapy, Dr. Rouzier asserted the standards themselves were flawed and are not consistent with the latest evidence-based medicine. DVD IE, 3:06-3:08 p.m.

61. He provided numerous articles from professional journals and other publications that allegedly countered those cited by Dr. Krishnasamy in her reports and to support the medical practices of Dr. Bates. Exhibits 2E-49E, 56E, 58E-61E, and 64E.

62. Although disagreeing with Dr. Krishnasamy's opinions, Dr. Rouzier acknowledged they were correct based upon current medical education, training, and guidelines. DVD IE, 11:43, 11:48-11:49 a.m.

63. He asserted, however, that the current guidelines and standards of acceptable and prevailing medical practice related to hormone replacement therapy for hypothyroidism are wrong by focusing on TSH while ignoring T3 levels. DVD IE, 11:40 a.m., Exhibit 2E.

64. He asserted those guidelines are not based upon the most recent medical literature, are the result of the Endocrine Society's "suppression of evidence" that other scientific disciplines commonly accept, represent the old standard of care, and "should be trashed." DVD IE, 11:26-11:28 a.m., 11:50 a.m.

65. He also asserted that in spite of the overwhelming medical literature that shows the guidelines are wrong, they are kept because they're written by a "good-old-boy club" and due to "politics." DVD IE 11:39 a.m. and 11:45 a.m.

66. No credible evidence was provided in support of Dr. Rouzier's assertions of suppression of evidence and bias of the professional societies, and there was no suggestion in Dr. Krishnasamy's testimony that her opinions were based on anything other than the relevant and applicable medical standards and science.

67. As for treatment with testosterone, Dr. Rouzier asserted that the optimal level is above what is considered to be within the normal range. DVD IE, 2:09-2:11 p.m. and 2:16 p.m.

68. Dr. Bates herself acknowledged that her medical practice is not consistent with the guidelines for endocrinology, but she asserted they don't apply to her type of medical practice. DVD IIE, 2:06-2:07 p.m.

69. Dr. Bates attended four conferences hosted by Dr. Rouzier that focused exclusively on hormone optimization and that were sponsored by Worldlink Medical, The Academy of Preventive and Innovative Medicine, which she described as an innovative worldwide organization. DVD I, 10:01-10:05 a.m.; Exhibit 50E, page 25.

70. The first conference she attended was in the summer of 2014, which was several months after she began working at Body Shapes Medical. DVD I, 10:02 a.m.

71. Dr. Ashok Kadambi, who also testified at the administrative hearing as an expert on hormone optimization, gave presentations at the same conferences in which he discussed his own patients as part of the participants' collaborative discussions on their experiences in treating patients. DVD I, 10:04-10:05 a.m.; DVD III, 10:49 a.m.

72. He issued his own reports that support all aspects of Dr. Bates's hormone optimization medical practice. Exhibits 25 and 63E.

73. In one of his reports Dr. Kadambi reviewed Dr. Bates's care and treatment of the fifteen patients at issue in this action, and he found no concerns with any treatment that adjusted thyroid hormone levels based upon the patient's T3 or with raising testosterone and T3 levels above the normal range. Exhibit 25.

74. In addition to her attendance at the Worldlink Medical conferences, Dr. Bates has educated herself on hormone optimization through self-study, by talking with fellow practitioners

in the same field, and by participating in discussions about patients and cases on a website hosted by Worldlink Medical. DVD I, 10:02 a.m. and 10:06 a.m.

75. The preponderance of the evidence shows that Dr. Bates has adopted and implemented in her medical practice Dr. Rouzier's teachings related to hormone optimization, including his focus on providing treatment based upon T3 levels rather than on TSH and on raising T3 and testosterone levels up to and beyond the normal range in order to achieve an "optimal" hormone level.

76. Based upon his review of the evidence admitted at the administrative hearing, including a review of the testimony and reports of the parties' expert witnesses, the hearing officer finds that the preponderance of the evidence supports the conclusion that Dr. Bates's practice of hormone optimization does not comply within the standards of acceptable and prevailing medical practice in Kentucky and that there is not adequate medical and scientific support for Dr Bates's practice of hormone optimization.

77. Dr. Krishnasamy is an Associate Professor from the Division of Endocrinology, Metabolism and Diabetes at the University of Louisville School of Medicine, and is board certified in both Internal Medicine and Endocrinology. Exhibit 12.

78. She was qualified at the administrative hearing as an expert in Endocrinology. Exhibit 12; DVD II, 9:20 a.m.

79. She reviewed the fifteen patient charts that were obtained from Dr. Bates's medical practice and prepared Expert Review Worksheets for each of the patients. Exhibits 13.

80. She found Dr. Bates departed from the standards of acceptable and prevailing medical practice in her diagnosis of seven patients (Patients A, C, D, E, H, I, and L), and in her

treatment of eleven patients (Patients A, B, C, E, H, I, J, K, L, N, and O), and in Dr. Krishnasamy's "overall opinion" Dr. Bates was "clearly below minimum standards" for five patients (Patients A, C, E, I, and O). Exhibit 13, marked pages 28-88.

81. Dr. Krishnasamy found no deficiencies in Dr. Bates's record keeping for any of the patients. Id.

82. Dr. Krishnasamy also found that Dr. Bates displayed "gross ignorance" in her care and treatment of Patient I, a premenopausal woman, with high doses of testosterone. Exhibit 13, marked page 63.

83. In her written report issued with her Expert Review Worksheets for the fifteen patients Dr. Krishnasamy summarized her findings regarding the deficiencies in Dr. Bates's medical practice. Exhibit 13, marked pages 24-27.

84. Dr. Krishnasamy applied the American Thyroid Association [hereinafter "ATA"] and Endocrine Society screening guidelines to Dr. Bates's medical practice. Exhibit 13, marked page 24.

85. Dr. Krishnasamy found multiple deficiencies in Dr. Bates's treatment of the patients that called into question the very legitimacy of her hormone optimization practice.

86. The standards in the applicable guidelines require the measurement of TSH for diagnosing hypothyroidism and to repeat the test if the TSH is mildly abnormal, and contrary to Dr. Bates's practice, the guidelines do not recommend screening for free T3 and free T4 except in certain, specific circumstances. Exhibit 13, marked pages 24-25.

87. The ATA recommends treatment with levothyroxine instead of Armour Thyroid for most patients because of the difficulty in monitoring levels of free T3 caused by the medication's half-life and the normal fluctuations in T3 levels. Exhibit 13, marked page 25.

88. Levothyroxine consists of T4, and Armour Thyroid is an extract of both T4 and T3 with a ratio of approximately 4 to 1. DVD II, 10:37-10:38 a.m.

89. In her report Dr. Krishnasamy also noted that "there is a lot more data available on outcomes on levothyroxine" than is available for Armour Thyroid. Exhibit 13, marked page 25.

90. Dr. Krishnasamy found that use of Armour Thyroid "as the first treatment of choice is also not standard of practice in most patients unless there is a documented reaction or intolerance to standard preparations" and that "targeting T3 levels as treatment goal is not current standard of practice." Id.

91. Furthermore, Dr. Krishnasamy noted that TSH levels were taken just once and that the majority of patients were in the normal range prior to Dr. Bates beginning treatment, "which is not current standard of practice" for the diagnosis and treatment of hypothyroidism. Id.

92. Lastly, Dr. Krishnasamy found that Dr. Bates performed "no physical exam, except for one patient" prior to initiating treatment with hormones. Id.

93. Dr. Ali, who reviewed Dr. Bates's medical practice from the perspective of a specialist in Internal Medicine, applied those same guidelines and expressed similar criticisms and concerns as Dr. Krishnasamy in his own reports issued after reviewing the fifteen patient charts. Exhibits 4 and 5; See for example, DVD I, 11:52 a.m., 1:34 p.m., 1:38 p.m., 1:45 p.m., and 3:52 p.m.

94. Dr. Ali's report contains a chart that shows the TSH, T3 and T4 levels for each of the fifteen randomly selected patient charts were normal at the time Dr. Bates initiated treatment with 30mg to 60mg of Armour Thyroid, and she adjusted that medication for most patients without attempting to maintain TSH levels within the normal range. Exhibit 4, marked pages 20-21.

95. In her written report Dr. Krishnasamy also found multiple deficiencies in Dr. Bates's treatment of both male and female patients with testosterone that further challenged the legitimacy of her hormone optimization practice.

96. As for Dr. Bates's treatment of male patients with testosterone, the standard of care is to screen patients in the morning, but Dr. Bates had the tests performed in the afternoon when the levels tend to be lower. Exhibit 13, marked page 25.

97. Dr. Bates failed to repeat tests for patients who were borderline low before initiating testosterone therapy, but most of the male patients had normal to high levels at the time Dr. Bates initiated treatment. Id.

98. Dr. Bates failed to perform physical examinations prior to initiating treatment, which "is warranted in all patients who undergo evaluation of male hypogonadism," and the "men had quite high levels on treatment." Exhibit 13, marked page 26.

99. For men with normal levels of testosterone, treatment is not recommended because of "concerns for cardiovascular safety and other adverse effects." Id.

100. Even when the testosterone treatment caused high red blood cell levels, Dr. Krishnasamy noted that Dr. Bates had the men donate blood in order to reduce those levels rather than decrease the testosterone dosage, which is "not standard practice" and is contrary to "all

national and international expert panel consensus guidelines from societies [which] recommend reducing the strength/dose of preparations.” Id.

101. In her written response to Dr. Krishnasamy’s report, however, Dr. Bates maintained that her treatment of men with testosterone was appropriate since she monitors free testosterone, rather than total testosterone, and although their actual testosterone levels may not have been low, she asserted the men had symptoms consistent with low testosterone. Exhibit 50E, pages 113-114.

102. Dr. Bates asserted that as men age, there is not much fluctuation in testosterone levels and therefore, measuring testosterone levels in the afternoon rather than in the morning was appropriate. Exhibit 50E, page 112.

103. At the administrative hearing, however, Dr. Krishnasamy noted free testosterone may be monitored only when total testosterone is at the lower end of the normal range and that the normal fluctuations in testosterone decrease for men starting approximately at age 70, which would not apply to the men at issue in this action. DVD II, 9:42 a.m. and 11:16 a.m.

104. Dr. Krishnasamy expressed similar concerns for Dr. Bates’s prescriptions of testosterone for women. Exhibit 13, marked pages 26-27.

105. Dr. Krishnasamy found that testosterone use by females “is not standard practice and is not FDA approved,” and is not recommended by either the Endocrine Society nor the North American Menopausal Society. Exhibit 13, marked page 26.

106. One concern for testosterone therapy for women is that the “long term safety for adverse cardiovascular outcomes and breast cancer and other sex hormone dependent cancers is unknown at this time.” Id.

107. In her Expert Review Worksheet for Patient I Dr. Krishnasamy explained that Dr. Bates's care of the patient constituted gross ignorance because the leading medical societies for endocrinology and gynecology "recommend against routine use of androgen replacement in young women such as this patient," who was thirty-five years old, because "the long term safety of androgen replacement in young premenopausal women is unknown and is not FDA approved at this time." Exhibit 13, marked page 63.

108. Dr. Bates asserted, however, that her treatment of premenopausal women with testosterone was authorized as an "off label" use of the medication, but unlike with her example of the use of Benadryl as a sleep aide, there is a specific recommendation that young women such as Patient I not be prescribed testosterone. DVD 1, 10:48-10:49 a.m.

109. Dr. Krishnasamy found that none of the female patients treated with testosterone had been diagnosed with Hypoactive Sexual Desire disorder, which is the one condition that clinical studies show "efficacy for short term off label use of low dose (150-300 mcg) topical testosterone" by postmenopausal women. Exhibit 13, marked page 26.

110. Dr. Krishnasamy found, however, that many of the women who received testosterone were premenopausal, that some had extremely high levels of testosterone, and that some had undesirable side effects. Id.

111. Dr. Krishnasamy further noted that "neither menopausal hormone therapy (MHT) nor testosterone should be used for weight management." Id.

112. In her written report, Dr. Krishnasamy noted that Dr. Bates performed a physical exam on just one patient, Patient F, prior to initiating hormone treatment. Id.

113. Based upon her review of Dr. Bates's medical records Dr. Krishnasamy stated "there seems to be departure from current acceptable and prevailing standards of medical practice with (sic) the Commonwealth of Kentucky," and she recommended for Dr. Bates "remedial education and training and subsequent monitoring by board." Exhibit 13, marked pages 26-27.

114. Dr. Bates submitted a written response to Dr. Krishnasamy's report that challenged many of her findings and conclusions related to treatment based on T3 hormone levels rather than on TSH levels. Exhibit 50E, pages 108-119.

115. Dr. Bates also testified that she was not required to perform a complete physical examination of her patients since a hormone deficiency is "more appearance and visual related," and includes a consideration of how the patient is acting and behaving along with an assessment of the patient's "ways of being." DVD I, 10:40 a.m.; DVD IV, 10:01 a.m.

116. At the administrative hearing Dr. Bates acknowledged that when she first began practicing at Body Shapes Medical, she did not perform a complete physical examination as part of the patient's initial evaluation for hormone replacement therapy and that a large majority of medical charts reviewed by the Board's consultants do not have physical exams documented. DVD I, 10:40-10:41 a.m.

117. Dr. Bates asserted, however, that as she progressed in the hormone optimization medical practice, she started performing once a year more complete physical examinations, rather than specialty type exams, because more of her patients are using her as their primary care physician. DVD I, 10:40 a.m.; DVD IV, 10:01-10:02 a.m.

