BEFORE THE

OREGON MEDICAL BOARD

STATE OF OREGON

In the Matter of KENNETH JAY WELKER, MD LICENSE NO. MD 22731	)))))	DEFAULT FINAL ORDER

1.

The Oregon Medical Board (Board) is the state agency responsible for licensing, regulating and disciplining certain health care providers, including physicians, in the state of Oregon. Kenneth Jay Welker, MD (Licensee) is a licensed physician in the state of Oregon.

2.

2.1 This case has a lengthy procedural history as a result of an ongoing investigation, which brought to light numerous violations of the Medical Practice Act throughout the course of the investigation. The Board issued a Complaint and Notice of Proposed Disciplinary Action on August 5, 2012. Licensee requested a hearing. On June 17, 2013, Licensee signed an Interim Stipulated Order, in which he agreed to certain terms and conditions affecting his practice. On September 18, 2013, Licensee signed another Interim Stipulated Order, in which he agreed to immediately cease performing or providing Adipose Derived Mesenteric Cell Harvesting and Transfer (stem cell) therapy for any patient. After additional evidence of professional misconduct came to the Board's attention, the Board issued an Order of Emergency Suspension on January 9, 2014. On April 8, 2014, the Board issued an Amended Complaint and Notice of Proposed Disciplinary Action. On July 11, 2014, the Board issued the Second Amended Complaint and Notice of Proposed Disciplinary Action, in which the Board proposed taking disciplinary action by imposing up to the maximum range of potential sanctions identified in ORS 677.205(2), to include the revocation of license, a $10,000 fine, and assessment of costs, pursuant to ORS 677.205 against Licensee for violations of the Medical Practice Act, to wit: ORS 677.190(1)(a) unprofessional or

dishonorable conduct, as defined by ORS 677.188(4)(a)(b) and (c); ORS 677.190(9) making statements that licensee knows, or should know, are false or misleading regarding skill or the efficacy or value of the medicine or remedy prescribed or administered by the licensee or at the direction of the licensee in the treatment of any disease or condition of the human body; and ORS 677.190(13) gross or repeated acts of negligence.

2.2 On July 9, 2014, the Board received a letter from Licensee stating that he had "fired his attorney" and that he had the "right to rescind the request for a contested case hearing previously agreed to and I am doing so now." On July 11, 2014, the Board subsequently issued the Second Amended Complaint and Notice of Proposed Disciplinary Action. Licensee submitted another letter, which the Board received on July 25, 2014. In this letter, Licensee acknowledged receiving the Board's correspondence dated July 11, 2014, which contained the Second Amended Complaint and Notice of Proposed Disciplinary Action. In this letter, Licensee made reference to previous correspondence, stating: "I noted the Board acknowledged and agreed to my request to rescind the contested case hearing which my former attorney arranged for me without explaining to me the legal ramifications." Licensee went on to state that he was "again renewing my right to rescind same...." The Board replied to this letter on July 25, 2014, which Licensee received on July 28, 2014. In this letter, the Board reiterated that it would not provide suggestions or legal advice, but stated the following: "At this time the Board does not have a request for a hearing from you on this matter. Failure to request a hearing by **August 1, 2014**, waives your right to a hearing and will result in the Board issuing a default order." Licensee did not submit a request for hearing by that specified deadline. On August 29, 2014, the Board received a letter from Licensee in which he reiterated his request to waive his right to an administrative hearing. The Board finds that Licensee has expressly waived his right to a contested case hearing and stands in default.

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NOW THEREFORE, after considering the Board's file relating to this matter, the Board enters the following Order.

