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STATE OF WISCONSIN
BEFORE THE DENTISTRY EXAMINING BOARD

IN THE MATTER OF THE DISCIPLINARY PROCEEDINGS AGAINST	:	FINAL DECISION AND ORDER
RICHARD L. VANDER HEYDEN, DDS, RESPONDENT.	:	Case No. LS0312302DEN

Division of Enforcement Case File No. 97 DEN 123

PARTIES

The parties in this matter under § 227.44, Stats., and for purposes of review under § 227.53, Stats., are:

Richard L. Vander Heyden, DDS
2313 South Webster Avenue
Green Bay, WI 54301

Dentistry Examining Board
P.O. Box 8935
Madison, WI 53708-8935

Department of Regulation and Licensing
Division of Enforcement
P.O. Box 8935
Madison, WI 53708-8935

This proceeding was commenced by the filing of a Notice of Hearing and Complaint on December 30 , 2003. The Answer was filed on February 4, 2004. The hearing was held on April 3, April 25 and May 2, 2003. The hearing transcript was filed on June 8-9, 2004. Closing arguments were filed by July 27, 2004. Attorney James E. Polewski appeared on behalf of the Department of Regulation and Licensing, Division of Enforcement. Dr. Vander Heyden appeared pro se in this matter.

Based upon the record herein, the Administrative Law Judge recommends that the Dentistry Examining Board adopt as its final decision in this matter the following Findings of Fact, Conclusions of Law and Order.

FINDINGS OF FACT

1. Richard L. Vander Heyden (d.o.b., 08/27/53), 2313 South Webster Avenue, Green Bay, WI, is licensed to practice dentistry by the state of Wisconsin pursuant to license #5002025, which was first granted on June 9, 1978.

2. In December of 1988, Dr. Vander Heyden started providing dental care to Patient KP and continued to provide dental care to her for about 8 years.

3. Patient KP is trained as a registered nurse. She has an associate degree in Registered Nursing and a bachelor's degree in Psychology and Human Development.

4. Patient KP saw Dr. Vander Heyden to see if she was reacting to the resin fillings in her teeth. Dr. Vander Heyden told Patient KP that he felt she was reacting to the resins, and that the resins needed to come out. Eventually, he replaced the resin fillings with an intermediary restorative material (IRM). His plan was to restore her teeth with pure porcelain cast material.

5. At various times during the time period relevant to the Complaint filed in this matter, Dr. Vander Heyden used an EAV (electro-acupuncture according to Voll) device in his dental practice that was referred to either as the "Dermatron" or as

the "Intero". Both machines measure skin resistance and both are used to perform EAV testing. The Intero is a computer system that has information stored in it and also has measuring capabilities. The Dermatron is just a measuring device. EAV is a general term that describes the procedures and theories behind the use of EAV devices.

6. Part of Dr. Vander Heyden's initial examination of Patient KP, in December of 1988, included the use of an EAV device to see if Patient KP had an autonomic system response to the resins in her mouth.

7. When asked to describe a regular visit with Dr. Vander Heyden, Patient KP stated that most of the time he checked her, using the Dermatron, to find out if she was reacting to anything. In reference to medications, Patient KP said that Dr. Vander Heyden prescribed mostly homeopathic remedies that he made up using the Dermatron.

8. Patient KP described the Dermatron as a machine that is "kind of like a box" that has a computer screen. Dr. Vander Heyden held a metal object in his hand that he used "like a probe" on her fingers.

9. Patient KP stated that Dr. Vander Heyden made up homeopathics "off of the Dermatron" to treat her. Dr. Vander Heyden used a box to put onto the Dermatron machine, and then made the homeopathics by transferring the energy off of it into a glass bottle that contained water.

10. In addition to making the homeopathic remedies using the Dermatron, Dr. Vander Heyden also used a "black box" to make the homeopathic remedies. Patient KP stated that Dr. Vander Heyden informed her that "you put a bottle of just water on one side, and then you put in like a vial of the homeopathic to whatever you have on the other, and then the energy transfers from one to the other. And that makes up the homeopathic basically like it does on the Dermatron, only without the machine".

11. Homeopathic remedies, such as the ones that Dr. Vander Heyden used to treat Patient KP, are available in the form of "prepared solutions" or they may be made through a "serial dilution process". The serial dilution process involves taking a "mother tincture solution" and adding one part of that solution to nine parts of water and re-diluting or repeating the process until the desired potency is obtained.

12. During at least two office visits, Dr. Vander Heyden "balanced" Patient KP's spleen. Dr. Vander Heyden told Patient KP that he was putting energy into that area so it would help whatever problem that organ was having. On one occasion, Dr. Vander Heyden balanced Patient KP's spleen with the probe from the Dermatron. That provided a small "shock". On another occasion, Dr. Vander Heyden balanced Patient KP's spleen by placing his hands quickly around the spleen area. On that occasion, Dr. Vander Heyden told Patient KP that he was directing energy to that spot. Other organs that Dr. Vander Heyden "balanced" using the Dermatron or his hands, during office visits, included Patient KP's lungs, throat and colon.

13. At some point in time during Dr. Vander Heyden's treatment of Patient KP, he used an EAV device to diagnose and treat her for botulism, pneumonia, meningitis and hepatitis.

14. In January 1989, Dr. Vander Heyden provided treatment to Patient KP for bacteria and viruses. Dr. Vander Heyden, using the Dermatron, found evidence of klebsiella (bacteria), staphylococcinum (bacteria), coxsackie (virus) and cytomegalovirus (virus). Dr. Vander Heyden then made up homeopathics "off of the Dermatron" to treat them.

15. On February 6, 1989, Dr. Vander Heyden, using the Dermatron, found evidence that Patient KP had coxsackie (virus), Epstein-Barr virus, E. Coli, and klebsiella (bacteria). Using the Dermatron, Dr. Vander Heyden gave Patient KP homeopathics to treat the viruses and bacteria.

16. On February 10, 1989, Dr. Vander Heyden, using the Dermatron, diagnosed Patient KP as having Pertussin (whooping cough) and treated her with homeopathic remedies that he made.

17. On May 25, 1990, Dr. Vander Heyden, using the Dermatron, diagnosed Patient KP as having cholecystitis (inflammation of the gallbladder), chronic cholecystitis nosode, and colonitis (inflammation of the colon). Dr. Vander Heyden then gave Patient KP homeopathic remedies that he made on the Dermatron to treat those conditions.

18. On September 10, 1998, B… D… [Patient BD] saw Dr. Vander Heyden for evaluation of his dental condition and

preparation of a proposed treatment plan.

19. Dr. Vander Heyden used an EAV device on Mr. D… [Patient BD] to diagnose the existence and cause of systemic disorders, and to prepare a substance for Mr. D… [Patient BD] to ingest to treat the conditions.

20. As of April 20, 2004, the Food and Drug Administration (FDA), had issued only one 501K clearance for a Dermatron device. That clearance was granted to Raymar Electronics (England, UK) in 1989, for use of the, "Dermatron Skin Resistance Meter". The Dermatron approved by the FDA is classified as a "galvanic skin response measurement device". A galvanic skin response measurement device is defined by the FDA to mean "a device used to determine autonomic responses as psychological indicators by measuring the electrical resistance of the skin and the tissue path between two electrodes applied to the skin". Based upon guidelines issued by the FDA, the device is intended only for the measurement of skin resistance. The device should not be used for the diagnosis or treatment of any medical condition and is not approved by the FDA for such usage.

21. The EAV devices (the Dermatron/Intero) used by Dr. Vander Heyden to treat Patient KP have not been approved by the FDA for the diagnosis or treatment of systemic disorders or allergies.

22. Dr. Vander Heyden knew or should have known that the EAV device that he used was not approved for the uses to which he put it in treating Patient KP.

23. In July 2003, the Complainant, Division of Enforcement, served a Subpoena Duces Tecum ("Subpoena") on Dr. Vander Heyden in which the Division requested that Dr. Vander Heyden appear before Atty. Polewski on August 18, 2003, to answer questions relating to his treatment of Patients KP and BD.

24. The Division also requested in its Subpoena, dated July 15, 2003, that Dr. Vander Heyden produce the following documents for inspection and copying [Exhibit 4, p. 7-8]:

1. All documents related to all experimental medical-dental research conducted by Richard Vander Heyden, DDS, including:

> The names of all persons who have consented to be subjects of such research on and after January 1, 1999.
>
> The complete written thesis and protocol for each research project.
>
> The complete operation manual and all documents relating to the training completed by Richard Vander Heyden in the use of the device, for each and every electro-dermal screening device and each and every electro-acupuncture according to Voll (EAV) device used in such research projects.
>
> The complete research data collected from the participation of … KP and … BD in such research.
>
> The names, addresses, telephone numbers, and relation of all other persons Richard Vander Heyden knows to be collating, collecting, receiving, analyzing or in any other way having contact with the data from such research.