118. As a result of the patients' annual physical examinations, Dr. Bates has found many medical issues or conditions that need to be addressed by the patient's primary care physician, which is one of the reasons she now performs those annual examinations. DVD IV, 10:05 a.m.

119. By April 1, 2016, which was after the time period at issue in this action, she was documenting full physical examinations in the patients' medical records. DVD IV, 10:04 a.m.

120. In spite of the fact that she now performs a physical examination, Dr. Bates asserted that she does not need to perform such an examination before initiating hormone replacement therapy because her diagnosis hinges very little on the physical findings, and hormone optimization does not require examinations such as listening to a patient's heart or lungs. DVD I, 10:41 a.m.; DVD IV, 10:04 a.m.

121. Consistent with Dr. Bates' opinion, Dr. Kadambi asserted that prior to initiating thyroid or testosterone treatment the actual physical exam "is not all that important simply because 99% of the time the physical exam is pretty much normal." DVD III, 1:47 p.m.

122. Dr. Bates also asserted that she did not need to establish a diagnosis to treat patients as part of her hormone optimization practice, but if she is required to do so, she would diagnose her patients with "peripheral or low thyroid function," which is distinct from the patients having low thyroid hormone levels. DVD IV, 12:43 p.m.

123. Dr. Krishnasamy also expressed concern that there's a long list of problems associated with a patient having low TSH and high T3 and T4 levels over a long period of time. DVD II, 11:24 a.m.

124. In response to Dr. Krishnasamy's criticism of Dr. Bates having her testosterone patients with high red blood cell counts donate blood rather than her reducing their testosterone

prescriptions, she asserted that only a small number of her patients are referred to blood banks, and she asserted that the referrals were a “safe, convenient, and charitable donation process” that at the same time “effectively manages their deficiency symptoms and improves their health.” Exhibit 50E, marked page 115.

125. As for treating female patients with testosterone, Dr. Bates asserted her practice was appropriate as an off-label use of the hormone. *Id.*, pages 115-116.

126. After reviewing Dr. Bates’ response, Dr. Krishnasamy reiterated many of the points made in her original report and concluded with the statement: “The pattern of multiple hormone replacements in individual patients such as for low ‘thyroid,’ ‘low sex hormones,’ is not well substantiated in evidence based literature. While we all as providers have great commitment to the wellbeing (sic) of our patients and are in a constant quest for improved and more effective treatment, we also need to conform to evidence based practices.” Exhibit 14, page 3.

127. At the administrative hearing Dr. Bates asserted several additional grounds for objecting to Dr. Krishnasamy serving as a Board consultant in the review of her medical practice.

128. Dr. Bates asserted that Dr. Krishnasamy had a bias or conflict of interest due to the fact that fellow physicians associated with the University of Louisville medical school are Board members, but Dr. Krishnasamy was not even aware of that fact until it was called to her attention at the administrative hearing. DVD II, 9:16-9:18 a.m.

129. After being notified that university officials were on the Board, Dr. Krishnasamy did not change any of the opinions set forth in her written reports, and the hearing officer did not find that the information had any impact upon her testimony or the opinions expressed at the administrative hearing. Consequently, the objection had no merit.

130. Dr. Bates also suggested that due to Dr. Krishnasamy's involvement in academic medicine, she is not qualified to evaluate Dr. Bates's medical practice.

131. The hearing officer finds that assertion has no merit since Dr. Krishnasamy is board certified in both Endocrinology and Internal Medicine, has extensive experience in treating patients for hormone related conditions and disorders, and has particular and extensive experience treating patients for testosterone deficiency through her clinical work with a Veterans Administration medical facility. Exhibit 12; DVD II, 8:59-9:01 a.m. and 9:12-9:14 a.m.

132. Furthermore, Dr. Krishnasamy testified that her own patient population is very similar to Dr. Bates's in terms of age, weight, and BMI index and that many of her patients are also high functioning and have medical issues similar to Dr. Bates's patients, such as diabetes and prediabetes. DVD II, 4:41 p.m.

133. The hearing officer found Dr. Krishnasamy's testimony and opinions to be based upon an objective review of the medical records and the treatment provided to patients, and he found her opinions and testimony to be both convincing and trustworthy as a result of her extensive knowledge, training, research, and experience in diagnosing and treating patients with hormone related health issues. DVD II, 9:20 a.m.

134. In preparation for her review of Dr. Bates's patient records, Dr. Krishnasamy was unable to find in any published peer reviewed journals related to the practice of hormone optimization, and unlike other specialized fields of medicine, hormone optimization has no major professional medical organization associated with it with recognized leaders who have done studies with data and science in support of their research. DVD II, 9:10-9:11 a.m.

135. Dr. Krishnasamy did find a few articles published “here and there at random” on hormone optimization, but “most were not peer reviewed” and had “no science to it.” Consequently, she found hormone optimization as a field of medicine “hard to believe” because “it’s not evidence based.” DVD II, 9:11 a.m.

136. At the administrative hearing Dr. Krishnasamy dismissed the relevance of the peer reviewed articles cited by Dr. Rouzier in his testimony since the articles addressed treatment for patients whose thyroid and testosterone hormone levels that were well below the normal range at the start of treatment. DVD II, 4:40 p.m. and 4:44-4:45 p.m.

137. In fact, Dr. Krishnasamy indicated that the articles cited by Dr. Rouzier contained nothing new or novel about the treatment of patients with hormone deficiencies, and she offered to provide at the administrative hearing a more detailed review of each article to explain why they had no relevance to the issues in this action or to the care and treatment of Dr. Bates’s patients, who unlike the patients discussed in the articles, were not severely hypothyroid and did not have low testosterone. DVD II, 4:37-4:40 p.m.

138. In commenting on some of the other articles cited by Dr. Rouzier, Dr. Krishnasamy stated that it’s well known that T4 supplementation with levothyroxine does not work for some patients, which may result in them receiving treatment with T3, but that type of patient has no relevance to the core of Dr. Bates’s patients. DVD II, 10:36-10:37 a.m. and 4:45 p.m.

139. Dr. Krishnasamy also noted that at least one article cited by Dr. Rouzier, Exhibit 2E, was not peer reviewed, and the medical school librarian could not even identify the journal in which it was published, the *Journal of Orthomolecular Medicine*, in a catalog of published medical journals. DVD II, 4:38-4:39 p.m.

140. That was the first article referenced by Dr. Rouzier in his testimony, and Dr. Kadambi cited that same article in his report and declared it to be the “seminal article” on the “narrow approach of the guidelines” and on “the apparent reason for reluctance of more endocrinologists to use T3.” He attached a copy of the article to his report. DVD III, 2:55-2:57 p.m.; Exhibit 2E and Exhibit 63E, page 5, and attached *Reducing the Scope of Guidelines and Policy Statements in Hypothyroidism*.

141. At the administrative hearing Dr. Kadambi acknowledged that the author of the article is an engineer and is not a physician. DVD III, 2:58 p.m.

142. The articles cited by Dr. Rouzier in his testimony changed none of Dr. Krishnasamy’s opinions about the deficiencies in Dr. Bates’s medical practice, and Dr. Krishnasamy reiterated the fact that hormone optimization is not recognized or accepted in the field of endocrinology. DVD II, 4:42-4:45 p.m.

143. Dr. Krishnasamy also noted substantial concerns for any patients who stopped treatment with Dr. Bates after receiving high levels of hormones since the treatment causes the hormonal system to “rest,” resulting in the patients not feeling well for a few weeks or months until the system recovers. DVD II, 4:43 p.m.

144. In light of Dr. Krishnasamy’s testimony and the fact that Dr. Rouzier himself acknowledged that his opinions were not consistent with the current standards for the practice of endocrinology, the hearing officer found Dr. Rouzier’s and Dr. Kadambi’s opinions not to be credible or trustworthy.

145. While Dr. Rouzier and Dr. Kadambi may disagree with Dr. Krishnasamy and Dr. Ali about what should be the appropriate standards for the care and treatment of the patients seen

by Dr. Bates in her medical practice, there is no disagreement as to the current standards of accepted and prevailing medical practice in Kentucky for hormone replacement therapy, which is the relevant issue under KRS 311.597(4), and the opinions of Board's experts reflect those standards.

146. In addition to finding that the very practice of hormone optimization is not evidence based medicine or supported by the medical literature, Dr. Krishnasamy found several deficiencies in Dr. Bates's evaluation of patients complaints and associated symptoms that served as the basis for their treatment with hormones.

147. In her position at the university Dr. Krishnasamy sees many patients for follow-up examinations and requests for second opinions, and as a result, she has seen some patients who have been treated for hormone optimization. DVD II, 9:09-9:10 a.m.

148. Dr. Krishnasamy explained there is a three-part process to a physician making a diagnosis for hormone related medical issues. DVD II, 9:14 a.m.

149. The first part is a review and consideration of the patient's complaints, symptoms, and history. DVD II, 9:15 a.m.

150. The second part, which Dr. Krishnasamy described as "very important," is the "complete head to toe physical exam" that is relevant to the endocrine practice. DVD II, 9:15 a.m.

151. The third part is a review of the biochemical or lab evidence. Id.

152. The physician uses a combination of the three to make a diagnosis prior to initiating treatment. DVD II, 9:15 a.m.

153. In reviewing medical records for the fifteen patients at issue in this action, however, Dr. Krishnasamy found that Dr. Bates performed no physical exams, except on Patient F, and therefore, Dr. Bates did not satisfy a basic standard for diagnosing a patient's complaint. Exhibit 13, marked pages 25-26, Exhibit 19, page 30; DVD II, 3:05 p.m.

154. Dr. Krishnasamy explained that if a patient has a TSH level within the normal range but the physician suspects there may be a hormone related problem, the physician must conduct a physical exam that involves checking the goiter, and reflexes, which are slower in hypothyroid patients, and listening to the heart for tachycardia and checking other symptoms associated with low thyroid function. DVD II, 9:32 a.m.

155. Thus, Dr. Bates' failure to conduct physical examinations undermined her very rationale for initiating any kind of hormone treatment, and her assertion that a complete physical examination is unnecessary because a hormone deficiency is "more appearance and visual related" has no merit. DVD I, 10:40 a.m.; DVD IV, 10:01 a.m.

156. The TSH assay is now in its third generation, is extremely sensitive, and is the primary screening tool for most healthy individuals in evaluating them for a thyroid hormone disorder. DVD II, 9:28 a.m.

157. Dr. Krishnasamy stated that LabCorp, which was the testing provider for Dr. Bates, provides "great results" with its TSH tests. DVD II, 9:30 a.m.

158. The normal range for TSH is based on major population studies and has been tested and retested over the years, which has resulted in some movement in the range. DVD II, 9:29 a.m.

159. Dr. Bates based her thyroid treatment, however, upon the patients' T3 and Free T4 results, which are not used as the basis for treatment unless there are exceptional circumstances, such as with pregnant patients. DVD II, 9:31 a.m.

160. Dr. Krishnasamy noted that using T3 levels for treatment is "challenging" due to its short half-life. Exhibit 13, marked page 25; DVD II, 9:31 a.m.

161. In addition, treatment with Armour Thyroid, rather than with levothyroxine, does not represent the standard of care for treatment of hypothyroidism. DVD II, 9:31-9:32 a.m.; Exhibit 13, marked page 25.

162. Because there is always concern about when to initiate treatment for a patient who is at the lower end of the normal range, a treatment decision depends upon the particular circumstances of the patient and might involve the retesting of the patient in a few weeks. DVD II, 9:30 a.m.

163. Dr. Krishnasamy explained that hormones "pulse" or fluctuate with significant individual variation over time, and each person has a set point within a wide range and will feel terrible when moved from that set point. DVD II, 9:32-9:33 a.m.

164. Consequently, prior to initiating treatment, the physician should confirm that a hormone deficiency is causing the patient's symptoms by obtaining a second, independent value of the hormone level. DVD II, 9:33 a.m.

165. In the majority of the patients treated by Dr. Bates, however, their TSH was in the normal range, and there was no process for retesting or for performing an assessment after pulling all the data together to support the treatment provided, which was the basis for Dr.

Krishnasamy describing Dr. Bates's medical practice as "cookie cutter style" medicine. DVD II, 9:31-9:33 a.m.

166. Thus, one of Dr. Krishnasamy's concerns with Dr. Bates's medical practice was that anyone with normal thyroid hormone values will receive hormone treatment irrespective of test results. DVD II, 9:32 a.m.

167. In her testimony Dr. Krishnasamy addressed similar concerns regarding Dr. Bates's testosterone replacement therapy for both male and female patients.

168. Dr. Krishnasamy sees a significant number of patients with testosterone deficiencies as part of her VA hospital medical practice. DVD II, 9:35 a.m.

169. The physical examination is also "very important" for those patients since testicle size and breast enlargement may be important indicators of the cause of the condition, but Dr. Bates did not perform such exams. DVD II, 9:36-9:38 a.m.

170. In addition, most guidelines recommend that testosterone levels be tested in the morning since testosterone, like other hormones, pulse and is highest in the morning. DVD II, 9:38-9:39 a.m.

171. Dr. Krishnasamy testified that if the goal is to find a lower testosterone level for a patient, the testing sample should be drawn in the afternoon. DVD II, 9:39 a.m.