FINDINGS OF FACT

Licensee is a board certified surgeon, but has ceased practicing as a surgeon, and up until the Order of Emergency Suspension, practiced medicine at a clinic called Optimal Health, in Eugene, Oregon. Licensee states that he is a Diplomat of the American Academy of Anti-Aging Regeneration and Functional Medicine. This organization is not recognized by the American Board of Medical Specialties or the American Osteopathic Association. Licensee engaged in acts and conduct that violated the Medical Practice Act, as follows:

3.1 Patient A, a 56-year-old female, presented to Licensee on November 19, 2010, with complaints of a non-healing ulcer on her left calf. Patient A was morbidly obese with underlying insulin dependent adult onset diabetes with renal insufficiency and a history of congestive heart failure, and chronic obstructive pulmonary disease. Licensee estimated her weight to be between 350 and 400 pounds. Licensee noted that Patient A was interested in hydrogen peroxide intravenous (IV) therapy and that she did not want her conventional medicine providers to know that she was receiving other forms of therapy. Licensee initiated a course of IV hydrogen peroxide therapy that was to be done twice a week while she continued with ongoing conventional medical treatment from her primary care provider (PCP). Licensee failed to explain (or document that he explained) the risks, alternatives and side effects associated with this type of treatment, and whether the patient had any questions regarding the treatment. Patient A returned to the clinic on November 22, 2010 for a repeat treatment, received hydrogen peroxide IV therapy from another provider, and experienced unexpected adverse side effects during the initial treatment.

3.2 Patient B, a 77-year-old adult male, presented to Licensee on November 30, 2011, with complaints of fatigue, joint pain, sleep deprivation, and benign prostate hypertrophy. Licensee examined Patient B, noted an elevated blood pressure of 163/91 and

ordered both conventional and unorthodox laboratory studies, but did not conduct a digital rectal examination (DRE) or check Patient B's prostate-specific antigen (PSA), which was last checked in 2005, when Patient B's PSA level was 10, which is elevated. Licensee diagnosed Patient B with hypercholesterolemia, hypertension, and fatigue due to "heavy metal burden chronic toxicity." Licensee's chart note for this initial visit lists thirty eight (38) distinct diagnoses. Licensee started Patient B on a course of medications and supplements, to include clonazepam (Schedule IV), Pregnenolone, hydrochlorothiazide, and ultimately 29 dietary supplements. Patient B underwent a test infusion of disodium ethylene diamine tetra-acetic acid (EDTA) on December 2, 2011 as well as heavy metal testing and other studies. Patient B's testosterone level was 396 (within the normal range) and his thyroid stimulating hormone (TSH) level was 2.99 (also within the normal range). On December 19, 2011, Licensee reviewed the recent lab studies with Patient B and decided to treat Patient B with 10 sessions of IV chelation, and prescribed an additional one half grain of thyroid and began treating Patient B with injections of 0.5 mL of testosterone (200 mg/ml) per week along with anastrozole (Armidex) (a medication normally used for breast cancer prophylaxis for women) 1 mg per week. Licensee told Patient B that his testosterone level should be in an optimal range of 850 to 950. Licensee did not check Patient B's PSA level or conduct a DRE. Licensee did not advise Patient B of the risks and possible side effects associated with the regimen of medications and supplements that he was taking. On January 13, 2012, Patient B came in for chelation treatment, and complained that his arthritic right knee had caused him to stop playing basketball. Licensee injected his right knee with "1 mm" (sic) aqueous testosterone and 6 mL of prolotherapy. Patient B returned for repeated treatments of aqueous testosterone and prolotherapy. Although Patient B had a history of hypertension, Licensee did not record a blood pressure reading at the January 13th visit. On February 24, 2012, Patient B's blood pressure was noted to be 178/101, and on February 29th, Patient B collapsed at his chiropractor's office. Later that day, his blood pressure readings at Licensee's office were 196/109 and 178/126. Licensee failed to address the issue of hypertension in his progress