2. The originals of Richard Vander Heyden's patient records for … (KP) and ... BD.

3. All documents in the possession or control of Richard Vander Heyden related to the "Brain Wellness" technique, including all materials of whatever description received by Richard Vander Heyden during any and all training sessions in the technique, and all promotional materials related to the technique.

4. All of the diplomas, certificates, and credentials of any description relating to

Richard Vander Heyden's training in the use of homeopathy.

5. All of the diplomas, certificates, and credentials of any description relating to Richard Vander Heyden's training in the use of cranial-sacral therapy.

6. The name, address, and telephone number of each individual or entity from whom or which Richard Vander Heyden obtained possession of any electro dermal screening device, any electro-acupuncture according to Voll (EAV) device, any device for the preparation of any homeopathic remedy, and the instruction, operation, and maintenance manuals for each such device

25. On or about August 15, 2003, Dr. Vander Heyden informed the Division that he would not participate in an interview, but that he would provide written information within ten days.

26. On or about August 26, 2003, Dr. Vander Heyden delivered a document to the Division that is titled "Demurrer to Spurious Subpoena Tecum Allegedly Issued Under Authority of Wis. Stats ss. 440.03 (4) and 885.23 With Change of Authority and Competency of Issuing Official and Official Notice of Non-Waiver of Rights" (Demurrer).

27. In his Demurrer, Dr. Vander Heyden noted at least 14 objections to the information requested in the Division's Subpoena. The first seven objections noted by Dr. Vander Heyden state, in part, the following [Exhibit 4, p. 1-6]:

1. The hearing requested under color of law and authority by James E. Polewski is invalid as a matter of law in violation of Article I, Section 8 (1) of the Constitution of the State of Wisconsin (hereinafter "CSW") in that no agen[t, cy] of bureaucracy (erroneously known as "government") has authority to require a "person much less a [wo]Man created in the image and likeness of ALMIGHTY GOD, "to be compelled to testify against himself.";

2. The hearing proposed by James E. Polewski is invalid as a matter of law in violation of Article I, Section 2 of the CSW and the issuance of the subpoena to promulgate a "fishing expedition" to gather evidence to a support a future charge to be made by James E. Polewski is intended to subject the undersigned to slavery or involuntary servitude by requiring a [wo]Man created in the image and likeness of ALMIGHTY GOD to do the bidding of a shyster [1] and usurper ***apparently*** clothed with delegated authority, which authority is strictly limited by provisions of the Constitution of the united States for the United States of America (hereinafter "CUSA" and the Constitution of the State of Wisconsin which, by law, Polewski was required to swear or affirm [2] to uphold prior to entering upon the office which he has chosen to abuse (the same being conspicuous in its absence).

3. Respondent demands Polewski produce proof upon the Administrative Record of Polewski's qualifications to "practice" law; of having made and recorded the necessary and appropriate oath [s] and/or affirmations to uphold the Constitution of the united States for the United States of America and that of the State of Wisconsin; of Polewski' s qualifications to competently evaluate any "experimental medical dental research"; to evaluate collected research data relative

to electro-dermal and/or electro-acupuncture devices; to provide proof on the record of a complaining party:

4. The "requirements" made by James E. Polewski are invalid as a matter of law in violation of Article I, Section 24 of the CSW in that it assumes to impair the obligation of a private contract;

5. The "requirements" made by James E. Polewski are invalid as a matter of law in violation of Article I, Section 1 of the CSW in that its issuance deprives, and is intended to deprive, Respondent of equal protection of the laws;

6. The "requirements" made by James E. Polewski are invalid as a matter of law as in violation of Article I, Section 3 of the CSW in that they seek to require Respondent In Propria Persona, to be subjected to examination for exercise of Respondent's Right to freedom of thought and speech where no abuse of that Right had been alleged by an injured party;

7. The "requirements" made by James E. Polewski are invalid as a matter of law as in violation of the sanctity of the "doctor-patient" relationship in that they seek to require Respondent In Propria Persona, to violate the confidences of Respondent's patients and seeks to improperly interfere with the privacy of third parties who cannot lawfully be subjected to examination for association with Respondent in private contract;

28. None of the 14 objections contained in the Demurrer submitted by Dr. Vander Heyden in response to the Division's Subpoena are valid and none of the responses that he provided in the Demurrer, as described in paragraph 27 above, are relevant to the information requested in the Subpoena or to his treatment of Patients KP and BD.

CONCLUSIONS OF LAW

1. The Dentistry Examining Board has jurisdiction in this matter pursuant to s. 447.07 (3) Wis. Stats.

2. Respondent's conduct, as described in Findings of Fact 2-22 herein, in using an EAV device to diagnose systemic diseases and allergies; provide treatment for those conditions, and create homeopathic remedies for those conditions, constitutes practice beyond the scope of the practice of dentistry, in violation of s. DE 5.02 (3), Wis. Adm. Code.

3. Respondent's conduct, as described in Findings of Fact 2-22 herein, in using an EAV device to diagnose systemic diseases and allergies; provide treatment for those conditions, and create homeopathic remedies for those conditions, constitutes unprofessional conduct, in violation of s. 447.07 (3) (f), Stats.

4. Respondent's conduct in failing to cooperate with the regulation of the practice of dentistry by refusing to respond to the Division of Enforcement's request for information relating to its investigation of respondent's practices, as described in Findings of Fact 23-28 herein, constitutes a violation of s. 447.07 (3) (a), Stats.

ORDER

NOW, THEREFORE, IT IS ORDERED that the license of respondent, Richard L. Vander Heyden, D.D.S., to practice dentistry in the State of Wisconsin be and hereby is, **REVOKED**.

IT IS FURTHER ORDERED that pursuant to s. 440.22 Wis. Stats., the full cost of this proceeding shall be assessed against Respondent, and shall be payable to the Department of Regulation and Licensing.

This Order is effective on the date on which it is signed on behalf of the Dentistry Examining Board.

OPINION AND EXPLANATION OF VARIANCE

The Division of Enforcement alleges in its Complaint that by engaging in the conduct described therein, respondent violated s. 447.07 (3) (a) and (f), Wis. Stats.; s. DE 5.02 (3), Wis. Adm. Code, and 21 CFR Part 800 et seq. Dr. Vander Heyden denies that the violations occurred. Except for violations of 21 CFR Part 800 et seq., and violations relating to Patient BD, the evidence presented establishes that the violations occurred.

I. Applicable Law

447.01 Definitions. In this chapter:

(8) "Dentistry" means the examination, diagnosis, treatment, planning or care of conditions within the human oral cavity or its adjacent tissues and structures. "Dentistry" includes any of the following:

(a) Examining into the fact, condition or cause of dental health or dental disease or applying principles or techniques of dental science in the diagnosis, treatment or prevention of or prescription for any of the lesions, dental diseases, disorders or deficiencies of the human oral cavity, teeth, investing tissues, maxilla or mandible, or adjacent associated structures.

(b) Extracting human teeth or correcting their malposition.

(c) Directly or indirectly, by mail, carrier, person or any other method, furnishing, supplying, constructing, reproducing or repairing prosthetic dentures, bridges, appliances or other structures to be used or worn as substitutes for natural human teeth; or placing such substitutes in the mouth directly or indirectly or adjusting the same; or taking, making or giving advice or assistance or providing facilities for the taking or making of any impression, bite, cast or design preparatory to, or for the purpose of, or with a view to the making, producing, reproducing, constructing, fitting, furnishing, supplying, altering or repairing of any such prosthetic denture, bridge or appliance; or taking impressions for or fitting athletic mouthguards.

(d) Administering anesthetics, either general or local, while performing or claiming to perform dental services.

(e) Prescribing or administering drugs in the course of or incident to the rendition of dental services, or as part of a representation that dental services have been or will be rendered.

(f) Engaging in any of the practices, techniques or procedures included in the curricula of accredited dental schools.

(g) Penetrating, piercing or severing the tissues within the human oral cavity or adjacent associated structures. This paragraph does not apply to care or treatment rendered by a physician, as defined in s. 448.01 (5), acting within the scope of the practice of medicine and surgery, as defined in s. 448.01 (9).

