



Oregon

Theodore R. Kulongoski, Governor

Oregon Board of Chiropractic Examiners

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OBCE Public Session Minutes

Morrow-Crane Building
3218 Pringle Road SE, Large Conference Room
Salem, Oregon

May 17, 2007

Board Members Present

Minga Guerrero, DC, president
Michael Vissers, DC vice-President
Joyce McClure, DC, secretary
Steve Koc, DC
Cookie Parker-Kent, Public Member

Excused: Kevin Shuba, Esq. Public Member
Michael Megehee, DC

Staff Present

Dave McTeague, Exec Director
Michael Summers, Investigator
Kelly Bird, Administrative Assistant
Lori Lindley, AAG

Sandra Burns, DC (re: EPFX-SCIO)
Judith Boothby, DC (re: EPFX-SCIO)
J. Michael Burke, DC (re: IME policy)

CONVENE 1:20 p.m.

ADOPTION OF THE AGENDA - The agenda is adopted without change.

PUBLIC COMMENTS

Dr. Burns and Boothby appeared to discuss recent information regarding the EPFX-SCIO biofeedback device. See Public Discussion #4. Dr. Burke presented to discuss the Board's IME policy, discussion #6.

IN THE MATTER OF

Thomas Shleifer, DC applicant

The Board determined to Deny License. This applicant's Nevada licensed was revoked; he has not re-applied for that license. Cookie Parker-Kent moved to accept the Board's determination; Steve Koc seconded the motion. All in favor. Steve Koc, aye; Joyce McClure, aye; Michael Vissers, aye; Minga Guerrero, aye; and Cookie Parker-Kent, aye.

Case #2007-1035

The Board determined insufficient evidence to find a violation. Parker-Kent moved to accept the Board's determination; Minga Guerrero seconded the motion. Joyce McClure abstained. All in favor Steve Koc, aye; Joyce McClure, aye; Michael Vissers, aye; Minga Guerrero, aye; and Cookie Parker-Kent, aye.

Case #2007-5003 Thomas Gilliland, DC

The Board will issue a Notice of Disciplinary Action Letter of Reprimand with a requirement to complete six hours of chart note CE. Guerrero moved to accept the Board's determination. Parker-Kent seconded the motion. All in Favor. Steve Koc, aye; Joyce McClure, aye; Michael Vissers, aye; Minga Guerrero, aye; and Cookie Parker-Kent, aye.

Case #2007-1001

The Board determined case closed, however the Board will send a (non-disciplinary) letter of concern. McClure moved to accept the Board's determination Steve Koc seconded the motion. All in favor. Steve Koc, aye; Joyce McClure, aye; Michael Vissers, aye; Minga Guerrero, aye; and Cookie Parker-Kent, aye.

Case #2007-1006

The Board determined insufficient evidence to find a violation. Parker-Kent moved to accept the Board's determination; Michael Vissers seconded the motion. All in favor. Steve Koc, aye; Joyce McClure, aye; Michael Vissers, aye; Minga Guerrero, aye; and Cookie Parker-Kent, aye.

Case #2007-1008

The Board found no statutory violation; however, the Board will send a (non-disciplinary) letter of concern. Guerrero moved to accept the Board's determination; Vissers seconded the motion. All in favor. Steve Koc, aye; Joyce McClure, aye; Michael Vissers, aye; Minga Guerrero, aye; and Cookie Parker-Kent, aye.

Case #2007-1010

The Board found no statutory violation; however, the Board will send a (non-disciplinary) letter of concern. McClure moved to accept the Board's determination; Vissers seconded the motion. All in favor. Steve Koc, aye; Joyce McClure, aye; Michael Vissers, aye; Minga Guerrero, aye; and Cookie Parker-Kent, aye.

Case #2007-1014

The Board found no statutory violation. Vissers moved to accept the Board's determination; McClure seconded the motion. All in favor. Steve Koc, aye; Joyce McClure, aye; Michael Vissers, aye; Minga Guerrero, aye; and Cookie Parker-Kent, aye.