172. In addition, because the testosterone level fluctuates, the physician should repeat the test prior to initiating treatment if the first test showed a low hormone level, but Dr. Bates did not repeat the test for any of the patients at issue in this action. DVD II, 9:40 a.m.

173. If the physician confirms that the patient has low testosterone, the next step is to investigate why the deficiency exists, or otherwise, Dr. Krishnasamy stated the physician will be

treating the problem with “a Band-Aid.” DVD II, 9:41 a.m.

174. Low testosterone levels may be caused by testicular damage, tumor on the pituitary gland, opiate abuse, or steroid use. DVD II, 9:41 a.m.

175. Dr. Krishnasamy found, however, that Dr. Bates performed no assessment or evaluation to determine the cause for the low testosterone prior to initiating treatment. DVD II, 9:42 a.m.

176. Dr. Bates also initiated treatment based upon free testosterone rather than total testosterone levels, but free testosterone should be used only for patients whose total testosterone level is at the lower end of the threshold for normal. DVD II, 9:42 a.m.

177. Since the ratio of red blood cells to total blood volume rises with testosterone therapy, Dr. Bates recommended patients with high red blood cell counts donate blood, but the standard of care requires the physician first to decrease the testosterone supplement to determine whether that resolves the issue, which will save the patient money on the cost of the treatment. DVD II, 9:44-9:45 a.m.

178. Dr. Bates also prescribed testosterone to women, but Dr. Krishnasamy had concerns for prescribing high dosages, for prescribing testosterone to premenopausal women, and for treating side effects with a diuretic rather than cutting back on the testosterone dosage. DVD II, 9:48-9:50 a.m.

179. In their reports and testimony at the administrative hearing Dr. Krishnasamy, Dr. Ali, and Dr. Bates provided detailed reviews of the individual care and treatment provided for the fifteen patients.

180. In light of the fact that Dr. Krishnasamy and Dr. Ali objected to the very principles of hormone optimization that provide treatment of patients who have normal levels of TSH and testosterone, that reference T3 levels for treatment rather than TSH levels, and that increase thyroid and testosterone hormone levels to the upper range of normal and above, there is no need to review those experts' testimony related to each of the fifteen patients to illustrate the findings and conclusions in their report.

181. In addition, there is no need to review Dr. Bates's testimony and written responses to the consultants' reports in light of the fact there is no disagreement that she treated her patients consistent with the principles for hormone optimization that Dr. Krishnasamy and Dr. Ali found objectionable.

182. There is also no disagreement that Dr. Bates performed minimal physical examinations for most of the patients at issue in this action and that Dr. Krishnasamy and Dr. Ali found the examinations to be inadequate.

183. The hearing officer will, however, review the care and treatment of one patient to illustrate Dr. Krishnasamy's concerns.

184. Patient A was a forty-nine year old male who presented with an inability to lose weight, easy fatigue, insomnia, erectile dysfunction, and low libido. Exhibit 13, marked page 28.

185. Dr. Krishnasamy found Dr. Bates's diagnosis to be below minimum standards for several reasons, including the lack of a physical examination. Exhibit 13, marked page 29-30.

DVD II, 9:52 a.m.

186. The patient presented with low testosterone at 125 ng/dL, but that test was

performed in the afternoon and was not repeated in the morning. DVD II, 9:53-9:54 a.m.; Exhibit 13, marked page 30.

187. In response to Dr. Krishnasamy's criticism, Dr. Bates asserted that a requirement to repeat a test that is below the range established in the guidelines shows their bias against treating patients with hormones, but the hearing officer finds that the essence of Dr. Krishnasamy's criticism is her concern that patients will receive treatment that is not justified under the appropriate medical standards. DVD IV, 10:24-10:26 a.m.

188. Prior to initiating testosterone treatment for Patient A, Dr. Bates did not assess possible causes for the low testosterone, such as a structural problem, a pituitary tumor, radiation, or medications. DVD II, 9:54-9:57 a.m.

189. Dr. Bates's treatment with testosterone also fell below minimum standards because the testosterone dosage was not reduced when the patient's total testosterone level became elevated and when his hemoglobin levels increased with treatment. Instead, Dr. Bates simply had the patient donate blood to reduce the hematocrit level, continued with the testosterone treatment, and never had the hematocrit levels rechecked. DVD II, 10:00-10:03 a.m.; Exhibit 13, marked page 30; Exhibit 15, pages 6-8.

190. In addition, Dr. Bates's treatment fell below minimum standards when she initiated thyroid replacement therapy with a normal TSH of 2.74 uIU/mL and without conducting a physical examination. DVD II, 10:04 a.m.; Exhibit 13, marked page 31; Exhibit 15, page 3.

191. Dr. Krishnasamy also noted that Patient A had mild elevated calcium at his initial presentation, and therefore, treatment with thyroid hormone could increase his risk of bone loss over time. DVD II, 10:09 a.m.; Exhibit 13, marked page 31.

192. Despite treatment with Armour Thyroid, Patient A's TSH levels were not suppressed, which could suggest a problem with his pituitary gland, but that was not addressed by Dr. Bates as part of a patient diagnosis. DVD II, 10:06-10:09 a.m.; Exhibit 13, marked page 31.

193. While agreeing generally with the proposition that a physician should not blindly use clinical guidelines for the treatment of patients but must exercise some level of independent judgement, Dr. Krishnasamy also asserted in the context of Dr. Bates's medical practice that utilizing independent judgment does not mean a physician ignores the guidelines and gives the same medication to the majority of her patients. DVD II, 10:24-10:25 a.m. and 10:33-10:35 a.m.

194. Dr. Krishnasamy also dismissed Dr. Bates's assertion that as an endocrinologist she doesn't use Armour Thyroid, asserting that the medication is used in unique settings when the standard treatment for a patient with levothyroxine does not work for the patient. DVD II, 10:36-10:37 a.m.

195. In a repudiation to Dr. Bates's general approach to her treatment of patients with hormones and not conducting physical examinations, Dr. Krishnasamy stated that if the patient has symptoms of a hormone deficiency but the lab results are normal, the physician must explore other reasons for the symptoms. DVD II, 10:41 a.m.

196. In addition, Dr. Krishnasamy testified that simply because the patient feels better after receiving the hormone, that does not necessarily answer the question concerning what is causing the symptoms. DVD II, 10:42 a.m.

197. In response to Dr. Bates's assertion that she practices evidence based medicine and that there's no need to conduct a physical exam, Dr. Krishnasamy asked rhetorically at the

administrative hearing that when a patient comes in with fatigue, and the physician prescribes Armour Thyroid in response after conducting just one lab test, what is the logic and the principles behind that? DVD II, 10:54 a.m.

198. At the administrative hearing Dr. Ali was qualified as an expert in Internal Medicine. DVD I, 11:43 a.m. In his internal medicine practice Dr. Ali treats hypothyroid patients “every day” with hormone replacement medications. DVD I, 11:39 a.m.

199. He is familiar with Armour Thyroid and the standards of acceptable and prevailing medical practice in Kentucky for the thyroid gland and for prescribing hormones for the thyroid conditions. DVD I, 11:40 a.m.; Exhibit 4.

200. In his review of the fifteen of the medical charts, Dr. Ali found there was not a single abnormal TSH, T3, or T4 level prior to Dr. Bates initiating treatment with Armour Thyroid. DVD I, 11:49 a.m.

201. Dr. Ali’s reports were consistent in their approach and conclusions with Dr. Krishnasamy’s, but his review was more focused on Dr. Bates operating her medical practice as a weight loss clinic and on his assertion that Armour Thyroid was prescribed for weight loss. Exhibits 4 and 5.

202. One of Dr. Bates’s main objections to Dr. Ali’s report was her assertion that he did not understand her medical practice because he referred to it as a weight loss clinic. Exhibit 50E, marked page 22.

203. Therefore, the hearing officer will review some of the evidence related to the weight loss component of Dr. Bates’s medical practice that shows Dr. Ali was not completely inaccurate in his characterization of her practice and that she did prescribe Armour Thyroid for weight loss.

204. Although part of the care and treatment of her patients includes discussions of nutrition, diet, and weight loss goals, Dr. Bates asserted that she offers weight loss advice only as part of the overall goal of making the patients healthier and happier. DVD IIE, 9:33-9:34 a.m., 9:40 a.m.; Exhibit 50E, page 22.

205. She asserted that weight loss was not a large part of the medical practice, but six out of the fifteen patients whose charts were reviewed by the Board's consultants participated in the human Chorionic Gonadotropin (hCG) weight loss program. DVD I, 9:59 a.m.; DVD IV, 12:25 p.m.

206. During the first year of her practice at Body Shapes Medical, Dr. Bates did offer a "weight loss only" option as part of her hormone treatment program, but she ended that separate option in May 2015. DVD I, 9:56 a.m.; Exhibit 50E, pages 3-4.

207. Currently, patients are offered the additional weight loss program when they join the hormone optimization program, and Dr. Bates oversees both programs. DVD I, 9:57 a.m.

208. Dr. Bates explained that she wanted the patients to feel better through the hormone optimization and not just to lose weight. DVD I, 9:56 a.m.

209. As part of the weight loss program patients are placed on a high protein and low carbohydrate diet and are given the option of taking hCG or the more traditional weight loss medication, phentermine. DVD I, 9:55 a.m and 9:59 a.m.

210. Dr. Bates has found hCG to be more effective than phentermine for her patients' weight loss, and she asserted that she does not prescribe Armour Thyroid as part of the weight loss program. DVD I, 11:15 a.m.

211. Dr. Bates's assertion that she did not prescribe Armour Thyroid for weight loss is contradicted by the record.

212. On March 31, 2016, Dr. Ali, issued a report based upon a review of fifteen medical charts from Dr. Bates's practice. Exhibit 4.

213. He issued a second, supplemental report in reply to Dr. Bates' response to his initial report. Exhibit 5.

214. Based upon his review of the fifteen medical charts provided by the Board, Dr. Ali found that Dr. Bates violated the standards of acceptable and prevailing medical practice for each of the patients. DVD I, 11:47 a.m.; Exhibits 4 and 5.

215. Although Dr. Ali was asked to address the specific issue of the use of Armour Thyroid for weight loss, his report also challenged the very foundation of Dr. Bates's medical practice with his assertion that "if a physician takes upon him or herself to change [normal hormone levels] thinking that the level needs to be changed according to the age and the complaints of the patient, then it is completely wrong." Exhibit 4, marked page 22.

216. In her written response to Dr. Ali's report, Dr. Bates took issue with most of his findings and conclusions. Exhibit 50E, pages 21-30.

217. She specifically challenged Dr. Ali's level of expertise based upon his assertion that she was operating a weight loss clinic. Exhibit 4 and Exhibit 50E, page 22.

218. Dr. Ali acknowledged that he initially reviewed Dr. Bates' medical and prescription practices based upon the information received from the Board indicating she was operating a weight loss clinic. DVD I, 3:19-3:20 p.m.; Exhibit 4.

219. Dr. Ali asserted that part of his confusion as to the nature of Dr. Bates' medical practice was the fact that she was not managing the patients' hypertension, cholesterol, or diabetes as would be expected of someone operating a regular medical clinic. DVD I, 3:37 p.m.; Exhibit 5, page 2.

220. He testified at the administrative hearing, however, that because Dr. Bates did not operate solely as a weight loss clinic, he retracts his criticism that there were no consultations with dieticians or exercise plans from physical therapists. DVD I, 3:19-3:20 p.m.; Exhibit 4, marked page 22.

221. Dr. Ali did not retract, however, his original assertion that the medical records indicated that one of the main reasons Armour Thyroid was prescribed was for weight loss, but at the administrative hearing he acknowledged that was not the sole reason. DVD I, 3:20 p.m.

222. The patient records themselves show that Dr. Bates prescribed Armour Thyroid at least in part to help her patients lose weight.

223. One of the reasons Patient I began treatment with Dr. Bates in January 2014 was to lose weight. Exhibit 10, page 49-50.

224. On July 1, 2014, Dr. Bates increased Patient I's Armour Thyroid from 30 to 60 mg daily and wrote the following patient note, "I thyroid to optimize n hopefully will I metabolism I weight." Exhibit 10, page 6.

225. Thus, Dr. Bates's assertion that she did not write prescriptions for Armour Thyroid as part of the effort to help her patients lose weight is contradicted by her own notes, and Dr. Ali reasonably and correctly concluded that the medical records were consistent with the initial

information provided to him that Dr. Bates was prescribing the hormone for weight loss. DVD I, 3:37-3:38 p.m.

226. The established guidelines state that Armour Thyroid should not be prescribed for weight loss, and Dr. Bates violated them in her prescription practices for that medication. DVD I, 1:38-1:41 p.m.

227. Dr. Bates also challenged Dr. Ali's expertise based upon his assertion that Armour Thyroid was prescribed "to make the thyroid work harder." Exhibit 4, marked page 22.

228. He acknowledged that was a poor choice of words since the thyroid wasn't working harder but was in a hyperthyroid state as a result of the Armour Thyroid medication. DVD I, 3:36 p.m.

229. Although Dr. Ali's use of a colloquial expression rather than medical terminology could be misleading, the hearing officer did not find Dr. Ali's use of that term detracted from his overall expertise and understanding of thyroid hormones, their effect on the body, and the appropriate treatment for any deficiency.