(h) Developing a treatment plan for a dental patient to treat, operate, prescribe or advise for the patient by any means or instrumentality. Nothing in this paragraph prohibits a dental hygienist from participating in the development of a dental patient's dental hygiene treatment plan.

447.07 Disciplinary proceedings.

(3) Subject to the rules promulgated under s. 440.03 (1), the examining board may make investigations and conduct hearings in regard to any alleged action of any dentist or dental hygienist, or of any other person it has reason to believe is engaged in or has engaged in the practice of dentistry or dental hygiene in this state, and may, on its own motion, or upon complaint in writing, reprimand any dentist or dental hygienist who is licensed or certified under this chapter or deny, limit, suspend or revoke his or her license or certificate if it finds that the dentist or dental hygienist has done any of the following:

(a) Engaged in unprofessional conduct.

(f) Violated this chapter or any federal or state statute or rule which relates to the practice of dentistry or dental hygiene.

(7) In addition to or in lieu of a reprimand or denial, limitation, suspension or revocation of a license or certificate under sub. (3), the examining board may assess against an applicant, licensee or certificate holder a forfeiture of not more than $5,000 for each violation enumerated under sub. (3).

DE 5.02 Unprofessional conduct. Unprofessional conduct by a dentist or dental hygienist includes:

(3) Practicing or attempting to practice beyond the scope of any license or certificate.

II. Summary of Evidence

(A) Testimony of Patient KP

Patient KP is trained as a registered nurse. She has an associate degree in Registered Nursing and a bachelor's degree in Psychology and Human Development.

Patient KP testified that she started seeing Dr. Vander Heyden in December of 1988. He was her dentist for about 8 years. She met Dr. Vander Heyden through Dr. Van Allsburg, a chiropractor she was seeing at that time. Dr. Van Allsburg moved to the same building where Dr. Vander Heyden's office was located so Patient KP followed him to the new location. She said that Dr. Van Allsburg thought that she might be reacting to the resins fillings that she had in her teeth. One day when she was in Dr. Van Allsburg's office, he went over to Dr. Vander Heyden's office and brought Dr. Vander Heyden back to his office to meet her. She said that Dr. Vander Heyden wanted to check to see if she was reacting to the resin fillings, so he took her into his office and checked her out on the Dermatron. She described the Dermatron as a machine that is "kind of like a

box" and she said that there was also a computer screen. She said that Dr. Vander Heyden held a metal object in his hand that he used "like a probe" on her fingers.

Patient KP further testified that Dr. Vander Heyden told her that he felt she was reacting to the resins, and that he felt they needed to come out. She said that she agreed to let Dr. Vander Heyden take the resins out. She said that she was really sick at the time, and she felt like she wanted to try it because it might help. She said that she did not know what else to do.

Patient KP said that when she started seeing Dr. Vander Heyden, she had most of her teeth. Her wisdom teeth had been taken out and she had already had root canal work. When asked what happened to the rest of her teeth while she was seeing Dr. Vander Heyden, she said that he pulled them out. She said that in the beginning, he pulled maybe 4, 5 or 6 out, just based on when he checked her on the Dermatron. She said that Dr. Vander Heyden told her that her teeth were "dead". She said that she really wasn't having symptoms in those teeth, but he said that they needed to come out because they were dead, and that they could harm her if they were left in.

When asked to describe a regular visit with Dr. Vander Heyden, Patient KP testified that most of the time he checked her, using the Dermatron, to find out if she was reacting to anything. In reference to medications, Patient KP said that Dr. Vander Heyden prescribed mostly homeopathic remedies.

In reference to balancing her spleen, Patient KP said that Dr. Vander Heyden told her that he was putting energy into that area so it would help whatever problem that organ was having. When he balanced her spleen, he sometimes did it with the probe from the Dermatron. It would provide a small "shock". And the other times, he balanced her spleen by placing his hands quickly around her spleen area. She said that he would put his hand like on one side of it and on the other side of it. He told her that he was directing energy into that spot. Other organs that he balanced included her lungs, throat and colon. He said the purpose of balancing her organs was to help some of the problems that the organs were having.

In reference to the treatment that Dr. Vander Heyden provided to her in January 1989 for bacteria and viruses, Patient KP said that when Dr. Vander Heyden checked her out on the Dermatron, he found evidence of klebsiella (bacteria), staphylococcinum (bacteria), coxsackie (virus) and cytomegalovirus (virus). She said that Dr. Vander Heyden then made up homeopathics to treat them. According to Patient KP, Dr. Vander Heyden made the homeopathics up off of the Dermatron. She said that there was a box you could put onto the machine, and then make them up by transferring the energy off of it into a glass bottle that contained water. *Tr. p. 38-41; Exhibit 1A, p 76.*

Patient KP further testified that on February 6, 1989, Dr. Vander Heyden, using the Dermatron, found evidence of coxsackie (virus), Epstein-Barr virus, E. Coli, and klebsiella (bacteria). She said that Dr. Vander Heyden then gave her homeopathics to treat the virus and bacteria. She said that Dr. Vander Heyden told her that she had Epstein-Barr virus and that he told her to take the homeopathic that he made up. *Tr. p. 41-42; Exhibit 1A, p. 77.*

Patient KP testified that on February 10, 1989, Dr. Vander Heyden, using the Dermatron, told her that she had Pertussin (whooping cough). She said that she could not really remember back to that day, but she did not believe she had whooping cough. She said that sometimes he told her that some of the conditions could show up "like they were inherited". That you might not actually have them, "but they're still in your system, but might have been inherited from your parents and that you still needed to treat them with the homeopathics". *Tr. p. 41-42; Exhibit 1A, p. 78.*

Patient KP further testified that on May 25, 1990, Dr. Vander Heyden, using the Dermatron, diagnosed her as having cholecystitis (inflammation of the gallbladder), chronic cholecystitis nosode, and colonitis (inflammation of the colon). She said that Dr. Vander Heyden then gave her homeopathics to treat those conditions. *Tr. p. 43-46; Exhibit 1A, p. 80.*

Finally, when asked how Dr. Vander Heyden decided what remedies she needed, Patient KP testified that he used the Dermatron. She said that he did not always make his homeopathic remedies on the Dermatron. She said that he had a "black box" in another room that he used to make them (the homeopathics) up in there. She said that he told her "that you put a bottle of just water on one side, and then you put in like a vial of the homeopathic to whatever you have on the other, and then the energy transfers from one to the other. And that makes up the homeopathic basically like it does on the Dermatron, only without the machine". *Tr. p. 46.*

(B) Evidence Relating to Patient BD

(1) In General

Patient BD did not testify at the hearing and no statement signed or approved by him relating to the treatment that he received from Dr. Vander Heyden was offered into evidence.

(2) Respondent's Admission of Allegations in the Complaint

The Division argues that, based upon Dr. Vander Heyden's failure to deny the factual allegations of the complaint and his refusal to produce any evidence to rebut the allegations at his deposition when he was specifically required to bring it, the Board should find that the allegations in the Complaint are proven. *Division of Enforcement Closing Argument, p. 6-7.*

Section RL 2.09, Wis. Adm. Code reads as follows:

> **RL 2.09 Answer.** (1) An answer to a complaint shall state in short and plain terms the defenses to each cause asserted and shall admit or deny the allegations upon which the complainant relies. If the respondent is without knowledge or information sufficient to form a belief as to the truth of the allegation, the respondent shall so state and this has the effect of a denial. Denials shall fairly meet the substance of the allegations denied. The respondent shall make denials as specific denials of designated allegations or paragraphs but if the respondent intends in good faith to deny only a part or a qualification of an allegation, the respondent shall specify so much of it as true and material and shall deny only the remainder.
>
> (2) The respondent shall set forth affirmatively in the answer any matter constituting an affirmative defense.
>
> (3) Allegations in a complaint are admitted when not denied in the answer.
>
> (4) An answer to a complaint shall be filed within 20 days from the date of service of the complaint.

The Division of Enforcement alleges the following in its Complaint:

> 12. On September 10, 1998, Patient B… D… [BD] presented to Respondent for evaluation of his dental condition and preparation of a proposed treatment plan.
>
> 13. Respondent used an EAV device on Mr. D… [BD] to diagnose the existence and cause of systemic disorders, and to prepare a substance for Mr. D… [BD] to ingest to treat the conditions.
>
> 14. Respondent's use of the EAV device to diagnose any condition, determine the treatment for the condition, or produce the substances to be used in treating the condition, was in violation of the regulations governing medical devices in 21 CFR Part 800 et seq.
>
> 15. Respondent knew or should have known that the EAV device was not approved for the uses to which he put it in treating Patient KP and Patient B.. D..