Case #2007-1015

Case closed. The Board will send a (non-disciplinary) letter of concern to the doctor. A letter will be mailed to the patient as well. Koc moved to accept the Board's determination; Parker-Kent seconded the motion. All in favor. Steve Koc, aye; Joyce McClure, aye; Michael Vissers, aye; Minga Guerrero, aye; and Cookie Parker-Kent, aye.

Case #2007-1016

The Board found no statutory violation. Guerrero moved to accept the Board's determination; Vissers seconded the motion. All in favor. Steve Koc, aye; Joyce McClure, aye; Michael Vissers, aye; Minga Guerrero, aye; and Cookie Parker-Kent, aye.

Case #2007-1017

The Board found no statutory violation. Koc moved to accept the Board's determination; McClure seconded the motion. All in favor. Steve Koc, aye; Joyce McClure, aye; Michael Vissers, aye; Minga Guerrero, aye; and Cookie Parker-Kent, aye.

Case #2007-2004

The Board determined case closed. A (non-disciplinary) letter of concern will be sent. Vissers moved to accept the Board's determination; Guerrero seconded the motion. All in favor. Steve Koc, aye; Joyce McClure, aye; Michael Vissers, aye; Minga Guerrero, aye; and Cookie Parker-Kent, aye.

Case #2007-5007 and 2007-3001 Ranan Shahar

1. The Board authorizes staff to pursue temporary restraining orders and preliminary permanent injunctions to prevent unlicensed person from continued practice in Oregon. Parker-Kent moved to accept the Board's determination; Guerrero seconded the motion. All in favor.

Steve Koc, aye; Joyce McClure, aye; Michael Vissers, aye; Minga Guerrero, aye; and Cookie Parker-Kent, aye.

2. The Board also proposed to issue a Notice of Proposed Disciplinary Action for unlicensed practice to levy a civil penalty of \$10,000 for the first violation, and \$5,000 for each of the three other violations (\$25,000 to date). Parker-Kent moved to accept the Board's determination; Koc seconded the motion. All in favor.

Steve Koc, aye; Joyce McClure, aye; Michael Vissers, aye; Minga Guerrero, aye; and Cookie Parker-Kent, aye.

3. The Board authorizes disclosure of the confidential complaint file and investigative information to sister or other regulatory organizations as a matter of public protection; Parker-Kent moved to accept the Board's determination; Guerrero seconded the motion. All in favor.

Steve Koc, aye; Joyce McClure, aye; Michael Vissers, aye; Minga Guerrero, aye; and Cookie Parker-Kent, aye.

DISCUSSION ITEMS

1. Strategic Plan discussion: Professional Competency

Joyce McClure suggests that the Board reconsider how it handles the functions of the Board (regarding the Strategic Plan). She proposed organizing a new strategic plan meeting (especially considering our new membership since the last plan was developed). The Board will tentatively schedule its September meeting for the fourth Thursday (the 27th) to be held in Central Oregon (Kah Nee Tah) We could begin the Strategic Plan Thursday evening and continue on Friday September 28th. Board members will check their calendars, and will email Dave. Dave will also begin to search for facilitators. The Board would like to invite one or two previous members for their insight.

Outcomes Based Management CE – there is concern about the availability of programs. Dr. McClure feels everyone has had enough time to prepare; folks tend to procrastinate. Board members recommend auditing (for the pain and outcomes assessment CE) during the regular license renewal. Joyce is also recommending a small note inside of license renewals to remind the licensees of the coming deadline.

Staff questions the value of the Course Evaluation form. It was originally intended to encourage licensees to think about continued competence. Omitting the use of the form would require an administrative rule change. Put the topic on the July agenda.

New licensees at the recent New Licensee Introduction (and recently graduated) asked if they need to take the outcomes assessment. There is no exception.

The current administrative rule already addresses the matter about instructors and continuing education.