CONCLUSIONS OF LAW

1. The Board has jurisdiction over this action pursuant to KRS 311.591 and KRS 311.595.

2. The administrative hearing was conducted in accordance with the provisions of KRS Chapter 13B and KRS 311.591.

3. Under KRS 13B.090(7), the Board had the burden to prove by a preponderance of the evidence the allegations against Dr. Bates.

4. The Board has met its burden to prove Dr. Bates has violated KRS 311.595(9), as illustrated by KRS 311.597(3) and (4).

5. Pursuant to KRS 311.595(9), as illustrated by KRS 311.597(3), a physician is subject to discipline if she has “engaged in dishonorable, unethical, or unprofessional conduct of a character likely to deceive, defraud, or harm the public or any member thereof” by engaging in “a serious act, or a pattern of acts committed during the course of his medical practice which, under the attendant circumstances, would be deemed to be gross incompetence, gross ignorance, gross negligence, or malpractice.”

6. The preponderance of the evidence supports the conclusion that Dr. Bates engaged in conduct that constituted gross ignorance in violation of KRS 311.595(9), as illustrated by KRS 311.597(3), by prescribing high doses of testosterone to Patient 1.

7. Pursuant to KRS 311.595(9), as illustrated by KRS 311.597(4), a physician is subject to discipline if she has “engaged in dishonorable, unethical, or unprofessional conduct of a character likely to deceive, defraud, or harm the public or any member thereof” by engaging in “conduct which is calculated or has the effect of bringing the medical profession into disrepute, including but not limited to any departure from, or failure to conform to the standards of acceptable and prevailing medical practice within the Commonwealth of Kentucky”

8. The preponderance of the evidence supports the conclusion that Dr. Bates violated KRS 311.595(9), as illustrated by KRS 311.597(4), and the standards of acceptable and prevailing medical practice in her hormone optimization practice by failing to perform adequate and appropriate physical examinations of patients prior to prescribing thyroid or testosterone hormones, by initiating treatment for patients with TSH and testosterone levels within the normal

range and without appropriate justification for treatment, by treating all patients with thyroid hormones by reference to T3 levels instead of TSH levels, and by initiating treatment with Armour Thyroid instead of levothyroxine since none of the patients had exceptional circumstances that required treatment with a different medication. She also violated those statutes by prescribing Armour Thyroid for weight loss and by having the patients donate blood, instead of reducing their testosterone prescriptions, when their red blood cell levels increased as a result their testosterone treatment.

RECOMMENDED ORDER

Based upon the foregoing findings of fact and conclusions of law, the hearing officer recommends the Board find Dr. Bates in violation of KRS 311.595(9), as illustrated by KRS 311.597(3) and (4), and impose any appropriate sanctions for those violations.

NOTICE OF EXCEPTION AND APPEAL RIGHTS

Pursuant to KRS 13B.110(4) a party has the right to file exceptions to this recommended decision:

A copy of the hearing officer's recommended order shall also be sent to each party in the hearing and each party shall have fifteen (15) days from the date the recommended order is mailed within which to file exceptions to the recommendations with the agency head.

A party also has a right to appeal the Final Order of the agency pursuant to KRS 13B.140(1) which states:

All final orders of an agency shall be subject to judicial review in accordance with the provisions of this chapter. A party shall institute an appeal by filing a petition in the Circuit Court of venue, as provided in the agency's enabling statutes, within thirty (30) days after the final order of the agency is mailed or delivered by

personal service. If venue for appeal is not stated in the enabling statutes, a party may appeal to Franklin Circuit Court or the Circuit Court of the county in which the appealing party resides or operates a place of business. Copies of the petition shall be served by the petitioner upon the agency and all parties of record. The petition shall include the names and addresses of all parties to the proceeding and the agency involved, and a statement of the grounds on which the review is requested. The petition shall be accompanied by a copy of the final order.

Pursuant to KRS 23A.010(4), "Such review [by the circuit court] shall not constitute an appeal but an original action." Some courts have interpreted this language to mean that summons must be served upon filing an appeal in circuit court.

SO RECOMMENDED this 11th day of April, 2018.



THOMAS J. HELLMANN
HEARING OFFICER
810 HICKMAN HILL RD
FRANKFORT KY 40601
(502) 330-7338
thellmann@mac.com

CERTIFICATE OF SERVICE

I hereby certify that the original of this RECOMMENDATION was mailed this 11th day of April, 2018, by first-class mail, postage prepaid, to:

JILL LUN
KY BOARD OF MEDICAL LICENSURE
HURSTBOURNE OFFICE PARK STE 1B
310 WHITTINGTON PKWY
LOUISVILLE KY 40222

for filing; and a true copy was sent first-class mail, postage prepaid, to:

SARA FARMER
ASSISTANT GENERAL COUNSEL
KY BOARD OF MEDICAL LICENSURE
HURSTBOURNE OFFICE PARK STE 1B
310 WHITTINGTON PKWY
LOUISVILLE KY 40222

JENNIFER L WINTERGERST
CAROLE D CHRISTIAN
WYATT TARRANT & COMBS LLP
500 WEST JEFFERSON ST SUITE 2800
LOUISVILLE KY 40202-2898


THOMAS J. HELLMANN

1810FC2

Commonwealth of Kentucky
Court of Appeals

NO. 2017-CA-001860-I

KENTUCKY BOARD
OF MEDICAL LICENSURE

MOVANT

v.

MOTION FOR INTERLOCUTORY RELIEF
PURSUANT TO CR 65.07
ACTION NO. 17-CI-004991

RECEIVED
MAY 14 2018
K.B.M.L.

ELIZABETH BATES, M.D.

RESPONDENT

ORDER
GRANTING MOTION FOR INTERLOCUTORY RELIEF

** ** *

BEFORE: KRAMER, CHIEF JUDGE; JOHNSON AND MAZE, JUDGES.

Movant, Kentucky Board of Medical Licensure, filed a motion for interlocutory relief pursuant to Kentucky Rules of Civil Procedure (CR) 65.07 from an order granting a stay pending judicial review. Having considered the

motion for interlocutory relief, the response, and being otherwise sufficiently advised, the Court ORDERS that the motion be, and it is hereby, GRANTED.

As a preliminary matter, Respondent, Elizabeth Bates, M.D., filed a motion for additional time to file a response to the motion for interlocutory relief. Having considered the motion for additional time and being otherwise sufficiently advised, the Court ORDERS that the motion be, and it is hereby, GRANTED. The tendered response is ORDERED FILED as of the date of entry of this order.

On August 10, 2017, the Board issued a formal complaint and an emergency order restricting Dr. Bates from practicing medicine in the context of hormone replacement therapy pending the resolution of the complaint. On September 11, 2017, a hearing officer issued a final order affirming the emergency order of restriction. The hearing officer concluded that Dr. Bates had failed to conform to the standards of acceptable and prevailing medical practice in Kentucky through her use of hormone therapy. Pursuant to Kentucky Revised Statutes (KRS) 13B.125(4), Dr. Bates filed a petition for judicial review of the emergency order in Jefferson Circuit Court. On November 3, 2017, the trial court entered an order staying the enforcement of the emergency order. This motion for interlocutory relief followed.

KRS 13B.125(4) provides that an aggrieved party may take an appeal from an administrative emergency order in the same manner provided by KRS

13B.140. KRS 13B.140(4)(c) authorizes a circuit court to stay a final administrative order pending judicial review. A temporary stay pending judicial review is equivalent to a temporary injunction and may be properly reviewed under CR 65.07. *Norsworthy v. Kentucky Board of Medical Licensure*, 330 S.W.3d 58, 61-62 (Ky. 2009).

The standard governing the issuance of a temporary injunction is well established. In *Maupin v. Stansbury*, 575 S.W.2d 695, 699 (Ky. App. 1978), this Court stated:

First, the trial court should determine whether plaintiff has complied with CR 65.04 by showing irreparable injury. This is a mandatory prerequisite to the issuance of any injunction. Secondly, the trial court should weigh the various equities involved. Although not an exclusive list, the court should consider such things as possible detriment to the public interest, harm to the defendant, and whether the injunction will merely preserve the status quo. Finally, the complaint should be evaluated to see whether a substantial question has been presented. If the party requesting relief has shown a probability of irreparable injury, presented a substantial question as to the merits, and the equities are in favor of issuance, the temporary injunction should be awarded. However, the actual overall merits of the case are not to be addressed in CR 65.04 motions. Unless a trial court has abused its discretion in applying the above standards, we will not set aside its decision on a CR 65.07 review.

The Board first argues that the trial court erred by concluding that Dr. Bates had established irreparable injury resulting from the emergency order of restriction. In support of its finding of irreparable injury, the trial court stated:

However, this is not the ordinary case. Dr. Bates has worked diligently over a considerable period of time building her practice in a unique area of medicine—the area of hormone optimization therapy. She has spent essentially her entire professional career developing her expertise in this newly emerging field of medicine. Due to the unique nature of her practice, a prolonged suspension of her ability to practice in this area would effectively render her unable to work, would result in her clients being forced to seek new providers, and would go beyond simply creating an economic hardship but would in fact destroy the practice that she has developed.

The trial court did not conduct an evidentiary hearing and apparently relied upon the written record. In contrast to the trial court’s finding that Dr. Bates “has spent essentially her entire professional career developing her expertise” in hormone optimization therapy, Dr. Bates herself stated that she began focusing on hormone optimization therapy in 2014 after thirteen years practicing internal medicine. The hearing officer found that “[t]here is no recognized medical specialty or residency program available for hormone optimization.” Dr. Bates further testified before the hearing officer that she does not practice the recognized medical specialty of endocrinology and that her expertise in hormone optimization therapy was the result of self-study.

The emergency order restricted Dr. Bates from practicing in the context of hormone replacement therapy. Because there is no recognized specialty of hormone optimization therapy, the trial court’s finding that the order of restriction would “effectively render her unable to work...” is speculative and not

supported by substantial evidence of record. Further, the finding that the temporary restriction would completely destroy Dr. Bates's practice is also speculative.

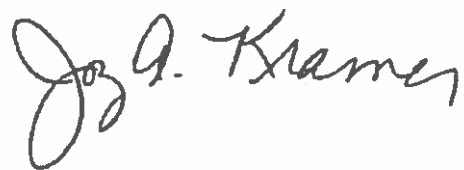
While the lack of irreparable injury itself supports the dissolution of the temporary injunction, this Court will examine the trial court's weighing of the equities. In weighing the equities, the trial court stated:

This Court finds it illogical that the KBML found in their order of restriction that Dr. Bates 'engaged in conduct in violation of KRS 311.595 {which} constituted an immediate danger to the public health, safety, and welfare" yet determined that she could continue practicing medicine outside of the field of Hormone Replacement Therapy. Simply put, they cannot have it both ways--- either allowing her to practice medicine creates an immediate danger to the public or it does not. This Court is well aware that it is not to substitute its judgment of the facts for the judgment of the KBLM's hearing officer however it can take notice that the Board did not feel that Dr. Bates's conduct was egregious enough to warrant a full suspension of her practicing privileges. If in fact she does pose a danger to the public health, a full suspension would have been ordered.

In finding that the Board could not establish an immediate danger to the public in the absence of a complete suspension under any circumstances, the trial court has essentially ruled upon the merits of the petition for review. KRS 311.595 specifically authorizes the Board to suspend, limit, restrict, or revoke a medical license. The trial court has further altered the status quo by the issuance of the temporary injunction. Such a determination on the merits exceeds the scope and

purpose of a temporary injunction, which is simply to prevent irreparable injury pending final judgment on the merits. *See Kentucky Board of Medical Licensure v. Chaney*, ---S.W.3d. --- 2014 WL 5488174 at *2 (2014-CA-001338-I)(Ky. App. 2014).

Accordingly, the Court ORDERS that the motion for interlocutory relief is hereby GRANTED. The temporary injunction issued on November 3, 2017, is hereby DISSOLVED.



ENTERED: 05/11/18

CHIEF JUDGE, COURT OF APPEALS

CASE NO. 17-CI-4991

JEFFERSON CIRCUIT COURT
DIVISION ELEVEN (11)
JUDGE BRIAN C. EDWARDS

ELIZABETH BATES, M.D.

RECEIVED

NOV 06 2017

PLAINTIFF

v.

K.B.M.L.
OPINION AND ORDER
GRANTING MOTION FOR STAY

KENTUCKY BOARD OF MEDICAL LICENSURE

DEFENDANTS

This matter comes before the Court on Plaintiff Elizabeth Bates' ("Dr. Bates") Motion to Stay Emergency Order of Restriction or in the alternative for a Temporary Injunction. The Kentucky Board of Medical Licensure ("KBML") has responded and objected to the Motion, Bates has filed a written reply brief, and oral argument has been presented to the court. Having carefully reviewed the pleadings and relevant case and statutory law as well as having given due consideration to the proffered oral arguments, the Court will at this time GRANT Dr. Bates' Motion.

SUMMARY OF FACTS

Dr. Bates is an internal medical physician licensed to practice in the Commonwealth of Kentucky. Her most recent employment was as the Medical Director of Body Shapes Medical where she focused on "optimizing patient's' hormone levels to promote general health and well being." On August 13, 2015, an anonymous pharmacist filed a written grievance with the KBML alleging that Dr. Bates was running a weight loss clinic and that she was improperly prescribing the drug Armour Thyroid. Dr. Bates subsequently filed a written response to the grievance.

At the behest of the KBML, the grievance along with the response was reviewed by Dr.