16. Respondent's use of the EAV on Patient KP and Patient B … D … is unprofessional conduct as defined in s. 447.07 (3) (f), Stats.

17. Respondent's use of the EAV to diagnose systemic diseases and allergies is practice beyond the scope of his license to practice dentistry, and is unprofessional conduct defined by s. DE 5.02 (3), Wis. Admin. Code.

In paragraph 12 of his Answer, Dr. Vander Heyden denied "each and every allegation concerning any alleged violation of any statute, regulation, rule or law".

Dr. Vander Heyden's response is in essence a "general denial" of the allegations, which does not satisfy the requirement in s. RL 2.09 (1), Code. That provision requires that he make specific denials of designated allegations or paragraphs in the Complaint. In addition, Dr. Vander Heyden's response does not "fairly meet the substance of the allegations denied". Finally, subs. RL 2.09 (3), Code, states that allegations in a complaint are admitted when not denied in the answer.

Based upon Dr. Vander Heyden's failure to specifically deny the allegations contained in paragraphs 12, 13 and 15 of the Complaint, those allegations are deemed admitted.

(C) Dr. Richard L. Vander Heyden, D.D.S.

(1) Background

Dr. Vander Heyden graduated from Marquette University - School of Dentistry in 1978. He is licensed to practice dentistry by the state of Wisconsin pursuant to license #5002025, which was first granted on June 9, 1978. Dr. Vander Heyden practices dentistry in Green Bay, Wisconsin.

(2) Use of Galvanic Skin Response Measurement Devices in Dental Practice

(a) Use of EAV (Electro-Acupuncture According to Voll) Devices

Dr. Vander Heyden testified, at a deposition held on January 28, 2000, that during certain time periods between 1988 and 1999, he used either a Dermatron or an Intero device in his dental practice. Both machines measure skin resistance and both are used to perform EAV testing. The Intero is a computer system that has information stored in it and also has measuring capabilities, whereas a Dermatron is just a measuring device. According to Dr. Vander Heyden, EAV is more of a general term describing the procedures and theory behind the use of the machines. Dr. Vander Heyden said that he did not know if the Dermatron or Intero devices had been approved by the Federal Food and Drug Administration for the diagnosis and treatment of dental related problems. Hearing Exhibit 9, p. 27-29, 33.

In addition, Dr. Vander Heyden testified at a deposition held on April 23, 2004 that, starting around 1991 through the late 1990s, he was a member of the Great Lakes Association of Clinical Medicine, a professional organization of medical practitioners. While a member of the Association, Dr. Vander Heyden heard about a study that the Association was conducting relating to the use of an EAV (Electro-Acupuncture according to Voll) device. The study was referred to as the Colquitt-Regianni study. Dr. Vander Heyden inquired about the study and at some point in time agreed to participate in conducting the study. He purchased an EAV device for use in the study from Esion, a company located in Utah, for about $28,000. The device was called Interro ("Intero"). Hearing Exhibit 6, p. 9-14.

Dr. Vander Heyden testified that his role in the Interro project conducted by Colquitt and Regianni was to gather data for the research. He used information that he obtained from his treatment of several of his patients from his dental practice, including Patients KP and BD, to gather data for the study. He charged his patients between $100 and $225 for the time that he spent doing the research. He compared the patients' response on the EAV testing to the results from the Clifford materials reactivity testing. He kept records of the testing and comparison and, at some point in time, turned the patients' records of the

EAV results over to Great Lakes. In reference to the Clifford materials reactivity testing, Dr. Vander Heyden testified that the test is done to determine the immune system response to dental materials. He said that a blood sample is drawn at a doctor's office someplace and the blood sample is sent in to Clifford Diagnostics out in Colorado. He said that he used the test to determine if a person had an IGG, IGA or IGE immune system response to materials that are used in dentistry. He then printed out a computer printout of materials that would either be considered to be suitable or not suitable according to the test results. Hearing Exhibit 6, p. 4-15.

In reference to training, Dr. Vander Heyden testified that he received training in the use of EAV (electro-acupuncture according to Voll) over many years. He initially objected to disclosing where he obtained his training in the use of the EAV device, but later testified that the person who set up the Interro unit showed him how it worked. He also said that he spoke with other people who had similar devices. He admitted that his training at the Marquette University School of Dentistry did not include training in the use of electro-acupuncture machines. Hearing Exhibit 5, p. 46-51; Hearing Exhibit 6, p. 7-8; 13-14; 25-26.

In addition, Dr. Vander Heyden testified at the hearing regarding his use of the EAV in his dental practice as follows [Tr. p. 178-179]:

BY HEARING OFFICER JEFFERSON-MOORE

Q Give your statement regarding the EAV and how it's used in your office.

A Okay.

Q Or has been used or is currently being used.
A Okay. Thank you.

MR. POLEWSKI: Ma'am, are you going to give him the warning about the Fifth Amendment?

HEARING OFFICER JEFFERSON-MOORE: No. I'm not. If he wants to claim the Fifth Amendment, he has the option to do that.

MR. POLEWSKI: All right.

THE WITNESS: Thank you. The way that I use electrical acupuncture in my office is that I go through all of the established clinical means of diagnostics that we all learned in dental school, and I use many of the techniques that I learn in continuing education after. I use the electrodiagnostic as adjunct added to those, to help clarify issues like this, where we have dead teeth, where there are just not conclusive ways to determine this. That is how I use that.

By HEARING OFFICER JEFFERSON-MOORE:

Q Okay. Primarily for diagnosis --
A Yes.

Q -- treatment?
A Yes. It can also be used --

Q Not it can, but do you?

A Oh, yes, I do use it -- I'm sorry. I do use it also for determining some treatments.
Q Again, what treatments are those?

A If, indeed, a person has, for example, a tooth, as mentioned, that has cold sensitive, the homeopathic remedy for that would be what is called acute pulpitis. And I could just give acute pulpitis and see. Or you can also use the electroacupuncture device to see if the body has a response that would tend to make that more favorable. And then you can be more precise with the treatment that you're rendering to that patient.

Dr. Vander Heyden further testified during cross-examination at the hearing as follows [Tr. p. 180-181, in part]:

EXAMINATION BY MR. POLEWSKI:

Q Doctor, when I asked you -- well, this is a little difficult, but you pled the Fifth every time I asked you why you were prescribing homeopathics to K…P..; correct?

A Correct.

Q You said that you refused to answer this question on the grounds that it would incriminate you?

A No. I refused to answer it on the grounds that it could incriminate me.

Q You refused to answer on the grounds of the possibility of criminal liability?
A Yes.

Q Throughout the course of the deposition on April 23rd, you claimed the Fifth Amendment to the question, "Do you" -- the question, page 87, Line 3, "Do you deny that your use of the EAV device to create substances for treatment of systemic diseases and illnesses which you diagnosed is practice beyond the scope of your license to practice dentistry? Your answer on Line 8, "I am going to claim the Fifth Amendment not to answer that question." Correct?

A Correct.

Q There are dozens of similar questions and responses in the deposition on April 23rd, are there not?

A Yes.

Q And in each case, you refused to provide me the information which you are now saying is your defense here today; correct?

A No.

Dr. Vander Heyden's testimony during cross-examination at the hearing continued as follows [Tr. p. 181-184, in part]:

BY MR. POLEWSKI:

Q You denied that you refused to -- you refused to say whether your use of the EAV device to create substances for the treatment of K…. P…. was beyond the scope of the practice of dentistry; correct?

A Yes.

Q And it is your defense here today that your use of the EAV device was within the scope of practice of dentistry; correct?

THE WITNESS: Yes.

BY MR. POLEWSKI:

Q You refused to tell me at any point during the deposition on February of 2000 -- 2004 or the deposition of April 20, 2004, why your use of the EAV device was within the scope of the practice; correct?

A Yes.

Q Despite numerous opportunities to explain why you believed that you were appropriately practicing dentistry, you refused to give me the answer; correct?

A Yes.

BY MR. POLEWSKI:

Q You're now putting on a witness to testify to a scenario which you refused to say was what you did in practice; correct?

A Yes.

MR. POLEWSKI: Your Honor, I move for the witness currently on

the stand, Dr. Bouquot, to be excused as sanctioned for discovery violations. Dr. Vander Heyden has clearly traversed the rules of any notion of honesty or cooperation with the Tribunal.