2. Policy Issue: 2007 Legislative issues

The OBCE bills are moving forward without issue. The Physical Therapist scope issue has drawn some attention, but Dave believes there will be an interim discussion. We (Dr. Verne Saboe, Lori Lindley and Dave) had a meeting with the PT assn. lobbyist, the PT Board's AAG and a member of the PT board. We received a letter from the PT Board telling us "we don't do chiropractic, but thrust-force manipulation has always been in our scope of practice." Dave drafted a letter back to them. He said this is a professional association issue, but the Board has a role to play. The letter says we do not agree with the PT Boards interpretation of their scope of practice. There is a big question about their training versus chiropractic training; Dr. Saboe provided an updated comparison of DC vs. PT education. PTs do not have the same training in differential diagnosis, radiology, and the thrust force adjusting techniques, as DCs.

There is another bill that is going to pass which is an attempt to address and mediate scope of practice disputes (SB 717). The process will be facilitated by the Board of Medical Examiners. We tried to get them to change it over to the Governor's Office of Health Policy - a neutral entity, but to no avail. There will be a six member committee formed when requested. For example, there will be two chiropractors and two physical therapists, and together they appoint two neutrals. Then altogether, they come up with a report or recommendation back to the legislature. Our letter back to the PT Board and Association says we would like to participate in this process. Both the ODOC lobbyist and Dr. Saboe think we should meet during the interim to talk this out. Unless, we get better information about what the true minimum training qualifications are (and not just for PTs, but for all practitioners of thrust-force manipulation) we are going to have a hard time sorting out this issue.

The Board authorized Dave McTeague to send the letter (with minor edits) to the Physical Therapy Association Chair, and the Physical Therapy Board Vice-chair.

On another matter, the Oregon State Bar Administrative Law Division is attempting to attach a proposed contested case process to competency exam laws, like we have. They say they are concerned about due process for the licensees in that they do not have an opportunity to request a contested case hearing. (These can currently be appealed to circuit court.) They lobbied legislators and their amendment to the Naturopathic Board and Psychology Board's bills were adopted in the House Health Policy Committee. Now some of these legislators are having second thoughts about these amendments.

House Bill 2756, an expansion on workers compensation is clearing the legislature; this increases the workers compensation treatment parameters from 12/30 to 18/60 (treatments or days).

3. Policy Issue: Spinal Decompression/traction advertising claims

The Board developed some specific dos and don'ts in the advertising of chiropractic devices and procedures. It reads, "When a statement is literally false, the Court presumes that it will cause injury to a competitor." Dave presented the Board with four draft statements for policy language. A fifth statement was created with the language, "When a statement is literally false, the Board presumes that it will cause injury to a competitor (*Cf. Energy Four, Inc. v. Dornier Medical Sys., Inc. 765 F. Supp. 724, 734 (N.D. Ga 1991).*" Also, the introductory statement was edited to read, "Recent advertising issues related to spinal decompression have generated policy discussion applicable to all areas of advertising." The five new advertising policy statements were adopted unanimously.

4. Work Session: ETSDP Committee report on EPMX-SCIO device; continued

To provide responses to the Board's further questions in March 2007 about the EPMX device, Dr. Sandra Burns and Judith Boothby appeared before the Board. Dr. Guerrero re-posed the questions. "What is the IRB number on the device?" The "IRB" that is on the device is in Europe, and the FDA clearance for the biofeedback portion of the device is in the United States (the 510K number). Dr. Burns provided a list of programs on the EPMX-SCIO device. Each program is labeled indicating its allowable use, or not, in the United States. "IRB" refers to the Investigation Review Board in Europe; the designation of REG indicates that the device is approved for use in the USA. Dr. Guerrero noted that most of the programs have no FDA clearance in the United States. The European manufacturers of the device informed Burns that "the protocol for the clinical study is still being prepared and the final selection has to be performed by the investigator."

Dr. Burns also provided the Board copies of two other studies, the first performed by two women in Arizona, and researching ADHD ("The Quantum Xxroid Consciousness Interface and AD/HD Subjects). Dr. Guerrero noted a couple facts that concerned her: the unpublished study was performed on only 14 subjects (80% of whom were known by the researchers prior to the study) and there was no blind or double blind study. The second study "QX ltd Wellness Study." This study is in the computer program; it is going through the IRB study protocols; it is *in* the process (in Italy).