Ahsen Ali. On March 31, 2016, Dr. Ali issued a report which was critical of Dr. Bates' conduct. Dr. Bates then submitted a written response to Dr. Ali's report which was followed by a supplemental report being issued by Dr. Ali.

The KMBL then retained the services of a second physician to review the merits of the grievance against Dr. Bates. Dr. Sathya Krishnasamy, an endocrinologist, issued her findings in a March 16, 2017 report and this report expressed concerns over Dr. Bates practice of prescribing Armour Thyroid and testosterone. However, Dr. Krishnasamy did not believe that these concerns necessitated a suspension of Dr. Bates' license.

On July 18, 2017, the KMBL's inquiry panel then reviewed all of the aforementioned reports and responses and conducted a hearing to address the issues raised in the original grievance. On August 10, 2017, the KMBL issued a formal Complaint against Dr. Bates along with an Emergency Order of Restriction precluding her from practicing medicine in the context of hormone therapy pending a resolution of the Complaint.

On August 31, 2017, an emergency hearing addressing the Emergency Order of Restriction was convened. The Board took notice of the aforementioned consultants reports and took testimony from Dr. Bates at this hearing. On September 11, 2017, the Hearing Officer issued a Final Order Affirming the Emergency Order of Restriction finding that Dr. Bates "engaged in conduct in violation of KRS 311.595 {which} constituted an immediate danger to the public health, safety, or welfare." Dr. Bates subsequently initiated the action that is before this Court in order to obtain relief from that Order. Specifically, pursuant to KRS 13B.140(4)(c), Dr. Bates seeks a Stay of the Emergency Order of Restriction.

KRS 13B.140 does not expressly articulate what must be shown in order to authorize the granting of a Stay. However, in that a Stay would have the same practical impact as the granting

of injunctive relief, this Court will base its decision upon the standards necessary for the granting of injunctive relief.

Kentucky Courts have long held that Injunctions are considered an extraordinary remedy by the courts and will only be granted by clear showing of the right to the injunction and a necessity for it. *Victory Cab Co. v. Churchill Downs*, 227 S.W.2d 924, 925 (Ky. 1950). In order to obtain injunctive relief, the moving party must demonstrate “(1) that the movant's position presents “a substantial question” on the underlying merits of the case, i.e. that there is a substantial possibility that the movant will ultimately prevail; (2) that the movant will be irreparably impaired absent the extraordinary relief; and (3) that an injunction will not be inequitable, i.e. will not unduly harm other parties or disserve the public.” *Price v. Paintsville Tourism Commn.*, 261 S.W.3d 482, 484 (Ky. 2008), *Maupin v. Stansbury*, 575 S.W. 2d 695 (Ky. App. 1978)

The first prong of the *Maupin* test that the Court must consider in determining whether injunctive relief is appropriate is to determine whether Dr. Bates has shown that she will “suffer irreparable harm if the injunction is not granted.” Kentucky Courts have previously held that injuries resulting from a loss of employment are not irreparable in nature and “in the ordinary case, ... loss of income or damage to reputation is inadequate.” *Gharad v. St. Claire Med. Ctr., Inc.*, 443 S.W.3d 609, 611 (Ky. 2014) (citation omitted). However, this is not the ordinary case. Dr. Bates has worked diligently over a considerable period of time building her practice in a unique area of medicine --the area of hormone optimization therapy. She has spent essentially her entire professional career developing her expertise in this newly emerging field of medicine. Due to the unique nature of her practice, a prolonged suspension of her ability to practice in this area would effectively render her unable to work, would result in her clients being forced to seek

new providers, and would go beyond simply creating an economic hardship but would in fact destroy the practice that she has developed. Accordingly, the Court finds that Dr. Bates has demonstrated that she may suffer irreparable harm if the injunction is not granted.

Dr. Bates must next establish that the granting of the requested extraordinary injunctive relief she is seeking would not be inequitable and would not harm the public interest. This Court finds it illogical that the KBML found in their Order of restriction that Dr. Bates "engaged in conduct in violation of KRS 311.595 {which} constituted an immediate danger to the public health, safety, or welfare" yet determined that she could continue practicing medicine outside of the field of Hormone Replacement Therapy. Simply put, they cannot have it both ways --- either allowing her to practice medicine creates an immediate danger to public health or it does not. This Court is well aware that it is not to substitute its judgment of the facts for the judgment of the KBML's hearing officer however it can take notice that the Board did not feel that Dr. Bates's conduct was egregious enough to warrant a full suspension of her practicing privileges. If in fact she does pose a danger to the public health, a full suspension would have been ordered. The administrative record in this matter reflects that Dr. Bates was well regarded in her field of practice and that she demonstrated more than reasonable competence. Accordingly, this Court must conclude that she has adequately demonstrated that the granting of the requested injunctive relief would not be harmful to the public interest.

Finally, in order to grant the requested injunctive relief, this Court must conclude that Dr. Bates position presents "a substantial question" on the underlying merits of the case, i.e. that there is a substantial possibility that she will ultimately prevail. Review of the procedures employed during the administrative hearings, the concerns raised regarding the quantity of evidence relied upon by the KBML, and the concerns raised regarding the due process afforded

to Dr. Bates, the Court finds that there is a substantial possibility that she may ultimately prevail in this matter.

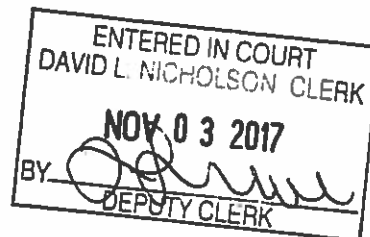
Accordingly, this Court finds that Dr. Bates has adequately satisfied the criteria for the granting of a stay of the KBML's September 11, 2017 Emergency Order of Restriction.

ORDER

WHEREFORE IT IS HEREBY ORDERED AND ADJUDGED that the Plaintiff's motion for a Stay of the KBML's September 11, 2017 Emergency Order of Restriction is **GRANTED.**

cc: all attorneys of record


BRIAN C. EDWARDS, JUDGE
JEFFERSON CIRCUIT COURT



COMMONWEALTH OF KENTUCKY
BOARD OF MEDICAL LICENSURE
CASE NO. 1810

FILED OF RECORD

AUG 10 2017

K.B.M.L.

IN RE: THE LICENSE TO PRACTICE MEDICINE IN THE COMMONWEALTH OF KENTUCKY HELD BY ELIZABETH VEENEMAN BATES, M.D., LICENSE NO. 36808, 4211 SPRINGHURST BOULEVARD, SUITE 101, LOUISVILLE, KENTUCKY 40241

COMPLAINT

Comes now the Complainant Russell L. Travis, M.D., Chair of the Kentucky Board of Medical Licensure's Inquiry Panel B, and on behalf of the Panel which met on July 20, 2017, states for its Complaint against the licensee, ELIZABETH VEENEMAN BATES, M.D., as follows:

1. At all relevant times, Elizabeth Veeneman Bates, M.D., was licensed by the Board to practice medicine within the Commonwealth of Kentucky.
2. The licensee's medical specialty is Internal Medicine.
3. The Board opened an investigation pursuant to an anonymous grievance received on or about August 3, 2015. The grievant stated that s/he was a concerned pharmacist who had seen a "slew of prescriptions called in from Body Shapes Medical for Armour Thyroid 60mg (always for the same strength.)" The grievant was concerned that Body Shapes Medical was using the medication to hyperstimulate the thyroid to promote weight loss in patients with normal thyroid activity.
4. The Board obtained fifteen (15) patient charts randomly selected from a list of patients seen by the licensee and prescribed Armour Thyroid 60mg between July 1, 2015 and July 31, 2015.

5. The licensee responded to the grievance, through her attorney, on or about October 28, 2015. The licensee stated that she practiced internal medicine for twelve and a half years before becoming the Medical Director of Body Shapes Medical in March 2013. The licensee described her practice and explained the use of Armour Thyroid in her practice.
6. A Board consultant who is Board-certified in Internal Medicine reviewed fifteen (15) of the licensee's patient charts and found that the licensee departed from or failed to conform to acceptable and prevailing medical practices in the following manner:

As is evident by the table that all the patients when initially seen had normal thyroid function tests. Patients were then given Armour thyroid, in 2/3 of cases started at a dose of Armor 60mg and 1/3 of cases were given Armor 30mg. The main reason of giving a euthyroid patient, thyroid medication is not to optimize his or her thyroid function, but only to increase the metabolism so as to make the patient lose weight. With the thyroid meds, then other meds were given to increase different functions such as libido, and energy.

...

Armor thyroid was increased gradually until it was seen that TSH was decreased and T4/T3 has increased. This was to make sure that patient was hyperthyroid and has an increased metabolism.

I did not see any consultations by the dietitians, or the exercise plans by any physical therapists. Sole reason was to make the thyroid work harder and patient to lose weight without doing any exercise or diet.

The Board consultant's report is attached and incorporated in its entirety.

7. A second Board consultant, who specializes in Endocrinology, reviewed the licensee's patient charts and found that the licensee departed from or failed to conform to acceptable and prevailing medical practices in regard to diagnoses in seven (7) charts, in regard to treatment in eleven (11) charts, overall in five (5) charts and was overall Borderline in nine (9) charts.

8. The Board consultant found concerns with thyroid hormone replacement and testosterone use in both males and females. The Board consultant's report is attached and incorporated in its entirety.
9. On or about May 10, 2016, the licensee responded in writing, through counsel, to the first Board consultant's review of her patient charts. In her response, the licensee responded to the Board consultant's concerns in detail.
10. On or about May 1, 2017, the licensee responded in writing, through counsel, to the second Board consultant's review of her patient charts. In her response, the licensee responded to the Board consultant's concerns in detail.
11. On or about July 21, 2016, the first Board consultant issued a final report after reviewing the licensee's response. The Board consultant refuted the arguments made by the licensee, and the Board consultant's opinion of the medical care of the cases he evaluated did not change.
12. On or about June 8, 2017, the second Board consultant issued a final report after reviewing the licensee's response. The second Board consultant refuted the arguments made by the licensee, and the Board consultant's opinion of the medical care of the cases she evaluated did not change.
13. On or about July 20, 2017, the Board's Inquiry Panel B determined that the licensee's practices placed her patients and the public at risk and in danger. As a result, the licensee was restricted from practicing medicine in the context of hormone replacement therapy, pending resolution of this Complaint.
14. By her conduct, the licensee has violated the provisions of KRS 311.595(9), as illustrated by KRS 311.597(3), and KRS 311.597(4).

15. Accordingly, legal grounds exist for disciplinary action against her Kentucky medical license.

16. The licensee is directed to respond to the allegations delineated in the Complaint within thirty (30) days of service thereof and is further given notice that:

(a) Her failure to respond may be taken as an admission of the charges;

(b) She may appear alone or with counsel, may cross-examine all prosecution witnesses and offer evidence in her defense.

17. NOTICE IS HEREBY GIVEN that a hearing on this Complaint is scheduled for January 8-11, 2018 at 9:00 a.m., Eastern Standard Time, at the Kentucky Board of Medical Licensure, Hurstbourne Office Park, 310 Whittington Parkway, Suite 1B, Louisville, Kentucky 40222. Said hearing shall be held pursuant to the Rules and Regulations of the Kentucky Board of Medical Licensure and pursuant to KRS Chapter 13B. This hearing shall proceed as scheduled and the hearing date shall only be modified by leave of the Hearing Officer upon a showing of good cause.

WHEREFORE, Complainant prays that appropriate disciplinary action be taken against the license to practice medicine held by ELIZABETH VEENEMAN BATES, M.D.


This 10th day of August, 2017.



RUSSELL L. TRAVIS, M.D.
CHAIR, INQUIRY PANEL B

CERTIFICATE OF SERVICE

I certify that the original of this Complaint was delivered to Mr. Michael S. Rodman, Executive Director, Kentucky Board of Medical Licensure, 310 Whittington Parkway, Suite 1B, Louisville, Kentucky 40222; a copy was mailed to Thomas J. Hellmann, Esq., Hearing Officer, 810 Hickman Hill Road, Frankfort, Kentucky 40601; and copies were mailed via certified-mail to the licensee, Elizabeth Veeneman Bates, M.D., License No. 36808, 4211 Springhurst Boulevard, Suite 101, Louisville, Kentucky 40241, and to her counsel, Jennifer Wintergerst, Esq., Wyatt, Tarrant & Combs, 500 West Jefferson Street, Suite 2800, Louisville, Kentucky 40202 on this 10th day of August, 2017.

A handwritten signature in dark ink, appearing to read "Sara Farmer", is written over a horizontal line.

Sara Farmer
Assistant General Counsel
Kentucky Board of Medical Licensure
310 Whittington Parkway, Suite 1B
Louisville, Kentucky 40222
Tel. (502) 429-7150



The Clinic
AHSEN ALI, MD, FACP

DIPLOMATE BOARD OF INTERNAL MEDICINE

March 31ST, 2016

Mr. John W. Lewis
Medical Investigator
Kentucky Board of Medical Licensure

RE: Elizabeth Bates, MD
KBML Case # 13384

Dear Mr. John Lewis:

I have been asked by the Kentucky Board of Medical Licensure to serve as a consultant in an ongoing investigation involving Dr. Elizabeth Bates. I had to review a series of charts so as to give an opinion. During this process, I reviewed the grievance report by a pharmacist, response by Dr. Bates, and medical records of many patients treated by Dr. Bates at Body shapes Medical.