notes. On March 4, 2012, Patient B was seen at the Sacred Heart Emergency Department (ED), with a blood pressure of 168/108, a normal computed tomography scan, normal magnetic resonance angiogram and unchanged electrocardiogram (EKG). Patient B was discharged from the ED with a diagnosis of Transient Ischemic Attack (TIA). On March 12, 2012, Patient B informed Licensee that he had an MRI that documented multiple small strokes in the left basal area and right frontal lobe, and that he had been placed on a statin drug and clopidogrel (Plavix), which reduces the risk of strokes by reducing platelet aggregation in the blood. On March 13, 2012, Patient B was again seen at Sacred Heart Emergency Department and diagnosed with a TIA. Licensee spoke by phone with Patient B while he was being seen at Sacred Heart and prescribed losartan 25 mg BID without coordination with the emergency department physicians. Patient B returned to see Licensee on March 19 for EDTA chelation, and informed Licensee that he had been hospitalized for two days the previous week due to a small stroke, and was having trouble with his peripheral vision and understanding the radio. On April 6, 2012, Patient B's testosterone level was 717, blood sugar of 124, A1C of 5.8, and cholesterol/HDL ratio of 6.2. Patient B presented to Licensee on April 9, 2012, for EDTA chelation (#12) treatment. He complained of being irritable and had a large ecchymosis on his left buttocks. Licensee informed Patient B that his ecchymosis may be a hemorrhage at his testosterone injection site caused by his Plavix. Licensee told Patient B to stop taking Plavix. Licensee did not consult with Patient B's PCP, and did not advise Patient B of the risks associated with discontinuing this medication, particularly in the context of his recent history of cerebrovascular disease. Licensee charted that he thought Patient B was "well covered to reduce his risk of stroke particularly on EDTA chelation." During this time, Patient B experienced difficulty urinating and asked Licensee if his symptoms could be attributed to the medications and supplements that Licensee had prescribed or recommended. Licensee rejected the idea, but on April 20, 2012, did prescribe tamsulosin (Flomax) 0.4 mg 30 tablets. On April 23, 2012, Patient B's PCP noted that Patient B did not understand the importance of taking Plavix as well as his statin medication and

recommended that Patient B and the Licensee not alter any of his allopathic medications. Patient B continued to experience urination problems, and on May 23, 2012, presented to his PCP with complaints of incomplete voiding. Patient B received a consultation with Oregon Urology Institute, where he presented on May 30, 2012, with complaints associated with urine retention. Patient B was found to have a PSA of 17.6 (elevated) and an enlarged prostate. Patient B declined a transurethral resection of the prostate and elected to discontinue testosterone and to continue taking Flomax. Patient B's symptoms gradually resolved. Licensee failed to inform Patient B of the health risks associated with his treatment plan, recommended unnecessary treatments to address his health condition, to include treatment with thyroid and testosterone, jeopardized Patient B's health by recommending that he discontinue Plavix without medical justification, did not inform the PCP of his intervention into the treatment plan, which included the prescribing of Plavix, and failed to effectively address Patient B's cerebrovascular disease while providing misleading information that chelation therapy is an effective treatment for cerebrovascular disease.

3.3 A review of the charts for Patients C – F revealed an ongoing pattern of conduct in which Licensee breached the standard of care by prescribing testosterone for men over the age of 60 that was not medically indicated and without checking their PSA or conducting a DRE. Patients C - F ranged in ages from 61 to 65, and presented to Licensee with various complaints of fatigue. Licensee tested the patients' testosterone level, informed these patients that their testosterone was low (although their test results were in the normal range), recommended that they take various supplements and began treating them with testosterone. Licensee put Patients C – F on a course of Arimidex (1 mg, 1 tablet twice a week) and intra muscular injections of testosterone (200mg/mL at 0.5 mL) that was not medically indicated. In addition, during the course of treatment, Licensee did not monitor PSA levels and did not conduct a DRE prior to initiating testosterone therapy and for three to six months after initiating therapy.

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3.4 Licensee treated Patients G – H with hydrogen peroxide therapy without documenting in the patients' charts that he explained the potential side effects, alternatives, risks, or answered his patients' questions.