Dr. Burns added, "When they teach you how to use this device, they teach you how to go through protocols that take in many programs, not just the REG ones, but the IRB ones, too." She understands the U.S.'s dilemma in accepting anything foreign; she is willing to do her own IRB. Judith Boothby asked the Board to approve the device as a low risk investigational device. Once they have the Board's approval for use, then they hope the (FDA) IRB says they can study it. They cannot go through the IRB process, unless the Board identifies the use of the device as usable within the scope of practice. Dr. Guerrero asked for clarification, if non-DCs could seek IRB approval? Dr. Burns said they (personal users) are supposed to be sending their information to the European IRB. Dr. Boothby restated her point; she wants the Board to approve the device (as a low-risk investigational device) to be used in a study as part of the IRB process.

Cookie Parker-Kent asked if the device was approved by the FDA for biofeedback only? Dr. Burns said it was approved for everything on the list she provided, programs that have REG after them. She said that the approval was not for "personal use" only; what Quantum Alliance said was brokers have approved contracts and have to abide by those rules. Based on the letter submitted from Quantum Alliance, Inc., Dr. Guerrero believes that the personal use definition seems to be focusing on resale of the device, not referring to the use of the machine on others.

Dr. Guerrero clarified that FDA provides clearance, "the device will not kill people," for those portions that say REG, the rest is approved under European IRB.

Board members read letters in opposition to the adoption of the EPMX-SCIO device as investigational – letters were submitted by Drs. Guillermo Bermudez, Lester Lamm, James Aungst, and Chris Clark. Dr. Lamm said "the claims made by the inventors/manufacturers of the EPMX-SCIO device are so outrageous as to make the device immediately suspect...most of the scientific community has already turned its back on this thinly veiled radionics device..." He also provided a copy of the National Institute of Health's "Research Involving Human Subjects" and the Federal Department of Health and Human Services CFR Part 45 "Protection of Human Research Subjects," as evidence that involving patients in investigational, experimental research efforts should not be undertaken lightly and certainly

not by or through a single practitioner's office." Dr. Boothby said that human protection is covered by the U.S. FDA IRB process.

Dr. Bermudez's letter was read. He restated the ETSDP Committee's opinion about the device, "We the ETSDP committee have discussed this device at length and compromised its use as a biofeedback device. We the committee were told by the users of this device that they understand that it is ILLEGAL to use this device for diagnostic and therapeutic purposes in the U.S and that they intend to use it only as a biofeedback machine. The distribution, sale, approval and purported use of this machine has been deceptive at best, targeting those patients whom are most vulnerable in our society." He opposes use of this device for any use, including experimental.

Dr. Burns said the biofeedback includes measurements. She pointed out the REG list includes risk profiles, and gave an example of an 82 year old man she's treating, and she used the device to see what he's absorbing and not absorbing. She said that a substance he was taking reduced his stomach acid so he wasn't digesting his mineral supplements.

Dr. Aungst's letter was read, and he stated, "Radionics for use on humans may be legal in Europe and elsewhere, it is not legal in the U.S." He said that an EPPX testing function was registered with the FDA in 1990, but a proposal to register an integrated testing and therapy device was rejected by the FDA. "As far as I've been able to determine, importation of the device is legal and is purchased only from vendors outside the U.S., then shipped to the ultimate end-user. If FDA approval were otherwise, sales would be occurring within the U.S. and buyers would not have to sign an importation agreement stating, *I declare that the hardware and software are for my personal use and not for resale.*" He said this device treats (without operator control) as it tests, and that approving this device for ANY use may jeopardize the legitimate legal use of biofeedback by Oregon chiropractors. He supports a complete ban.

Dr. Chris Clark, ETSDP committee member, also provided a letter. He opposes the device and asks that "it be disallowed for use in any form and for any purpose."

Dr. Joyce McClure asked Drs. Burns and Boothby to explain exactly how the biofeedback is done with this machine, because based on the company informational website, the literature provided and the explanations they have so far given, it appears that there is not "classic biofeedback" performed wherein the patient has active control of their bodily responses as monitored by the machine, but rather the machine seems to do the work without active patient interaction. Dr. Burns responded that this machine does not do "classic biofeedback, it does Quantum biofeedback," and agreed that this does not require the consciousness of the person, which was proved by putting this on a person in a coma.