Six Nurse practitioners are working under Dr. Bates, in five different clinics. Most of the cases seen at these clinics by all the medical professionals are for the purpose to improve the general health and to help the patients lose weight.

Initial grievance of 11/11/2013 by a pharmacist stated that:

- 1) Only Armour thyroid 60mg was always called in.
- 2) Never a "typical" weight loss drug was called in, and
- 3) Concern was that the medication was used to hyper stimulate the normal thyroid gland to promote weight loss

Dr. Elizabeth Bates responded to the initial grievance two years later on October 28th, 2015 by stating that:

- 1) "I only start Armour in patients that have low thyroid activity with non-optimized free T3 level"
- 2) "Armour 60mg is a common starting dose"
- 3) "I do increase the dosage to 90mg or even 120mg daily as dictated by blood levels"
- 4) "We regularly ask the patients about hyper stimulation symptoms".
- 5) "In May 2015, I revamped our offered programs and removed the weight loss only option"

Before I give my opinion, I would like to go through the physiology of the Thyroid.

The endocrine system is the body's communication hub, controlling cell, and therefore organ, function. The thyroid is the largest exclusively endocrine gland in the body.

The hormones secreted by the thyroid gland are essential in this process, targeting almost every cell in the body (only the adult brain, spleen, testes, and uterus are immune to their effects.) Inside cells, thyroid hormone stimulates enzymes involved with glucose oxidation, thereby controlling cellular temperature and metabolism of proteins, carbohydrates, and lipids. Through these actions, the thyroid regulates the body's metabolic rate and heat production.

160 Hospital Drive
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(606) 237-4800
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In its behavior, TH functions somewhat similarly to steroid hormones.

The two major thyroid hormones are unique in that, unlike most hormones, they are neither protein nor cholesterol based. Instead, they incorporate iodine as an active constituent; the amount of iodine differentiates between thyroxine (also known as tetraiodothyronine or T₄) with four iodine molecules and triiodothyronine (T₃) with, predictably, three iodine molecules. While T₄ exists in greater abundance than T₃ in the body- thought to be at a fifty to one ratio, T₃ is considered to be ten times more active. There is much debate about the physiological difference between the two hormones. It is currently thought that T₄ may act as the reserve form, having a more direct role in the hypothalamus/pituitary negative feedback loop, while T₃ has a more dynamic physiological effect in the body. Others suggest that both have a critical part in physiological activity.

Symptoms of Hyperthyroidism:

The symptoms of hyperthyroidism include the following:

- Fatigue or muscle weakness
- Hand tremors
- Mood swings
- Nervousness or anxiety
- Rapid heartbeat, Heart palpitations, Atrial fibrillation
- Shortness of breath, particularly during exercise
- Skin dryness
- Insomnia
- Diarrhea
- Light menstrual periods or skipping menstrual periods
- Hair loss
- Excessive sweating
- Weight loss despite an increase in appetite. A few patients will gain weight.
- Vision problems with red irritated eyes, double vision.

Diet can effect thyroid function, as a high calorie/high carbohydrate diet can lead to increased conversion of T₄ to T₃- a mechanism that likely assists in keeping an organism's weight stable. Meanwhile, prolonged fasting can result in a decrease in T₃ production - which may be adaptive for conditions of food scarcity, slowing down the body's metabolism and energy consumption.

The majority of dietary thyroid supplements contained clinically significant amounts of T₃ and T₄. This could potentially expose patients to the risk of altering thyroid-function tests and could even cause thyrotoxicosis.

It has been appreciated for a very long time that there is a complex relationship between thyroid disease, body weight and metabolism. Low thyroid hormone levels were associated with low BMRs and high thyroid hormone levels were associated with high BMRs (Basal Metabolic rate).

The relationship between metabolic rates, energy balance, and weight changes is very complex. There are many other hormones (besides thyroid hormone), proteins, and other chemicals that are

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The Clinic
AHSEN ALI, MD, FACP

DIPLOMATE BOARD OF INTERNAL MEDICINE

very important for controlling energy expenditure, food intake, and body weight. Because all these substances interact on both the brain centers that regulate energy expenditure and tissues throughout the body that control energy expenditure and energy intake, no one can predict the effect of altering only one of these factors (such as thyroid hormone) on body weight as a whole.

Since the BMR in patients with hyperthyroidism is elevated, many patients with an overactive thyroid do, indeed, experience some weight loss. Furthermore, the likelihood of weight loss occurring is related to the severity of the overactive thyroid. Thus, if the thyroid is extremely overactive, the individual's BMR increases which leads to increased caloric requirements to maintain that weight. If the person does not increase the calories consumed to match the excess calories burned, then weight loss will ensue. As I said earlier, the factors that control our appetite, metabolism, and activity are very complex and thyroid hormone is only one factor in this complex system.

Nevertheless, on average the more severe the hyperthyroidism, the greater the weight loss observed. Since hyperthyroidism also increases appetite, some patients may not lose weight, and some may actually gain weight, depending on how much they increase their caloric intake.

On the average, any weight lost during the hyperthyroid state is regained when the hyperthyroidism is treated. One consequence of this observation is that the use of thyroid hormone to treat obesity is not very useful. Once thyroid hormone treatment is stopped, any weight that is lost while on treatment will be regained after treatment is discontinued.

Going back to our case, I was sent 15 charts of different patients to review. Patients were seen for Thyroid treatment for weight loss as well as for Testosterone, Estradiol, Vitamin D, and other treatments. .

I have made a table of all the 15 patient charts. Starting from the initial visit when patient came to the clinic, initial labs, then which meds were started, labs after the initial treatment, meds adjustment and then the response seen in the labs.

N= Normal

TSH= Thyroid stimulating hormone

T4= Tetraiodothyronine

T3= Triiodothyronine

A30= Armour 30 mg

A45= Armour 45 mg

A 60= Armour 60 mg

A 90= Armour 90 mg

D= Decreased

I= Increased

CAR.= Cardiologist of the patient refused to allow the patient to get any Thyroid Hormone treatment

Hyperthyroidism= Decreased TSH and Increased T4/T3

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The Clinic
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DIPLOMATE BOARD OF INTERNAL MEDICINE

Now, lets look at some charts of the patients:

<u>Name</u>	<u>TSH</u>	<u>T4/T3</u>	<u>Meds</u>	<u>TSH</u>	<u>T4/T3</u>	<u>Meds</u>	<u>TSH</u>	<u>T4/T3</u>	<u>Meds</u>
SB	N	N	A 60	N	D	A 90	D	I	A 60
VW	N	N	A 60	D	I	A 30		N	A 45
KL	N	N	A 60	D	N	A 60			
SG	N	N	A 60	CA R.					
JA	N	N	A 60	D	N	A 60		I	A 60
JD	N	N	A 60	D	I	A 60		N	
LF	N	N	A 30	N	N	A 60	D	N	A 90
BB	N	N	A 30	DC	N	A 30		I	A 60
LC	N	N	A 60	D	I	A 60		I	A 60
MJ	N	N	A 30	N	N	A 60	N	N	A 30
KM	N	N	A 60	N	N	A 60		N	
CP		N	A 30	N	N	A 60		I	A 60
HS	N	N	A 30	N	N	A 60	N	I	A 60
WD	N	N	A 60	D	N	A 90	D	I	A 60
SH	N	N	A 60	D	I	A 60		N	

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Patients had symptoms of being moody, anxious, irritability, constipation, headache, and insomnia. Some patient did lose weight while on Armour. Primary care physician of one patient did not like the decreased TSH. Cardiologist of one patient refused to allow the patient to get this treatment.

Conclusion:

Dr. Elizabeth Bates runs a boutique clinic by the name of Body shapes Medical. The patient is initially seen and asked a battery of questions, and then according to the patient preference of what concerns him more, gets treated.

As is evident by the table that all the patients when initially seen had normal thyroid function tests. Patients were then given Armour thyroid, in 2/3rd of cases started at a dose of Armour 60mg and 1/3rd of cases were given Armour 30mg. The main reason of giving a euthyroid patient, thyroid medication is not to optimize his or her thyroid function, but only to increase the metabolism so as to make the patient lose weight. With the thyroid meds, then other meds were given to increase different functions such as libido, and energy.

In my view, it is extremely unethical to increase the thyroid functions, knowing all the side effects of hyperthyroidism, for the sole reason to make the patient lose weight. There are a lot of other ways to make the patient lose weight without jeopardizing his general health. FDA has approved multiple medications for the sole purpose of weight loss.

Armour thyroid was increased gradually until it was seen that TSH was decreased and T4/T3 has increased. This was to make sure that patient was hyperthyroid and has an increased metabolism.

I did not see any consultations by the dietitians, or the exercise plans by any physical therapists. Sole reason was to make the thyroid work harder and patient to lose weight without doing any exercise or diet.

I, as a board certified Internal Medicine physician would not like any of my patients to go through this program and I do not think that I saw any physicians consulting Dr. Bates for this. It is documented in different charts, when patient's primary care physicians did not like the change in thyroid functions.

The normal levels of any tests are made with a lot of research and expertise, considering all the standard deviations. Now, if a physician takes upon him or herself to change them thinking that the level needs to be changed according to the age and the complaints of the patient, then it is completely wrong.

Patients to lose weight should have been given a diet and exercise plan, and then if some patients need medications, they can be prescribed under the supervision of a physician. That is the reason while obesity is an epidemic in America; these medications are given by the physicians and are not made OTC meds. Even these medications approved by FDA have side effects, which need to be followed by a physician. How can we make a normal person, do something wrong to get a right result?

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In my opinion, the business of making a human being lose weight by making his thyroid functions to work at a higher level by putting his body under a lot of stress is not only unethical, but also not proven by any medical research that it helps the patient.

In our medical practice, we strive to bring the levels to within normal limits. Level of hormones, meds, and labs - all should remain within normal limits to make the body function properly - and not the other way around.

Thanks,

Dr. Ahsen Ali

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March 16, 2017

Reg: Case No. 13384

John Lewis
Medical Investigator
Kentucky Board of Medical Licensure
Hurstbourne Office Park
310 Whittington Parkway, suite #18
Louisville, KY 40222

Dear Mr. Lewis,

I have reviewed the records sent to me. The letter sent to me indicated that the internist is the Medical Director for Body Shapes medical program.

I reviewed charts of 5 males and 10 females who were treated in the practice.

The following were available for review:

1. Medical history including family history and medication list completed by patient. (Except in 2 patients - I have mentioned in individual reports).
2. Symptom questionnaire relating to various hormonal deficiency completed by patient along with symptom score at initial visit and at follow up.
3. Body mass index, waist and neck circumference, anthropometrics, body composition and blood pressure and in some cases heart rate.
4. Labs at initial visit and at follow up visits.
5. Patient/provider communication comments and physician plan.
6. Detailed Medication log and injection log.

There were several concerns I had regarding hormone replacement.

Thyroid hormone replacement:

Principles:

1. Based on ATA (American Thyroid Association), and Endocrine Society screening guidelines, the standard on practice for Primary hypothyroidism is TSH and if found to be mildly abnormal it is recommended that we repeat the levels in few weeks to confirm diagnosis prior to initiating treatment.

2. Free t3 and free t4 are not recommended for screening unless patient has had recent radioliodine treatment for hyperthyroidism, during pregnancy (1st trimester) and if hypopituitarism is suspected.
3. ATA recommends levothyroxine (name brand or generic) in most patients. Armour, and other T4+T3 preparations are used in certain patients who are dissatisfied with levothyroxine but monitoring levels is challenging since free T3 fluctuates due to short half-life. There is a lot more data available on outcomes on levothyroxine. While we know that occasionally polymorphism in deiodinase genes exists, we don't have clear clinical trials/studies on intervention using liothyronine.

Concerns in this case:

1. In all the reviewed cases the TSH was done once and majority of the patients had TSH <3 uIU/ml.
While NACB recommends values of 0.5 to 2.5 uIU/ml, there is no strong clinical evidence for that except during pregnancy and pre-gestation and occasionally in patients with autoimmune thyroid disease measured by antibody titers. Hence diagnosis of hypothyroidism (I am assuming Primary) based on a normal value of TSH is not current standard of practice.
Majority of the patients were euthyroid based on the labs before initiating treatment.
2. Starting desiccated thyroid as the first treatment of choice is also not standard of practice in most patients unless there is a documented reaction or intolerance to standard preparations.
The few studies that have been done to compare T3 to T4 efficacy have not established benefit of using T3. More ever circulating T3 levels do not correlate with cellular/tissue T3 levels given we have no long acting T3 preparations available.
3. Targeting T3 levels as treatment goal is not current standard of practice. Several patients had low TSH on treatment.
4. No physical exam except for one patient.

#2 Testosterone Use in males:

My concerns:

1. Morning (am) Testosterone levels are recommended as standard for screening for male hypogonadism. Most levels were done at PM.
2. When levels are borderline low it is recommended to be repeated to confirm low levels. (300-350 ng/dl). There were no repeat levels before initiating therapy. More ever most men had normal or high levels before treatment was initiated.

3. Physical examination is warranted in all patients who undergo evaluation of male hypogonadism. No documented physical exam.

4. Men had quite high levels on treatment. Recommended levels are 400-700 ng/dl.

5. Using testosterone in eugonadal men is not recommended at this time given concerns for cardiovascular safety and other adverse effects.

6. Recommending phlebotomy or blood donation in men who had high levels on treatment is not standard practice. All national and international expert panel consensus guidelines from societies recommend reducing the strength/dose of preparations.