3.5 Patient I, a 44-year-old adult male, presented to Licensee on October 13, 2009 with a history of chronic fatigue, fibromyalgia, insomnia, and complained about numbness and tingling in the hands, with progressive clumsiness and weakness. Licensee examined Patient I and noted for the cardiovascular examination: "RRR [regular rate rhythm], No murmur." Licensee tested for heavy metals and initiated therapy with tramadol (Ultram). On October 26th, Patient I called Licensee to report that he was experiencing "a worsening in his irregular heartbeat and chest discomfort" as well as nausea, headaches and feeling of weakness. Patient I presented to Licensee on October 29, 2009, and reported an increase in his irregular heartbeats with an addition of racing heart and chest discomfort. Patient I attributed his symptoms of diarrhea, nausea, headaches and faintness to his increase of ProtoClear (a nutritional supplement). Licensee's assessment and plan follows: "Due to slight loss in lean body mass, will increase calorie intake to 1600 calories. Begin use of Chasteberry Plus to assist with symptoms of racing heart and thermo regulation." Licensee did not document that he conducted a cardiovascular examination, did not record Patient I's heart rate or blood pressure, did not order an EKG, check enzyme levels, obtain a consult with a cardiologist or contact Patient I's PCP. Licensee failed to document whether he recognized the significance of Patient I's potentially life threatening symptoms, and failed to follow up by examination, laboratory work or referral. By so doing, Licensee unnecessarily exposed Patient I to risk of harm.

3.6 The Board reviewed the medical records for Patients J – N, and found that Licensee conducted certain procedures on these patients that were not FDA approved (to include what the Licensee called stem cell and adipose cell transfer procedures) that were described by Licensee as "experimental and investigational." Licensee did not establish any Institutional Review Board for oversight of any experimental or investigational treatment that

he provided, and failed to do the following: document any subject selection criteria, document the investigational protocol, establish validated instruments to follow results objectively, describe a data collection and analysis system, establish a protocol for reporting adverse events, and disclosing to patients any potential conflict of interest, financial or otherwise, in asking them to participate in his study. Specific concerns pertaining to patient care follow:

a. Patient J, a 62-year-old female, initially presented to Licensee on January 28, 2013 with complaints of dizziness, ataxia, and a body mass index of 20. She had previously been diagnosed with multiple sclerosis, and a chiropractor had documented a finding of "lead heavy metal toxicity issues" after an April 2012 post provocative urine test. A November 2011 blood test reported normal lead and copper levels. Licensee discussed with Patient J the possibility of "fat transfer with respect to getting cells fat for the purposes of her first rating (sic) her neurological growth." Licensee noted a plan to "pursue a detox case of lead" via EDTA chelation. Patient J subsequently underwent a series of 20 IV calcium EDTA chelation treatments at Licensee's clinic. On May 14, 2013, Patient J signed an informed consent form to undergo a "Fat Transfer." This form states that this procedure is not FDA approved, is usually not covered by health insurance, and that there are "inherent risks." On that same day, Licensee performed a "stem cell transfer" procedure on Patient J, by removing 80 mL of fluid and fat from the patient's abdomen through liposuction as well as 120 mL of blood, and processing it. Licensee subsequently injected 8 mLs of the processed solution into the patient's spinal fluid by lumbar puncture, while the remainder was injected intravenously into Patient J. Within 5 minutes, Patient J complained of tingling in her body and both legs. Licensee noted that she had a high respiratory rate and elevated blood pressure with a lot of perspiration that lasted about 45 minutes. Licensee was surprised by the reaction and could not offer an explanation for the adverse reaction. Licensee did not report this adverse reaction to the Stem Cell therapy to any appropriate entity. Licensee discharged her home in stable condition with a normal blood pressure of 121/73. Patient J returned to the clinic two days

later and appeared to be stable, albeit with a mild amount of abdominal pain. Licensee's clinic records for this patient included two (2) different versions of her Vital Signs log for the period of 1/28/2013 through 6/11/2013. The first version has three (3) log entries for vital signs taken during the May 14, 2013, stem cell therapy, the second version of this log does not include any vital signs for this date. Licensee subjected Patient J to a series of EDTA chelation treatments that were not medically indicated and "stem cell transfer" that were not medically indicated and subjected her to an unnecessary risk of harm.