In closing, Drs. Boothby and Burns request the Board give them "clearance" to proceed with their research to do a study for the FDA approval. Dr. Burns will go to the IRB board to ask them what they want.

Dr. Vissers said he finds it difficult to approve a device so that that FDA clearance can be obtained, is like approving a drug before it is approved.

Cookie Parker-Kent said she has a problem approving a device for any use if it hasn't been approved (by the F.D.A.).

Dr. Vissers said the difficulty he has with this is that while it was reviewed earlier for classical active biofeedback, today it is “Quantum Biofeedback;” It seems that the entity keeps changing. We have a committee that is supposed to investigate this. They originally recommended this be approved for classical active biofeedback, and since then four members of this committee have written to say that this should not be approved for any type of use. He has difficulty understanding how we are supposed to approve this for investigational when it’s not even sold in the United States. He saw a video clip of this machine and was disturbed by what they are proposing that this machine can do. Most of the letters patients wrote didn’t write about standard classical feedback, they wrote about other things. We need to follow our committee. He said the Board can’t control what a physician does in their office with a machine that has all these other therapeutic and diagnostic abilities that are not allowed.

Dr. Guerrero says that an IRB can be obtained without the OBCE’s approval. Dr. Vissers said we don’t have anything in writing from the IRB regarding the SCIO machine.

After extensive discussion, Dr. Steve Koc moved the OBCE deny use of the EPPX-SCIO for any use. Michael Vissers seconded the motion. Steve Koc, aye; Joyce McClure, aye; Michael Vissers, aye, and Cookie Parker-Kent, aye. Minga Guerrero, opposed. Motion passed.

Dr. Koc also moves to reconsider the use of the device if there is new USA-FDA, or new USA-IRB clearance. Michael Vissers seconded the motion. All in favor. Parker-Kent, aye; Guerrero, aye; Koc, aye; Vissers, aye, and McClure aye.

5. Policy Issue: Laser/phototherapy for cosmetic treatments Hold over to July meeting

6. Policy Issue: IME policy clarifications

There have been suggestions made to edit the current board policy. The Board has seen in two separate complaints, the IME doctor did not make an attempt to get the full record, and made their final prognosis on incomplete records.

Both Joyce McClure and Dr. Burke provided written comment; Dr. Burke is not certain any changes are necessary. One of the simple issues is to maintain the term “independent medical examiner.” Board members agree to keep that term.

Dr. Burke thinks it is prudent for every chiropractor to request medical records if he knows they are there. Dr. Guerrero asked Dr. Burke if he thinks it’s reasonable to expect the IME to call the insurance company to tell them: “The file seems incomplete; is there more information?” Dr. Burke thinks it is an acceptable expectation. But the doctor is under some pressure to produce a report within 24-48 hours. Even if an IME has NO medical records from the treating chiropractor, it is probably not going to make much difference in my report. He can still make an opinion considering his exam and history, but he would still like to see those records.

Dr. Koc feels that the Clinical Justification rule can apply in any situation where an IME doctor is out of line, or forming unreasonable opinions. He also likes Joyce’s mention of the responsibility for retention of records in Joyce’s draft. Dr. Burke clarified that it is the keeping of our own records, i.e. his report. Members agree.

In discussing whether there should be a higher standard set for IME, Dr. Koc agrees with Dr. Burke in that it is not for this board to determine the standard of care. The Board sets the minimum standard, and

enforces that. If the legal system has a different standard, they have to battle it out there. The Board will not make any changes to the existing policy. Dr. Burke left.

7. Fee-splitting policy, Stark Laws, independent contractors etc. Hold over to July meeting

8. FCLB Report (Drs. Guerrero, McClure) Hold over to July meeting

9. Staff Report

Briefly, Dave discussed scheduling of the July board meeting; he is planning it for Portland, likely at WSCC (parking is better than the ODOT Building). Members agreed to meet in Portland.

ADJOURN 4:00 p.m.