7. Low testosterone in young men requires thorough evaluation including ruling out pituitary tumors by imaging in patients with secondary hypogonadism.

Testosterone use in females:

This is not standard practice and is not FDA approved. Long term safety for adverse cardiovascular outcomes and breast cancer and other sex hormone dependent cancers is unknown at this time.

Neither the Endocrine Society nor North American Menopausal Society (NAMS) recommend testosterone treatment as standard of care for women at this time. Neither menopausal hormone therapy (MHT) nor testosterone should be used for weight management.

The only group of women where clinical studies show efficacy for short term off label use of low dose (150-300 mcg) topical testosterone is postmenopausal women with established diagnosis of Hypoactive Sexual Desire disorder (Androgen therapy in Women: A Reappraisal: An Endocrine society Clinical Practice Guideline JCEM 2014). In the United States there is no approved female testosterone preparations available.

1. None of the women had established/documented diagnosis of Hypoactive Sexual desire Disorder although one could imply or presume they had it based on some of the symptoms.
2. Many premenopausal females were treated with androgen.
3. Levels on treatment were supraphysiologic. Some women had undesirable side effects including acne/ folliculitis, hirsutism, weight gain and insomnia. Hyperandrogenism in women can cause undesirable outcomes.
4. No physical exam documented except for one patient.

In summary based on above concerns, there seems to be departure from current acceptable and prevailing standards of medical practice with the Commonwealth of Kentucky.

While in few cases there was concern for gross ignorance, in majority of cases that would be a strong statement since there were no serious outcomes such as acute CV events, cancer or death.

Physician did screen for preexisting cardiovascular issues carefully and monitored labs as per guidelines.

To the final question:

Is it your opinion that the standard of practice violations you have identified may be addressed by the Board in an orderly process, extending over some period of time (6 months to 2-3 years) through remedial education and training, and subsequent monitoring by the Board.

Or,

Are the violations of such a nature that the Board must act immediately to restrict or suspend the doctor's license to protect patients or the public from imminent danger?

I recommend remedial education and training and subsequent monitoring by board.

Thank you for giving me the opportunity.

I have enclosed references for clinical practice guidelines from ATA, Endocrine Society.

Sincerely,



Sathya S. Krishnasamy, M.D.

Associate Professor, Division of Endocrinology, Metabolism and Diabetes

University of Louisville

550 S. Jackson St.

ACB, A3G11

Louisville, KY 40202

(502) 852-5237

COMMONWEALTH OF KENTUCKY
BOARD OF MEDICAL LICENSURE
CASE NO. 1810

AUG 10 2017

K.B.M.L.

IN RE: THE LICENSE TO PRACTICE MEDICINE IN THE COMMONWEALTH OF KENTUCKY HELD BY ELIZABETH VEENEMAN BATES, M.D., LICENSE NO. 36808, 4211 SPRINGHURST BOULEVARD, SUITE 101, LOUISVILLE, KENTUCKY 40241

EMERGENCY ORDER OF RESTRICTION

The Kentucky Board of Medical Licensure (hereafter "the Board"), acting by and through its Inquiry Panel B, considered this matter at its July 20, 2017, meeting. At that meeting the Panel considered a memorandum prepared by John Lewis, Medical Investigator, dated June 14, 2017; the licensee's response to the grievance submitted by her legal counsel, Jennifer Wintergerst, dated October 28, 2015; Board Consultant Reviews with Expert Review Worksheets, dated March 31, 2016 and March 16, 2017; the licensee's response to the consultant reviews submitted by Jennifer Wintergerst, dated May 10, 2016 and May 1, 2017; and responses from the Board Consultants, dated July 21, 2016 and June 8, 2017.

Having considered all of this information and being sufficiently advised, Inquiry Panel B ENTERS the following EMERGENCY ORDER OF RESTRICTION, in accordance with KRS 311.592(1) and 13B.125(1):

FINDINGS OF FACT

Pursuant to KRS 13B.125(2) and based upon the information available to it, Inquiry Panel B concludes there is probable cause to make the following Findings of Fact, which support its Emergency Order of Restriction:

1. At all relevant times, Elizabeth Veeneman Bates, M.D., was licensed by the Board to practice medicine within the Commonwealth of Kentucky.
2. The licensee's medical specialty is Internal Medicine.

3. The Board opened an investigation pursuant to an anonymous grievance received on or about August 3, 2015. The grievant stated that s/he was a concerned pharmacist who had seen a “slew of prescriptions called in from Body Shapes Medical for Armour Thyroid 60mg (always for the same strength.)” The grievant was concerned that Body Shapes Medical was using the medication to hyperstimulate the thyroid to promote weight loss in patients with normal thyroid activity.
4. The Board obtained fifteen (15) patient charts randomly selected from a list of patients seen by the licensee and prescribed Armour Thyroid 60mg between July 1, 2015 and July 31, 2015.
5. The licensee responded to the grievance, through her attorney, on or about October 28, 2015. The licensee stated that she practiced internal medicine for twelve and a half years before becoming the Medical Director of Body Shapes Medical in March 2013. The licensee described her practice and explained the use of Armour Thyroid in her practice.
6. A Board consultant who is Board-certified in Internal Medicine reviewed fifteen (15) of the licensee’s patient charts and found that the licensee departed from or failed to conform to acceptable and prevailing medical practices in the following manner:

As is evident by the table that all the patients when initially seen had normal thyroid function tests. Patients were then given Armour thyroid, in 2/3 of cases started at a dose of Armor 60mg and 1/3 of cases were given Armor 30mg. The main reason of giving a euthyroid patient, thyroid medication is not to optimize his or her thyroid function, but only to increase the metabolism so as to make the patient lose weight. With the thyroid meds, then other meds were given to increase different functions such as libido, and energy.

...

Armor thyroid was increased gradually until it was seen that TSH was decreased and T4/T3 has increased. This was to make sure that patient was hyperthyroid and has an increased metabolism.

I did not see any consultations by the dietitians, or the exercise plans by any physical therapists. Sole reason was to make the thyroid work harder and patient to lose weight without doing any exercise or diet.

The Board consultant's report is attached and incorporated in its entirety.

7. A second Board consultant, who specializes in Endocrinology, reviewed the licensee's patient charts and found that the licensee departed from or failed to conform to acceptable and prevailing medical practices in regard to diagnoses in seven (7) charts, in regard to treatment in eleven (11) charts, overall in five (5) charts and was overall Borderline in nine (9) charts.
8. The Board consultant found concerns with thyroid hormone replacement and testosterone use in both males and females. The Board consultant's report is attached and incorporated in its entirety.
9. On or about May 10, 2016, the licensee responded in writing, through counsel, to the first Board consultant's review of her patient charts. In her response, the licensee responded to the Board consultant's concerns in detail.
10. On or about May 1, 2017, the licensee responded in writing, through counsel, to the second Board consultant's review of her patient charts. In her response, the licensee responded to the Board consultant's concerns in detail.
11. On or about July 21, 2016, the first Board consultant issued a final report after reviewing the licensee's response. The Board consultant refuted the arguments made by the licensee, and the Board consultant's opinion of the medical care of the cases he evaluated did not change.
12. On or about June 8, 2017, the second Board consultant issued a final report after reviewing the licensee's response. The second Board consultant refuted the arguments

made by the licensee, and the Board consultant's opinion of the medical care of the cases she evaluated did not change.

CONCLUSIONS OF LAW

Pursuant to KRS 13B.125(2) and based upon the information available to it, Inquiry Panel B finds there is probable cause to support the following Conclusions of Law, which serve as the legal bases for this Emergency Order of Restriction:

1. The licensee's Kentucky medical license is subject to regulation and discipline by this Board.
2. KRS 311.592(1) provides that the Board may issue an emergency order suspending, limiting, or restricting a physician's license at any time an inquiry panel has probable cause to believe that a) the physician has violated the terms of an order placing him on probation; or b) a physician's practice constitutes a danger to the health, welfare and safety of his patients or the general public.
3. There is probable cause to believe that the licensee has violated the provisions of KRS 311.595(9), as illustrated by KRS 311.597(3) and (4).
4. The Panel concludes there is probable cause to believe this physician's practice constitutes a danger to the health, welfare and safety of her patients or the general public.
5. The Board may draw logical and reasonable inferences about a physician's practice by considering certain facts about a physician's practice. If there is proof that a physician has violated a provision of the Kentucky Medical Practice Act in one set of circumstances, the Board may infer that the physician will similarly violate the Medical Practice Act when presented with a similar set of circumstances. Similarly, the Board concludes that proof of a set of facts about a physician's practice presents representative

proof of the nature of that physician's practice in general. Accordingly, probable cause to believe that the physician has committed certain violations in the recent past presents probable cause to believe that the physician will commit similar violations in the near future, during the course of the physician's medical practice.

6. The United States Supreme Court has ruled that it is no violation of the federal Due Process Clause for a state agency to temporarily suspend a license, without a prior evidentiary hearing, so long as 1) the immediate action is based upon a probable cause finding that there is a present danger to the public safety; and, 2) the statute provides for a prompt post-deprivation hearing. Barry v. Barchi, 443 U.S. 55, 61 L.Ed.2d 365, 99 S.Ct. 2642 (1979); FDIC v. Mallen, 486 U.S. 230, 100 L.Ed.2d 265, 108 S.Ct. 1780 (1988) and Gilbert v. Homar, 117 S.Ct. 1807 (1997). Cf. KRS 13B.125(1).

KRS 13B.125(3) provides that the Board shall conduct an emergency hearing on this emergency order within ten (10) working days of a request for such a hearing by the licensee. The licensee has been advised of her right to a prompt post-deprivation hearing under this statute.

EMERGENCY ORDER OF RESTRICTION

Based upon the foregoing Findings of Fact and Conclusions of Law, Inquiry Panel B hereby ORDERS that the license to practice medicine in the Commonwealth of Kentucky held by ELIZABETH VEENEMAN BATES, M.D., is RESTRICTED and Dr. Bates is prohibited from practicing medicine in the context of hormone replacement therapy until the resolution of the Complaint setting forth the allegations discussed in this pleading or until such further Order of the Board.

Inquiry Panel B further declares that this is an EMERGENCY ORDER, effective upon receipt by the licensee.

SO ORDERED this 10th day of August, 2017.



RUSSELL L. TRAVIS, M.D.
CHAIR, INQUIRY PANEL B

CERTIFICATE OF SERVICE

I certify that the original of this Emergency Order of Restriction was delivered to Mr. Michael S. Rodman, Executive Director, Kentucky Board of Medical Licensure, 310 Whittington Parkway, Suite 1B, Louisville, Kentucky 40222; and copies were mailed via certified mail return-receipt requested to the licensee, Elizabeth Veeneman Bates, M.D., License No. 36808, 4211 Springhurst Boulevard, Suite 101, Louisville, Kentucky 40241, and to her counsel, Jennifer Wintergerst, Esq., Wyatt, Tarrant & Combs, 500 West Jefferson Street, Suite 2800, Louisville, Kentucky 40202 on this 10th day of August, 2017.



Sara Farmer
Assistant General Counsel
Kentucky Board of Medical Licensure
310 Whittington Parkway, Suite 1B
Louisville, Kentucky 40222
(502) 429-7150



The Clinic
AHSEN ALI, MD, FACP

DIPLOMATE BOARD OF INTERNAL MEDICINE

March 31ST, 2016

Mr. John W. Lewis
Medical Investigator
Kentucky Board of Medical Licensure

RE: Elizabeth Bates, MD
KBML Case # 13384

Dear Mr. John Lewis:

I have been asked by the Kentucky Board of Medical Licensure to serve as a consultant in an ongoing investigation involving Dr. Elizabeth Bates. I had to review a series of charts so as to give an opinion. During this process, I reviewed the grievance report by a pharmacist, response by Dr. Bates, and medical records of many patients treated by Dr. Bates at Body shapes Medical.

Six Nurse practitioners are working under Dr. Bates, in five different clinics. Most of the cases seen at these clinics by all the medical professionals are for the purpose to improve the general health and to help the patients lose weight.

Initial grievance of 11/11/2013 by a pharmacist stated that:

- 1) Only Armour thyroid 60mg was always called in.
- 2) Never a "typical" weight loss drug was called in, and
- 3) Concern was that the medication was used to hyper stimulate the normal thyroid gland to promote weight loss

Dr. Elizabeth Bates responded to the initial grievance two years later on October 28th, 2015 by stating that:

- 1) "I only start Armour in patients that have low thyroid activity with non-optimized free T3 level"
- 2) "Armour 60mg is a common starting dose"
- 3) "I do increase the dosage to 90mg or even 120mg daily as dictated by blood levels"
- 4) "We regularly ask the patients about hyper stimulation symptoms".
- 5) "In May 2015, I revamped our offered programs and removed the weight loss only option"

Before I give my opinion, I would like to go through the physiology of the Thyroid.

The endocrine system is the body's communication hub, controlling cell, and therefore organ, function. The thyroid is the largest exclusively endocrine gland in the body.

The hormones secreted by the thyroid gland are essential in this process, targeting almost every cell in the body (only the adult brain, spleen, testes, and uterus are immune to their effects.) Inside cells, thyroid hormone stimulates enzymes involved with glucose oxidation, thereby controlling cellular temperature and metabolism of proteins, carbohydrates, and lipids. Through these actions, the thyroid regulates the body's metabolic rate and heat production.