HEARING OFFICER JEFFERSON-MOORE: Okay. I will take it under advisement. And, of course, we have to move forward and establish a record so that the Board will have a record to make a decision on.

MR. POLEWSKI: Thank you.

HEARING OFFICER JEFFERSON-MOORE: So now there is something in the record regarding your use of the EAV -- as one aspect that you used for diagnosis, so you can continue with your questions.

(b) Treatment Provided to Patient KP

Dr. Vander Heyden first saw Patient KP in December 1988. A note in the patient's treatment record, dated December 15, 1988, states "Check and test resin from Dr. Cook". Dr. Cook had previously replaced Patient KP's silver amalgam fillings with resin composite fillings. Dr. Vander Heyden performed the check and test that is referenced in the December 15, 1988 note. He used an EAV (Electroacupuncture According to Voll) machine, which he referred to as an "Intero" machine, to see if it showed an autonomic system response to the resin in Patient KP's mouth. Hearing Exhibit 9, p. 27-29.

In reference to Patient KP's treatment, Dr. Vander Heyden testified at a deposition held on January 28, 2000, as follows [Hearing Exhibit 9, p. 33-35]:

Q. So based upon your testimony, then, do I understand correctly that it would have been the Intero device that would have been used to check and test resin with … [KP] on December 15 of 1988?

A. Yes.

Q. Okay. Describe for me what an Intero device is.

A. It is a computer system. You have a handheld probe, and then you have a pointed probe, and you test certain autonomic skin response points.

Q. While you're testing, is the patient holding something?

A. Yes.

Q. What are they holding?

A. They're holding a brass cylinder in one hand.

Q. What does the brass cylinder do?

A. It provides contact to create an electrical loop.

Q. Tell me specifically what you would have done with the Intero device to check the resins in K…'s mouth on December 15th, 1988?

A. I would have checked the measurements of the lymphatic point relating to the dental area. I would have checked points relating to the allergy system and to the nerve degeneration system.

Q. What are you testing for?

A. You're testing for skin response.

Q. And what type of skin response are you looking for to determine whether the resins are an appropriate filling material?

A. A change in a meter reading.

Q. And what did you find after you performed those tests?

A. It appeared that K… was reacting to the resins that Dr. Cook had placed.

Q. Did that reaction create symptoms?

A. Yes.

Q. And what symptoms would she have been experiencing that you would believe constituted a reaction to the resins?

A. Pain in the teeth.

Q. Were you trying to determine whether the reaction was coming from a source other than her teeth?

A. Yes.

Q. And what possible sources did you consider as being a cause of the pain in her teeth, other than the teeth themselves, or the tooth structure itself?

A. Myofascial pain, cervical vertebral referrals.

Q. And what course of treatment was then available to you after you made the determination as to the resins that you had tested?

A. The first course that I tried was to give her a homeopathic for the resin material.

Q. And what homeopathic was that?

A. I'm blanking on the name. It's a specific homeopathic for resins.

(3) Use of Homeopathic Remedies in Dental Practice

Dr. Vander Heyden used the EAV device to diagnose and treat Patient KP for numerous systemic diseases including, but not limited to, botulism, pneumonia, meningitis, hepatitis, Epstein-Barr virus, pertussin (whooping cough), cholecystitis (inflammation of the gallbladder), chronic cholecystitis nosode and colonitis (inflammation of the colon). He also determined the treatment for the diseases that he diagnosed for Patient KP and he produced homeopathic substances to treat those

diseases. Hearing Transcript, p. 38-46; Exhibit 6, p. 77-85; Exhibit 8, p. 53-57.

At a deposition held on January 28, 2000, Dr. Vander Heyden testified that he prescribed homeopathics during the time that he treated Patient KP in his office. He said that homeopathics are made from a base substance, through a serial dilution process. When asked what is a "serial dilution process", Dr. Vander Heyden said that you take what is called a "mother tincture solution", and from that solution you take one part of that to nine parts of water and re-dilute, and continue that process. He said that during the normal course of a homeopathic treatment, you would start at a particular potency, the person would respond, and you would go to an increased potency until you get the desired effect. When asked the form of the mother tincture solution, Dr. Vander Heyden said that he pretty much used the prepared solutions. He said that, theoretically, if you are making a strep, you would have a culture of strep, and then you would start diluting it, the same way that you do like for a vaccine. Exhibit 9, p. 47-55.

At a deposition held on April 23, 2004, Dr. Vander Heyden testified that he provided Patient KP with homeopathic remedies to treat sensitivity to dental materials and to restore her mouth. He said that she had very many sensitivities and reactions to different dental materials. Examples of the homeopathic remedies that Dr. Vander Heyden provided to Patient KP include the following [Hearing Exhibit 6, page 62-74]:

(1) There is a note in the patient's chart for 4/17/89, which states: "$10 to Travelers Insurance" for "diluted mercury homeopathic drops". Dr. Vander Heyden testified that the purpose of the homeopathic drops was to desensitize Patient KP to residual mercury left in her system.

(2) Another note reads: "Natrum Mur, Natrum Phos, Merc Sulf, and Calcium CV". Dr. Vander Heyden testified that these are homeopathic remedies. Natrum Mur is a constitutional homeopathic that is related to general body types. It enhances the general energy of the body. Natrum Phos is also a constitutional remedy and has a very similar effect as Natrum Mur. Mercury Surf is a homeopathic made from mercury. He used it to detoxify mercury out of the periodontal tissues of the patient's mouth. He also said that there can be some systemic effects from the use of the Mercury Surf.

(3) A note for April 1989 reads: "EAV check, gave homeo drops for strep. hemoliticus". D. Vander Heyden testified that he did not know what he gave the strep hemoliticus for, but did indicate that it can be used to treat infections in the mouth and to treat the strep hemoliticus, which is a bacteria.

(D) <u>Testimony of Jerry Bouquot, DDS</u>

Dr. Bouquot testified at the hearing at the request of Dr. Vander Heyden. Dr. Bouquot received his D.D.S. and M.S. degrees from the University of Minnesota, with postdoctoral fellowships to the Mayo Clinic and the Royal Dental College in Copenhagen, Denmark. He is now Professor of Oral and Maxillofacial Pathology at the University of Texas Dental Branch in Houston and Director of Surgical Pathology at the dental school. He is also an Adjunct Professor of the West Virginia University School of Dentistry. Hearing Transcript, p. 136; Hearing Exhibit 11.

Dr. Bouquot testified that EAV is simply the oral points of acupuncture and acupressure. EAV relates only to the acupuncture points that are in the mouth. There may be other meridians, but the points are only in the mouth. In reference to the acupuncture points, Dr. Bouquot said that there is a plexus of nerves and blood vessels that are just beneath the skin and mucous membranes. And every once in a while, there's a hole in the facial just beneath that plexus, and those points are where the vessels and nerves go down to a lower layer. That has been pretty well-established. Hearing Transcript, p. 165-167.

When asked if oral pathology can affect the rest of the body, Dr. Bouquot said that's one of the major roles they have in oral pathology, is to keep reminding general dentists that the mouth is part of the body and can cause changes elsewhere, and elsewhere can cause changes in the mouth.

In reference to his experience with EAV, Dr. Bouquot testified that he receives
biopsies from all over the country, and he has several contributors from the West Coast who indicate on their path report that "this was EAV positive", in addition to the other information that they give him. He does not now and has never used an EAV

device in his practice and has never owned an EAV device. He also has not done any formal research on the use of EAV devices. Hearing Transcript, p. 201.

In reference to the extent of his knowledge about EAV, Dr. Bouquot testified that he went to some seminars and saw a demonstration. About 8 to 10 years ago, he attended a half day seminar which consisted of maybe an hour of hands-on-training. He also attended a short seminar at West Virginia University where the EAV device was demonstrated but he did not receive hands-on training. Hearing Transcript, p. 202-205.

III Analysis of Evidence

(A) Unprofessional Conduct

(1) Practice Outside Scope of Practice of Dentistry

(a) Allegations

The Division of Enforcement alleges in paragraphs 7-17 of its Complaint that Dr. Vander Heyden's use of the EAV device to diagnose conditions, determine treatment for those conditions and to produce substances that were used in treating those conditions is practice beyond the scope of his license to practice dentistry and is unprofessional conduct defined by s. DE 5.02 (3), Wis. Admin. Code. As it relates to Dr. Vander Heyden's treatment of Patient KP, the evidence presented establishes that the violations occurred.