b. Patient K, a 60-year-old female, presented to Licensee on March 27, 2013 with complaints of rheumatoid arthritis and postherpetic neuralgia. Licensee started her on DHEA (dehydroepiandrosterone) 25 mg a day, with a plan to increase this to 50 mg a day, in order to "help modulate her immune system." On July 30, 2013, Patient K signed a "Fat Transfer" informed consent form and underwent a stem cell injection into both knees, breasts, shoulders as well as IV infusions. On August 27, 2013, Licensee attempted to conduct another stem cell transfer on Patient K. Licensee's chart note reflects he made multiple attempts to obtain blood from "L wrist R wrist R femoral a/v L femoral L & R carotid and ext jugular were unsuccessful." Patient K finally told Licensee to discontinue and that she wanted to go home. Licensee now asserts that his chart note is not accurate, and that "at no time was any effort made to gain access in an arterial vessel (neither carotid nor femoral)." Licensee's "stem cell transfer" procedure was not medically indicated, and subjected Patient K to significant and unwarranted risk of harm. Furthermore, either Licensee is responsible for an erroneous detailed dictation, or he attempted to draw blood from the femoral and carotid artery, thereby subjecting Patient K to an unnecessary risk of harm.

c. The Board also reviewed other cases where Licensee provided stem cell IV infusion treatments in 2013, pertaining to Patients L – N. Patient L was a 39-year-old female with a history of rheumatoid arthritis who first saw Licensee in July 2010. Patient L returned to Licensee's clinic on July 15, 2013 after an absence of over one year. On July 22, 2013, Licensee administered injections of autologous processed fat and blood into the right knee,

left and right wrist, right hip and right shoulder of Patient L. Excess fat was processed and injected into each breast for this patient. On January 10, 2013, Patient M, a 71-year-old male and former marathon runner, presented with complaints of knee pain and left medial knee arthropathy. This patient was seeking an alternative to knee replacement surgery. Licensee's note for the initial visit indicates the Patient "...is probably a good candidate to undergo fat transplant gets cartilage growth going (sic)" and "He understands this is an experimental investigational procedure". Patient M's labs in January 2013 reflect normal TSH level and an elevated total testosterone of 916, even though the patient was not on supplemental testosterone. On January 22, 2013, Licensee performed a "mini liposculpture and venipuncture for his platelet rich plasma." Licensee processed the extracted fat and blood and injected it into Patient M's left knee. Licensee wrapped Patient M's abdomen, prescribed him 20 tablets of Oxycodone (Schedule II) and discharged him. Licensee also started Patient M on DHEA, 50 mg, increased his Thyroid medication and failed to investigate the elevated testosterone level. Repeat labs for Patient M continued to reflect normal TSH values and elevated testosterone levels. Patient N, a 39-year-old male, initially presented to Licensee complaining of a tear in his left patellar ligament that he sustained from playing basketball. Licensee referred him to an orthopedic surgeon. At the initial visit on January 29, 2013, Licensee discussed stem cell therapy with Patient N, to include information that the procedure was experimental and investigational and performed a mini liposculpture, processed the extracted fat and blood, and injected it into Patient N's left knee in the patellar tendon and into the right knee. On February 28, 2013, Licensee injected platelet rich plasma into Patient N's left knee. These procedures were not medically indicated and subjected these patients to an unnecessary risk of harm. Licensee describes the stem cell therapy to patients as "experimental and investigational" but did not establish any Institutional Review Board for oversight of any experimental or investigational treatment that he provided. Licensee failed to document appropriate investigational protocol such as: patient selection criteria, data

collection and analysis, appropriate outcome evaluation, or adverse event reporting, among others.

4.

CONCLUSIONS OF LAW

4.1 Licensee's conduct, as described above, breached well recognized standards of practice and ethics of the medical profession. It is difficult to provide a summary of Licensee's acts of misconduct in view of their scope and the risk of harm that they presented to the public. Suffice it to say that Licensee engaged in multiple acts that placed his patients at serious risk of harm and made false and misleading statements to his patients regarding his skill and the efficacy of certain medications or therapies that he offered. He also engaged in multiple acts of unethical conduct. Licensee treated patients with forms of therapy that are not efficacious and exposed patients to the risk of adverse side effects without obtaining their informed consent. Licensee also advised a patient to cease taking medication prescribed by that patient's primary care physician (PCP) without prior coordination with the PCP medical practice or advising the patient of the risks associated with discontinuing the medication, and thereby unnecessarily exposed this patient to the risk of harm. Licensee prescribed testosterone to patients that were not medically indicated. Licensee treated with hydrogen peroxide without appropriate documentation and without adequate support in the chart. Licensee also failed to recognize life threatening health conditions while pursuing his quackery, and subjected his patients to forms of treatment that were not FDA approved under the guise of participating in a "study" that was potentially harmful.