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In its behavior, TH functions somewhat similarly to steroid hormones.

The two major thyroid hormones are unique in that, unlike most hormones, they are neither protein nor cholesterol based. Instead, they incorporate iodine as an active constituent; the amount of iodine differentiates between thyroxine (also known as tetraiodothyronine or T₄) with four iodine molecules and triiodothyronine (T₃) with, predictably, three iodine molecules. While T₄ exists in greater abundance than T₃ in the body- thought to be at a fifty to one ratio, T₃ is considered to be ten times more active. There is much debate about the physiological difference between the two hormones. It is currently thought that T₄ may act as the reserve form, having a more direct role in the hypothalamus/pituitary negative feedback loop, while T₃ has a more dynamic physiological effect in the body. Others suggest that both have a critical part in physiological activity.

Symptoms of Hyperthyroidism:

The symptoms of hyperthyroidism include the following:

- Fatigue or muscle weakness
- Hand tremors
- Mood swings
- Nervousness or anxiety
- Rapid heartbeat, Heart palpitations, Atrial fibrillation
- Shortness of breath, particularly during exercise
- Skin dryness
- Insomnia
- Diarrhea
- Light menstrual periods or skipping menstrual periods
- Hair loss
- Excessive sweating
- Weight loss despite an increase in appetite. A few patients will gain weight.
- Vision problems with red irritated eyes, double vision.

Diet can effect thyroid function, as a high calorie/high carbohydrate diet can lead to increased conversion of T₄ to T₃- a mechanism that likely assists in keeping an organism's weight stable. Meanwhile, prolonged fasting can result in a decrease in T₃ production - which may be adaptive for conditions of food scarcity, slowing down the body's metabolism and energy consumption.

The majority of dietary thyroid supplements contained clinically significant amounts of T₃ and T₄. This could potentially expose patients to the risk of altering thyroid-function tests and could even cause thyrotoxicosis.

It has been appreciated for a very long time that there is a complex relationship between thyroid disease, body weight and metabolism. Low thyroid hormone levels were associated with low BMRs and high thyroid hormone levels were associated with high BMRs (Basal Metabolic rate).

The relationship between metabolic rates, energy balance, and weight changes is very complex. There are many other hormones (besides thyroid hormone), proteins, and other chemicals that are



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DIPLOMATE BOARD OF INTERNAL MEDICINE

very important for controlling energy expenditure, food intake, and body weight. Because all these substances interact on both the brain centers that regulate energy expenditure and tissues throughout the body that control energy expenditure and energy intake, no one can predict the effect of altering only one of these factors (such as thyroid hormone) on body weight as a whole.

Since the BMR in patients with hyperthyroidism is elevated, many patients with an overactive thyroid do, indeed, experience some weight loss. Furthermore, the likelihood of weight loss occurring is related to the severity of the overactive thyroid. Thus, if the thyroid is extremely overactive, the individual's BMR increases which leads to increased caloric requirements to maintain that weight. If the person does not increase the calories consumed to match the excess calories burned, then weight loss will ensue. As I said earlier, the factors that control our appetite, metabolism, and activity are very complex and thyroid hormone is only one factor in this complex system.

Nevertheless, on average the more severe the hyperthyroidism, the greater the weight loss observed. Since hyperthyroidism also increases appetite, some patients may not lose weight, and some may actually gain weight, depending on how much they increase their caloric intake.

On the average, any weight lost during the hyperthyroid state is regained when the hyperthyroidism is treated. One consequence of this observation is that the use of thyroid hormone to treat obesity is not very useful. Once thyroid hormone treatment is stopped, any weight that is lost while on treatment will be regained after treatment is discontinued.

Going back to our case, I was sent 15 charts of different patients to review. Patients were seen for Thyroid treatment for weight loss as well as for Testosterone, Estradiol, Vitamin D, and other treatments. .

I have made a table of all the 15 patient charts. Starting from the initial visit when patient came to the clinic, initial labs, then which meds were started, labs after the initial treatment, meds adjustment and then the response seen in the labs.

N= Normal

TSH= Thyroid stimulating hormone

T4= Tetraiodothyronine

T3= Triiodothyronine

A30= Armour 30 mg

A45= Armour 45 mg

A 60= Armour 60 mg

A 90= Armour 90 mg

D= Decreased

I= Increased

CAR.= Cardiologist of the patient refused to allow the patient to get any thyroid Hormone treatment

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Now, lets look at some charts of the patients:

<u>Name</u>	<u>TSH</u>	<u>T4/T3</u>	<u>Meds</u>	<u>TSH</u>	<u>T4/T3</u>	<u>Meds</u>	<u>TSH</u>	<u>T4/T3</u>	<u>Meds</u>
SB	N	N	A 60	N	D	A 90	D	I	A 60
VW	N	N	A 60	D	I	A 30		N	A 45
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LF	N	N	A 30	N	N	A 60	D	N	A 90
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LC	N	N	A 60	D	I	A 60		I	A 60
MJ	N	N	A 30	N	N	A 60	N	N	A 30
KM	N	N	A 60	N	N	A 60		N	
CP		N	A 30	N	N	A 60		I	A 60
HS	N	N	A 30	N	N	A 60	N	I	A 60
WD	N	N	A 60	D	N	A 90	D	I	A 60
SH	N	N	A 60	D	I	A 60		N	

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Some patient did lose weight while on Armour.
Primary care physician of one patient did not like the decreased TSH.
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Conclusion:

Dr. Elizabeth Bates runs a boutique clinic by the name of Body shapes Medical. The patient is initially seen and asked a battery of questions, and then according to the patient preference of what concerns him more, gets treated.

As is evident by the table that all the patients when initially seen had normal thyroid function tests. Patients were then given Armour thyroid, in 2/3rd of cases started at a dose of Armour 60mg and 1/3rd of cases were given Armour 30mg. The main reason of giving a euthyroid patient, thyroid medication is not to optimize his or her thyroid function, but only to increase the metabolism so as to make the patient lose weight. With the thyroid meds, then other meds were given to increase different functions such as libido, and energy.

In my view, it is extremely unethical to increase the thyroid functions, knowing all the side effects of hyperthyroidism, for the sole reason to make the patient lose weight. There are a lot of other ways to make the patient lose weight without jeopardizing his general health. FDA has approved multiple medications for the sole purpose of weight loss.

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I, as a board certified Internal Medicine physician would not like any of my patients to go through this program and I do not think that I saw any physicians consulting Dr. Bates for this. It is documented in different charts, when patient's primary care physicians did not like the change in thyroid functions.

The normal levels of any tests are made with a lot of research and expertise, considering all the standard deviations. Now, if a physician takes upon him or herself to change them thinking that the level needs to be changed according to the age and the complaints of the patient, then it is completely wrong.

Patients to lose weight should have been given a diet and exercise plan, and then if some patients need medications, they can be prescribed under the supervision of a physician. That is the reason while obesity is an epidemic in America; these medications are given by the physicians and are not made OTC meds. Even these medications approved by FDA have side effects, which need to be followed by a physician. How can we make a normal person, do something wrong to get a right result?

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The Clinic
AHSEN ALI, MD, FACP

DIPLOMATE BOARD OF INTERNAL MEDICINE

In my opinion, the business of making a human being lose weight by making his thyroid functions to work at a higher level by putting his body under a lot of stress is not only unethical, but also not proven by any medical research that it helps the patient.

In our medical practice, we strive to bring the levels to within normal limits. Level of hormones, meds, and labs - all should remain within normal limits to make the body function properly - and not the other way around.

Thanks,

A handwritten signature in black ink, appearing to be 'A. Ali'.

Dr. Ahsen Ali

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March 16, 2017

Reg: Case No. 13384

John Lewis
Medical Investigator
Kentucky Board of Medical Licensure
Hurstbourne Office Park
310 Whittington Parkway, suite #18
Louisville, KY 40222

Dear Mr. Lewis,

I have reviewed the records sent to me. The letter sent to me indicated that the internist is the Medical Director for Body Shapes medical program.

I reviewed charts of 5 males and 10 females who were treated in the practice.

The following were available for review:

1. Medical history including family history and medication list completed by patient. (Except in 2 patients - I have mentioned in individual reports).
2. Symptom questionnaire relating to various hormonal deficiency completed by patient along with symptom score at initial visit and at follow up.
3. Body mass index, waist and neck circumference, anthropometrics, body composition and blood pressure and in some cases heart rate.
4. Labs at initial visit and at follow up visits.
5. Patient/provider communication comments and physician plan.
6. Detailed Medication log and injection log.

There were several concerns I had regarding hormone replacement.

Thyroid hormone replacement:

Principles:

1. Based on ATA (American Thyroid Association), and Endocrine Society screening guidelines, the standard on practice for Primary hypothyroidism is TSH and if found to be mildly abnormal it is recommended that we repeat the levels in few weeks to confirm diagnosis prior to initiating treatment.

2. Free T3 and free T4 are not recommended for screening unless patient has had recent radiolodine treatment for hyperthyroidism, during pregnancy (1st trimester) and if hypopituitarism is suspected.
3. ATA recommends levothyroxine (name brand or generic) in most patients. Armour, and other T4+T3 preparations are used in certain patients who are dissatisfied with levothyroxine but monitoring levels is challenging since free T3 fluctuates due to short half-life. There is a lot more data available on outcomes on levothyroxine. While we know that occasionally polymorphism in deiodinase genes exists, we don't have clear clinical trials/studies on intervention using liothyronine.

Concerns in this case:

1. In all the reviewed cases the TSH was done once and majority of the patients had TSH <3 uIU/ml.
While NACB recommends values of 0.5 to 2.5 uIU/ml, there is no strong clinical evidence for that except during pregnancy and pre-gestation and occasionally in patients with autoimmune thyroid disease measured by antibody titers. Hence diagnosis of hypothyroidism (I am assuming Primary) based on a normal value of TSH is not current standard of practice.
Majority of the patients were euthyroid based on the labs before initiating treatment.
2. Starting desiccated thyroid as the first treatment of choice is also not standard of practice in most patients unless there is a documented reaction or intolerance to standard preparations.
The few studies that have been done to compare T3 to T4 efficacy have not established benefit of using T3. More over circulating T3 levels do not correlate with cellular/tissue T3 levels given we have no long acting T3 preparations available.
3. Targeting T3 levels as treatment goal is not current standard of practice. Several patients had low TSH on treatment.
4. No physical exam except for one patient.

#2 Testosterone Use in males:

My concerns:

1. Morning (am) Testosterone levels are recommended as standard for screening for male hypogonadism. Most levels were done at PM.
2. When levels are borderline low it is recommended to be repeated to confirm low levels. (300- <350 ng/dl). There were no repeat levels before initiating therapy. More over most men had normal or high levels before treatment was initiated.

3. Physical examination is warranted in all patients who undergo evaluation of male hypogonadism. No documented physical exam.
4. Men had quite high levels on treatment. Recommended levels are 400-700 ng/dl.
5. Using testosterone in eugonadal men is not recommended at this time given concerns for cardiovascular safety and other adverse effects.
6. Recommending phlebotomy or blood donation in men who had high levels on treatment is not standard practice. All national and international expert panel consensus guidelines from societies recommend reducing the strength/dose of preparations.
7. Low testosterone in young men requires thorough evaluation including ruling out pituitary tumors by imaging in patients with secondary hypogonadism.

Testosterone use in females:

This is not standard practice and is not FDA approved. Long term safety for adverse cardiovascular outcomes and breast cancer and other sex hormone dependent cancers is unknown at this time.

Neither the Endocrine Society nor North American Menopausal Society (NAMS) recommend testosterone treatment as standard of care for women at this time. Neither menopausal hormone therapy (MHT) nor testosterone should be used for weight management.

The only group of women where clinical studies show efficacy for short term off label use of low dose (150-300 mcg) topical testosterone is postmenopausal women with established diagnosis of Hypoactive Sexual Desire disorder (Androgen therapy in Women: A Reappraisal: An Endocrine society Clinical Practice Guideline JCEM 2014). In the United States there is no approved female testosterone preparations available.

1. None of the women had established/documented diagnosis of Hypoactive Sexual desire Disorder although one could imply or presume they had it based on some of the symptoms.
2. Many premenopausal females were treated with androgen.
3. Levels on treatment were supraphysiologic. Some women had undesirable side effects including acne/ folliculitis, hirsutism, weight gain and insomnia. Hyperandrogenism in women can cause undesirable outcomes.
4. No physical exam documented except for one patient.

In summary based on above concerns, there seems to be departure from current acceptable and prevailing standards of medical practice with the Commonwealth of Kentucky.

While in few cases there was concern for gross ignorance, in majority of cases that would be a strong statement since there were no serious outcomes such as acute CV events, cancer or death.

Physician did screen for preexisting cardiovascular issues carefully and monitored labs as per guidelines.

To the final question:

Is it your opinion that the standard of practice violations you have identified may be addressed by the Board in an orderly process, extending over some period of time (6 months to 2-3 years) through remedial education and training, and subsequent monitoring by the Board.

Or,

Are the violations of such a nature that the Board must act immediately to restrict or suspend the doctor's license to protect patients or the public from imminent danger?

I recommend remedial education and training and subsequent monitoring by board.

Thank you for giving me the opportunity.

I have enclosed references for clinical practice guidelines from ATA, Endocrine Society.

Sincerely,



Sathya S. Krishnasamy, M.D.

Associate Professor, Division of Endocrinology, Metabolism and Diabetes

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