(b) Applicable Law

447.01 Definitions. In this chapter:

(8) "Dentistry" means the examination, diagnosis, treatment, planning or care of conditions within the human oral cavity or its adjacent tissues and structures. “Dentistry” includes any of the following:

(a) Examining into the fact, condition or cause of dental health or dental disease or applying principles or techniques of dental science in the diagnosis, treatment or prevention of or prescription for any of the lesions, dental diseases, disorders or deficiencies of the human oral cavity, teeth, investing tissues, maxilla or mandible, or adjacent associated structures.

(b) Extracting human teeth or correcting their malposition.

(c) Directly or indirectly, by mail, carrier, person or any other method, furnishing, supplying, constructing, reproducing or repairing prosthetic dentures, bridges, appliances or other structures to be used or worn as substitutes for natural human teeth; or placing such substitutes in the mouth directly or indirectly or adjusting the same; or taking, making or giving advice or assistance or providing facilities for the taking or making of any impression, bite, cast or design preparatory to, or for the purpose of, or with a view to the making, producing, reproducing, constructing, fitting, furnishing, supplying, altering or repairing of any such prosthetic denture, bridge or appliance; or taking impressions for or fitting athletic mouthguards.

(d) Administering anesthetics, either general or local, while performing or claiming to perform dental services.

(e) Prescribing or administering drugs in the course of or incident to the rendition of dental services, or as part of a representation that dental services have been or will be rendered.

(f) Engaging in any of the practices, techniques or procedures included in the curricula of accredited dental schools.

(g) Penetrating, piercing or severing the tissues within the human oral cavity or adjacent associated structures. This paragraph does not apply to care or treatment rendered by a physician, as defined in s. 448.01 (5), acting within the scope of the practice of medicine and surgery, as defined in s. 448.01 (9).

(h) Developing a treatment plan for a dental patient to treat, operate, prescribe or advise for the patient by any means or instrumentality. Nothing in this paragraph prohibits a dental hygienist from participating in the development of a dental patient's dental hygiene treatment plan.

447.07 Disciplinary proceedings.

(3) Subject to the rules promulgated under s. 440.03 (1), the examining board may make investigations and conduct hearings in regard to any alleged action of any dentist or dental hygienist, or of any other person it has reason to believe is engaged in or has engaged in the practice of dentistry or dental hygiene in this state, and may, on its own motion, or upon complaint in writing, reprimand any dentist or dental hygienist who is licensed or certified under this chapter or deny, limit, suspend or revoke his or her license or certificate if it finds that the dentist or dental hygienist has done any of the following:

(a) Engaged in unprofessional conduct.

DE 5.02 Unprofessional conduct. Unprofessional conduct by a dentist or dental hygienist includes:

(3) Practicing or attempting to practice beyond the scope of any license or certificate.

(c) <u>Analysis of Evidence Presented</u>

(1) <u>Scope of Practice of Dentistry</u>

The scope of practice of dentistry is set forth in the definition of "dentistry" found in s. 447.01 (8), Stats. The evidence presented establishes that Dr. Vander Heyden's use of an EAV device to diagnose and treat systemic diseases and allergies was outside the scope of practice of dentistry.

(2) <u>Patient KP</u>

The evidence presented establishes that Dr. Vander Heyden engaged in conduct outside the scope of the practice of dentistry by using the EAV device to diagnose and treat Patient KP for numerous systemic diseases including, but not limited to, botulism, pneumonia, meningitis, hepatitis, Epstein-Barr virus, pertussin (whooping cough), cholecystitis (inflammation of the gallbladder), chronic cholecystitis nosode and colonitis (inflammation of the colon). The evidence also establishes that Dr. Vander Heyden determined the treatment for Patient KP for the diseases that he diagnosed and he produced homeopathic substances to treat the diseases. In addition, at some point in time during Dr. Vander Heyden's treatment of Patient KP, he used an EAV device to diagnose and treat her for botulism, pneumonia, meningitis and hepatitis.
Tr. p. 38-46; Exhibit 6, p. 77-85; Exhibit 8, p. 53-57.

(3) Patient BD

Based upon Dr. Vander Heyden's failure to specifically deny the allegations contained in paragraphs 12, 13 and 15 of the Complaint, those allegations are deemed admitted. However, in my opinion, the allegations are insufficient to establish a violation because there is a lack of specificity relating to the systemic diseases or allergies that Dr. Vander Heyden diagnosed and treated with the EAV device. As noted previously, Patient BD did not testify at the hearing.

(4) Use of EAV Device

The EAV device that Dr. Vander Heyden used to diagnose and treat Patient KP is classified by the U.S. Food and Drug Administration (FDA) as a galvanic skin response measurement device. Galvanic skin response measurement devices are intended only for the measurement of skin resistance. The devices should not be used for the diagnosis or treatment of any medical condition and has not been approved by the FDA for such usage. Hearing Exhibit 2.

(2) Refusal to Cooperate with Regulation of Respondent's Practice

(a) Allegations

The Division alleges in paragraph 21 of its Complaint that the Respondent's refusal to cooperate with the regulation of his practice of dentistry constitutes unprofessional conduct within the meaning of s. 447.07 (3) (a), Stats. The evidence presented establishes that the violations occurred.

(b) Applicable Law

447.07 Disciplinary proceedings.

(3) Subject to the rules promulgated under s. 440.03 (1), the examining board may make investigations and conduct hearings in regard to any alleged action of any dentist or dental hygienist, or of any other person it has reason to believe is engaged in or has engaged in the practice of dentistry or dental hygiene in this state, and may, on its own motion, or upon complaint in writing, reprimand any dentist or dental hygienist who is licensed or certified under this chapter or deny, limit, suspend or revoke his or her license or certificate if it finds that the dentist or dental hygienist has done any of the following:

(a) Engaged in unprofessional conduct.

(c) Analysis of Evidence Presented

The Division filed its Complaint in this matter on December 30, 2003. Prior to the filing of its Complaint, in July 2003, the Division served a Subpoena Duces Tecum ("Subpoena") on Dr. Vander Heyden in which the Division requested that Dr. Vander Heyden appear before Atty. Polewski on August 18, 2003, to answer questions relating to his treatment of Patients KP and BD. *Exhibit 4, p. 7-8*.

The Division also requested in its Subpoena that Dr. Vander Heyden produce the following documents for inspection and copying [Exhibit 4, p. 7-8]:

1. All documents related to all experimental medical-dental research conducted by Richard Vander Heyden, DDS, including:

> The names of all persons who have consented to be subjects of such research on and after January 1, 1999.
>
> The complete written thesis and protocol for each research project.
>
> The complete operation manual, and all documents relating to the training completed by Richard Vander Heyden in the use of the device, for each and every electro-dermal screening device and each and every electro-acupuncture according to Voll (EAV) device used in such research projects.
>
> The complete research data collected from the participation of … KP and … BD in such research.
>
> The names, addresses, telephone numbers, and relation of all other persons Richard Vander Heyden knows to be collating, collecting, receiving, analyzing or in any other way having contact with the data from such research.

2. The originals of Richard Vander Heyden's patient records for … (KP) and ... BD.

3. All documents in the possession or control of Richard Vander Heyden related to the "Brain Wellness" technique, including all materials of whatever description received by Richard Vander Heyden during any and all training sessions in the technique, and all promotional materials related to the technique.

4. All of the diplomas, certificates, and credentials of any description relating to Richard Vander Heyden's training in the use of homeopathy.

5. All of the diplomas, certificates, and credentials of any description relating to Richard Vander Heyden's training in the use of cranial-sacral therapy.

6. The name, address, and telephone number of each individual or entity from whom or which Richard Vander Heyden obtained possession of any electro dermal screening device, any electro-acupuncture according to Voll (EAV) device, any device for the preparation of any homeopathic remedy, and the instruction, operation, and maintenance manuals for each such device

On or about August 15, 2003, Dr. Vander Heyden informed the Division that he would not participate in an interview, but he would provide written information within ten days.