4.2 The Board concludes that Licensee's conduct violated ORS 677.190(1)(a) unprofessional or dishonorable conduct, as defined in ORS 677.188(4)(a), (b), and (c); ORS 677.190(9) making statements that licensee knows or should know are false or misleading regarding skill or the efficacy or value of medicine or remedy prescribed or administered by the licensee or at the direction of the licensee in the treatment of any disease or condition of the human body; and ORS 677.190(13) gross or repeated acts of negligence.

4.3 Based upon its examination of the record in this case, the Board finds that each alleged violation of the Medical Practice Act is supported by reliable, probative and substantial evidence.

5.

ORDER

The Board has the statutory duty to protect the public from the practice of medicine from the unprofessional conduct by persons licensed to practice medicine, ORS 677.015. Licensee has engaged in various acts of unprofessional or dishonorable conduct, made misleading statements about his treatments, therapies and self-styled studies, and engaged in multiple acts of gross or repeated acts of negligence. In order to protect the public and appropriately address his conduct, his license must be revoked and pay the maximum civil penalty and costs.

IT IS HEREBY ORDERED THAT the license of Kenneth Jay Welker, M.D., to practice medicine is revoked and the Order of Emergency Suspension is affirmed. In addition, Licensee is assessed a civil penalty of $10,000 and he is assessed the costs of the disciplinary proceedings. The civil penalty is due 90 days from the effective date of this Order. The costs are due 90 days from the date the Board issues the Bill of Costs.

The Order of Emergency Suspension terminates when the revocation of Licensee's medical license goes into effect.

The Interim Stipulated Orders of June 19, 2013, and September 9, 2013, terminate when the revocation of Licensee's medical license goes into effect.

DATED this 2nd day of October, 2014.

OREGON MEDICAL BOARD
State of Oregon

SIGNATURE REDACTED

DONALD GIRARD, MD
BOARD CHAIR

APPEAL

If you wish to appeal the final order, you must file a petition for review with the Oregon Court of Appeals within 60 days after this default final order is served upon you. *See* ORS 183.480 et seq.

CERTIFICATE OF MAILING

On, October 8, 2014, I mailed the foregoing Default Final Order regarding Kenneth Jay Welker, MD, to the following parties:

By: First Class Certified/Return Receipt U.S. Mail
Certified Mail Receipt # 7014 1200 0000 8349 9217

Kenneth Jay Welker, MD
501 Elk Drive
Cottage Grove, OR 97424

By: UPS GROUND

Warren Foote
Department of Justice
1162 Court St NE
Salem OR 97301

Beverly Loder
Beverly Loder
Investigations Secretary
Oregon Medical Board

BEFORE THE

OREGON MEDICAL BOARD

STATE OF OREGON

In the Matter of:	)	
	)	
WELKER, KENNETH JAY, MD	)	BILL OF COSTS
License No. MD22731	)	
	)	

1.

On October 2, 2014, the Oregon Medical Board (Board) issued a Default Final Order in the matter of Kenneth Jay Welker, MD (Licensee). In this Order, Licensee was assessed the costs related to the disciplinary proceedings. This payment is due within 90 days from the date the Bill of Costs is mailed by the Board.

2.

The State of Oregon, by and through its Oregon Medical Board, claims costs related to disciplinary proceedings in the above-captioned case as follows:

Total Dept. of Justice costs	$	5,197.70
Rate: $ 159.00/hr – AAG hours: 23.2		3,688.80
$ 79.00/hr – Paralegal hours: 19.1		1,508.90
TOTAL COSTS DUE:	**$**	**5,197.70**

The above costs are certified as a correct accounting of actual costs related to the disciplinary proceedings in this matter.

Dated this 29th of December, 2014

OREGON MEDICAL BOARD
State of Oregon

SIGNATURE REDACTED

KATHLEEN HALEY, JD
EXECUTIVE DIRECTOR