On or about August 26, 2003, Dr. Vander Heyden delivered a document to the Division that is titled "Demurrer to Spurious Subpoena Tecum Allegedly Issued Under Authority of Wis. Stats ss. 440.03 (4) and 885.23 With Change of Authority and Competency of Issuing Official and Official Notice of Non-Waiver of Rights" (Demurrer). *Exhibit 4, p. 1-6.*

In his Demurrer, Dr. Vander Heyden noted at least 14 objections to the information requested in the Subpoena. The first seven objections noted by Dr. Vander Heyden are as follows [Exhibit 4, p. 1-6]:

1. The hearing requested under color of law and authority by James E. Polewski is invalid as a matter of law in

violation of Article I, Section 8 (1) of the Constitution of the State of Wisconsin (hereinafter "CSW") in that no agen[t, cy] of bureaucracy (erroneously known as "government") has authority to require a "person much less a [wo]Man created in the image and likeness of ALMIGHTY GOD, "to be compelled to testify against himself.";

2. The hearing proposed by James E. Polewski is invalid as a matter of law in violation of Article I, Section 2 of the CSW and the issuance of the subpoena to promulgate a "fishing expedition" to gather evidence to a support a future charge to be made by James E. Polewski is intended to subject the undersigned to slavery or involuntary servitude by requiring a [wo]Man created in the image and likeness of ALMIGHTY GOD to do the bidding of a shyster [1] and usurper ***apparently*** clothed with delegated authority, which authority is strictly limited by provisions of the Constitution of the united States for the United States of America (hereinafter "CUSA" and the Constitution of the State of Wisconsin which, by law, Polewski was required to swear or affirm [2] to uphold prior to entering upon the office which he has chosen to abuse (the same being conspicuous in its absence).

3. Respondent demands Polewski produce proof upon the Administrative Record of Polewski's qualifications to "practice" law; of having made and recorded the necessary and appropriate oath [s] and/or affirmations to uphold the Constitution of the united States for the United States of America and that of the State of Wisconsin; of Polewski' s qualifications to competently evaluate any "experimental medical dental research"; to evaluate collected research data relative to electro-dermal and/or electro-acupuncture devices; to provide proof on the record of a complaining party:

4. The "requirements" made by James E. Polewski are invalid as a matter of law in violation of Article I, Section 24 of the CSW in that it assumes to impair the obligation of a private contract;

5. The "requirements" made by James E. Polewski are invalid as a matter of law in violation of Article I, Section 1 of the CSW in that its issuance deprives, and is intended to deprive, Respondent of equal protection of the laws;

6. The "requirements" made by James E. Polewski are invalid as a matter of law as in violation of Article I, Section 3 of the CSW in that they seek to require Respondent In Propria Persona, to be subjected to examination for exercise of Respondent's Right to freedom of thought and speech where no abuse of that Right had been alleged by an injured party;

7. The "requirements" made by James E. Polewski are invalid as a matter of law as in violation of the sanctity of the "doctor-patient" relationship in that they seek to require Respondent In Propria Persona, to violate the confidences of Respondent's patients and seeks to improperly interfere with the privacy of third parties who cannot lawfully be subjected to examination for association with Respondent in private contract;

1. see Blacks Law, 6 Edition, page 1380
2. see Constitution of the united States for the United States of America, Article VI, sec. 2, 3.

[Note: Footnotes 1 and 2 relate to paragraph 2 above, which is part of Dr. Vander Heyden's 14 objections.]

None of the objections contained in the Demurrer submitted by Dr. Vander Heyden are valid and none of the responses that he provided in the Demurrer are relevant to the information requested in the Subpoena or to his treatment of Patients KP and BD.

(B) <u>Violation of Related Laws</u>

(1) <u>Allegations</u>

The Division of Enforcement alleges in paragraphs 3-13, and specifically paragraphs 14-15, of its Complaint that Dr. Vander Heyden's use of the EAV device to diagnose conditions, determine treatment for those conditions and to produce substances that were used in treating those conditions violated federal regulations governing medical devices. The evidence presented does not establish that the violation occurred.

The Division of Enforcement alleges the following in paragraphs 14-15 of its Complaint:

14. Respondent's use of the EAV device to diagnose any condition, determine the treatment for the condition, or produce the substances to be used in treating the condition, was in violation of the regulations governing medical devices in 21 CFR Part 800 et. seq.

15. Respondent knew or should have known that the EAV device was not approved for the uses to which he put it in treating Patient KP and Patient … BD.

(2) Applicable Law

447.07 Disciplinary proceedings.

(3) Subject to the rules promulgated under s. 440.03 (1), the examining board may make investigations and conduct hearings in regard to any alleged action of any dentist or dental hygienist, or of any other person it has reason to believe is engaged in or has engaged in the practice of dentistry or dental hygiene in this state, and may, on its own motion, or upon complaint in writing, reprimand any dentist or dental hygienist who is licensed or certified under this chapter or deny, limit, suspend or revoke his or her license or certificate if it finds that the dentist or dental hygienist has done any of the following:

(f) Violated this chapter or any federal or state statute or rule which relates to the practice of dentistry or dental hygiene.

(3) Analysis of Evidence Presented

(A) Treatment of Patient KP

Dr. Vander Heyden testified, at a deposition held on January 28, 2000, that during certain time periods between 1988 and 1999, he used either a Dermatron or an Intero device in his dental practice. Both machines measure skin resistance and both are used to perform EAV testing. The Intero is a computer system that has information stored in it and also has measuring capabilities, whereas a Dermatron is just a measuring device. According to Dr. Vander Heyden, EAV is more of a general term describing the procedures and theory behind the use of the machines. Dr. Vander Heyden said that he did not know if the Dermatron or Intero devices had been approved by the Federal Food and Drug Administration for the diagnosis and treatment of dental related problems. Hearing Exhibit 9, p. 27-29, 33.

In addition, Dr. Vander Heyden testified at a deposition held on April 23, 2004 that, starting around 1991 through the late 1990s, he was a member of the Great Lakes Association of Clinical Medicine, a professional organization of medical practitioners. While a member of the Association, Dr. Vander Heyden heard about a study that the Association was conducting relating to the use of an EAV (Electro-Acupuncture according to Voll) device. The study was referred to as the Colquitt-Regianni study. Dr. Vander Heyden inquired about the study and at some point in time agreed to participate in conducting the study. He purchased an EAV device for use in the study from Esion, a company located in Utah, for about $28,000. The device was called Interro ("Intero"). Hearing Exhibit 6, p. 9-14.

Dr. Vander Heyden testified that his role in the Interro project conducted by Colquitt and Regianni was to gather data for the research. He used information that he obtained from his treatment of several of his patients from his dental practice, including Patients KP and BD, to gather data for the study. He charged his patients between $100 and $225 for the time that he spent doing the research. He compared the patients' response on the EAV testing to the results from the Clifford materials reactivity testing. He kept records of the testing and comparison and, at some point in time, turned the patients' records of the EAV results over to Great Lakes. In reference to the Clifford materials reactivity testing, Dr. Vander Heyden testified that the test is done to determine the immune system response to dental materials. He said that a blood sample is drawn at a doctor's office someplace and the blood sample is sent in to Clifford Diagnostics out in Colorado. He said that he used the test to determine if a person had an IGG, IGA or IGE immune system response to materials that are used in dentistry. He then printed out a computer printout of materials that would either be considered to be suitable or not suitable according to the test results. Hearing Exhibit 6, p. 4-15.

According to a representative from the FDA, no investigational device exemption (IDE) has ever been granted for the Dermatron device. Even assuming that the Colquitt-Regianni study that Dr. Vander Heyden participated in, starting around 1991 through the late 1990s, was an FDA-approved investigational study, he testified that he used an EAV device in his dental practice in 1988 prior to his participation in the study. Exhibit 2, p. 11.

Dr. Vander Heyden fist saw Patient KP in December 1988. In January 1989, Dr. Vander Heyden provided treatment to Patient KP for bacteria and viruses. Using the Dermatron, Dr. Vander Heyden found evidence of klebsiella (bacteria), staphylococcinum (bacteria), coxsackie (virus) and cytomegalovirus (virus). He then made up homeopathics "off of the Dermatron" to treat them. On February 6, 1989, Dr. Vander Heyden, using the Dermatron, found evidence that Patient KP had coxsackie (virus), Epstein-Barr virus, E. Coli, and klebsiella (bacteria). Dr. Vander Heyden then gave Patient KP homeopathics to treat the virus and bacteria. On February 10, 1989, Dr. Vander Heyden, using the Dermatron, diagnosed Patient KP as having Pertussin (whooping cough) and treated her with homeopathic remedies that he made.

(B) FDA Requirements

The EAV device that Dr. Vander Heyden used to diagnose and treat Patient KP is classified by the U.S. Food and Drug Administration (FDA) as a galvanic skin response measurement device. Exhibit 2. [1]

Galvanic skin response measurement devices are approved by the Food and Drug Administration (FDA) under 21 CFR Part 882. That regulation states, in part, as follows:

PART 882--NEUROLOGICAL DEVICES--Table of Contents

Subpart B--Neurological Diagnostic Devices

Sec. 882.1540 Galvanic skin response measurement device.

(a) Identification. A galvanic skin response measurement device is a device used to determine autonomic responses as psychological indicators by measuring the electrical resistance of the skin and the tissue path between two electrodes applied to the skin.

(b) Classification. Class II (performance standards).

1. Exhibit 2: Ruling on the admissibility of Exhibit 2 was initially reserved. The Exhibit was received into evidence on the second day of the hearing. Transcript p. 23-25; 95-102.

Based upon correspondence that the Division of Enforcement received from a representative of the FDA, the FDA has granted only one premarket clearance, under Section 510 (k) of the Federal Food, Drug, and Cosmetic Act, for a Dermatron device. The clearance for the Dermatron Skin Resistance Meter, which is classified as a galvanic skin response measurement device, was issued to Raymar Electronics (England, UK) in 1989. According to the FDA representative, galvanic skin response instruments cannot be used for the diagnosis or treatment of any medical condition and are not cleared for such usage. Exhibit 2, cover page; p. 11-12.

In addition, the FDA has determined that there is no scientific evidence that Galvanic Skin Response ("GSR") devices can be used to diagnose any particular disease. In its Galvanic Skin Response Measurement Devices Draft Guidance for 510 (K) Content, dated August 1994, the FDA included the following information relating to the intended uses of GSR devices [Exhibit 2, pages 6-10]:

V. LABELING

The file must include copies of all proposed label, labeling, and advertisements. If this material has not been developed, drafts of the text must be provided which are sufficient to describe the intended use for which the device will be promoted

and to provide adequate directions for use. GSR devices which have labeling that implies that GSR can be useful in the diagnosis of any physiological condition or disease require prescription legend pursuant to Title 21, Code of Federal Regulations, Section 801.109 (21 CFR 801.109) (enclosed). Lack of a prescription legend can affect classification.

A. Intended Uses

Preamendment GSR device devices were intended only for the measurement of skin resistance (i.e., conductance). Any other intended use diagnostic capability must be supported by valid scientific data. Documentation must describe clinical studies that utilized the subject device, the results of the study, and analysis that supports the claim of effectiveness. If a new use raises new scientific issues, then the device is a new device, i.e., it is not equivalent to preamendment GSR devices. We are not aware of any predicate GSR device that has any specific diagnostic capability, nor is there any scientific evidence that GSR devices can be used to diagnose any particular disease.

(C) Alleged Violations

The evidence presented in this case establishes that Dr. Vander Heyden used an EAV device to diagnose systemic diseases and allergies and to treat Patient KP for those conditions. However, no violation of a federal law governing medical devices has been established because the Complaint filed in this matter does not allege a violation of a specific federal law. The reference in the Complaint to "21 CFR Part 800 et seq." is too vague and does not provide Dr. Vander Heyden with a specific citation that he can refer to in order to defend against the charges.

The caption headings for Title 21 CFR Parts 800 et seq., are as follows:

Title 21--Food and Drugs

(This index contains parts 800 to 1299)
CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Part	
800	General
801	Labeling
803	Medical device reporting
806	Medical devices; reports of corrections and removals
807	Establishment registration and device listing for manufacturers and initial importers of devices
808	Exemptions from Federal preemption of State and local medical device requirements
809	In vitro diagnostic products for human use
810	Medical device recall authority
812	Investigational device exemptions
813	[Reserved]
814	Premarket approval of medical devices
820	Quality system regulation
821	Medical device tracking requirements
822	Postmarket surveillance
860	Medical device classification procedures
861	Procedures for performance standards development
862	Clinical chemistry and clinical toxicology devices
864	Hematology and pathology devices

866	Immunology and microbiology devices
868	Anesthesiology devices
870	Cardiovascular devices
872	Dental devices
874	Ear, nose, and throat devices
876	Gastroenterology-urology devices
878	General and plastic surgery devices
880	General hospital and personal use devices
882	Neurological devices
884	Obstetrical and gynecological devices
886	Ophthalmic devices
888	Orthopedic devices
890	Physical medicine devices
892	Radiology devices
895	Banned devices
898	Performance standard for electrode lead wires and patient cables

Dr. Vander Heyden would have to review the above references in order to determine which ones relate to the charges in the Complaint. There are also numerous subparts under each Part. Part 812 relates to premarket applications that are filed under section 50l of the Federal Food, Drug and Cosmetic Act. Part 814 relates to the requirements for premarket approval applications for medical devices that are filed under section 515 of the Federal Food, Drug and Cosmetic Act. Other provisions may be relevant. In addition, Dr. Vander Heyden would need to review federal statutes ("codes") that relate to the various regulations to determine which ones relate to the charges in the Complaint.

IV. Discipline And Explanation of Variance

Having found that Dr. Vander Heyden violated laws relating to the practice of dentistry, a determination must be made regarding whether discipline should be imposed, and if so, what discipline is appropriate.

The Dentistry Examining Board is authorized under s. 447.07 (3), Stats., to reprimand a dentist, or limit, suspend or revoke his or her license if it finds that the dentist has engaged in any conduct prohibited under that section including, but not limited to, unprofessional conduct.

The purposes of discipline by occupational licensing boards are to protect the public, deter other licensees from engaging in similar misconduct and to promote the rehabilitation of the licensee. State v. Aldrich, 71 Wis. 2d 206 (1976). Punishment of the licensee is not a proper consideration. State v. MacIntyre, 41 Wis. 2d 481 (1969).

The Division of Enforcement recommends that Dr. Vander Heyden's license be revoked. Dr. Vander Heyden recommends that this matter be dismissed.

The Administrative Law Judge recommended that Dr. Vander Heyden be reprimanded.

The Board has determined that revocation of licensure is the appropriate discipline. This measure is designed primarily to assure protection of the public and to deter other licensees from engaging in similar misconduct. The respondent has been found to violate the professional standards in two respects. The conduct of treatment outside the scope of practice of dentistry was ongoing for a period of up to 8 years. Considering the seriousness of these violations, the length of time of the violations and the potential harm to the public if such violations were to continue, revocation is necessary to fulfill the goals of public protection, and deterrence to other licensees.

V. Costs of the Proceeding

Section 440.22(2), Stats., provides in relevant part as follows:

In any disciplinary proceeding against a holder of a credential in which

> the department or an examining board, affiliated credentialing board or board in the department orders suspension, limitation or revocation of the credential or reprimands the holder, the department, examining board, affiliated credentialing board or board may, in addition to imposing discipline, assess all or part of the costs of the proceeding against the holder. Costs assessed under this subsection are payable to the department.

The presence of the word "may" in the statute is a clear indication that the decision whether to assess the costs of this disciplinary proceeding against the respondent is a discretionary decision on the part of the Board, and that the Board's discretion extends to the decision whether to assess the full costs or only a portion of the costs. The Administrative Law Judge's recommendation that the full costs of the proceeding be assessed is based primarily on fairness to other members of the profession.

The Department of Regulation and Licensing is a "program revenue" agency, which means that the costs of its operations are funded by the revenue received from its licensees. Moreover, licensing fees are calculated based upon costs attributable to the regulation of each of the licensed professions, and are proportionate to those costs. This budget structure means that the costs of prosecuting cases for a particular licensed profession will be borne by the licensed members of that profession. It is fundamentally unfair to impose the costs of prosecuting a few members of the profession on the vast majority of the licensees who have not engaged in misconduct. Rather, to the extent that misconduct by a licensee is found to have occurred following a full evidentiary hearing, that licensee should bear the costs of the proceeding.

This approach to the imposition of costs is supported by the practice of the Wisconsin Supreme Court, which is granted similar discretionary authority by SCR 22.24 to impose costs in attorney disciplinary hearings. The Court acknowledges the logic of imposing the cost of discipline on the offender rather than on the profession as a whole, and routinely imposes costs on disciplined respondents unless exceptional circumstances exist. In the Matter of Disciplinary Proceedings against M. Joanne Wolf, 165 Wis. 2d 1, 12, 476 N.W. 2d 878 (1991); In the Matter of Disciplinary Proceedings against Willis B. Swartwout, III, 116 Wis. 2d 380, 385, 342 N.W. 2d 406 (1984).

Dated this 13th day of July, 2005.

DENTISTRY EXAMINING BOARD

Bruce Barrette, DDS
On behalf of the Board