STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504

RE: Geoffrey S. Ames, MD
Docket No.: 02-06-A-1012MD
Document: Amended Statement of Charges

Regarding your request for information about the above-named practitioner, certain information may have been withheld pursuant to Washington state laws. While those laws require that most records be disclosed on request, they also state that certain information should not be disclosed.

The following information has been withheld:

> The identity of the complainant if the person is a consumer, health care provider, or employee, pursuant to RCW 43.70.075 (Identity of Whistleblower Protected) and/or the identity of a patient, pursuant to RCW 70.02.020 (Medical Records - Health Care Information Access and Disclosure)

If you have any questions or need additional information regarding the information that was withheld, please contact:

> Adjudicative Clerk Office
> P.O. Box 47879
> Olympia, WA 98504-7879
> Phone: (360) 236-4677
> Fax: (360) 586-2171

You may appeal the decision to withhold any information by writing to the Deputy Secretary, Department of Health, P.O. Box 47890, Olympia, WA 98504-7890.

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

In the Matter of the License to Practice As a Physician and Surgeon of:	)	**Docket No. 02-06-A-1012MD**
GEOFFREY S. AMES, MD License No. MD00026961	)	FIRST AMENDED STATEMENT OF CHARGES
Respondent.	)	

The Program Manager of the Medical Quality Assurance Commission, (Commission), on designation by the Commission, makes the allegations below, which are supported by evidence contained in program case file 2001-08-0007MD. Any patients referred to in this First Amended Statement of Charges are identified in an attached Confidential Schedule.

Section 1: ALLEGED FACTS

1.1 Geoffrey S. Ames, MD, Respondent, was issued a license to practice as a physician by the state of Washington in December 1989.

1.2 On or about July 10, 2001, Respondent tested Patient One for food allergies using an electro-diagnostic device called the Life Information System Ten device (LISTEN device). Respondent later admitted to a Department of Health representative that he uses the LISTEN device to detect food allergies in patients.

1.3 The LISTEN device uses low voltage to measure galvanic skin resistance.

1.4 The LISTEN device is a medical device under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(h). A medical device may not be marketed until there is either an approved application for premarket approval, pursuant to 21 U.S.C. § 360e, or an approved application for an investigational device exemption, pursuant to 21 U.S.C. § 360j(g). There is no approved application for premarket approval or investigational device exemption for the LISTEN device.

1.5 A manufacturer is exempt from the requirements in the above paragraph if it files a pre-market notification under section 21 U.S.C. § 360(k), and the Food and Drug Administration (FDA) rules the device is "substantially equivalent" to a device already on the market. This is known as receiving "510(k) approval."

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1.6 In 1996, the FDA granted "510(k) approval" for the Digital Conductance Meter to be used for relaxation training in the biofeedback process.

1.7 The FDA has not granted "510(k) approval" for the LISTEN device.

1.8 Although a component of the LISTEN device is a digital conductance meter, the LISTEN is different in several significant respects, including using different software, and is, therefore, a new device, which must meet the requirements listed in paragraph 1.4, above.

1.9 Commercial distribution of a device prior to obtaining an approved application for premarket approval or an investigational device exemption, or receiving "510(k) approval" results in the device being adulterated under 21 U.S.C. § 351(f)(1)(B).

1.10 By receiving an adulterated device in interstate commerce, Respondent has violated 21 U.S.C. § 331(c).

1.11 Even if the "510(k) approval" for the digital conductance meter applied to the LISTEN device, Respondent did not use the digital conductance meter for its approved purpose.

1.12 The LISTEN device is a medical device under RCW 69.04.010. The use of an adulterated or misbranded device is prohibited under RCW 69.04.040(1) and (3).

1.13 On or about June 6, 2001, Respondent saw Patient One complaining of chronic fatigue. Respondent ordered urine and blood tests and hair analysis.

1.14 On or about July 10, 2001, Patient One returned to see Respondent to discuss the test results. Respondent told Patient One that the blood tests showed a number of food allergies. Respondent then used the LISTEN device on Patient One. Respondent had Patient One lie down on a table and hold his left arm straight up in the air. Respondent then asked Patient One to try to resist when Respondent attempted to push his arm down. Respondent pushed on Patient One's arm but did not push it down. Respondent then had Patient One hold a brass rod in his hand, which was connected to the LISTEN device, and typed in "eggs" into the device. Respondent asked Patient One to hold his left arm up in the air and to try to resist when Respondent attempted to push his arm down. Respondent then pushed Patient One's arm down and told Patient One that this showed he was allergic to eggs. Respondent repeated the test, but placed a piece of paper over the brass rod. When Patient One asked Respondent why he placed a piece of paper over the brass rod, Respondent told him he could emit the EMF frequency for eggs and many other foods through telepathy, so he hardly needed the device anymore.

Section 2: ALLEGED VIOLATIONS

2.1 The violations alleged in this section constitute grounds for disciplinary action, pursuant to RCW 18.130.180 and the imposition of sanctions under 18.130.160.

2.2 The facts alleged in paragraphs 1.2 through 1.14 constitute unprofessional conduct in violation of RCW 18.130.180(1), (7), and (16)which provides in part:

> (1) The commission of any act involving moral turpitude, dishonesty, or corruption relating to the practice of the person's profession, whether the act constitutes a crime or not.
>
> (4) Incompetence, negligence, or malpractice which results in injury to a patient or which creates an unreasonable risk that a patient may be harmed. The use of a nontraditional treatment by itself shall not constitute unprofessional conduct, provided that it does not result in injury to a patient or create an unreasonable risk that a patient may be harmed.
>
> (7) Violation of any state or federal statute or administrative rule regulating the profession in question, including any statute or rule defining or establishing standards of patient care or professional conduct or practice.
>
> The statutes Respondent violated are 21 U.S.C. § 331(c) and RCW 69.04.040(1) and (3), which provide as follows:
>
> > Sec. 331. - Prohibited acts
> > The following acts and the causing thereof are prohibited:
> > ...
> > (c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.
> >
> > RCW 69.04.040 Prohibited acts.
> > The following acts and the causing thereof are hereby prohibited:
> > (1) The sale in intrastate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.
> > (2) The adulteration or misbranding of any food, drug, device, or cosmetic in intrastate commerce.
> > (3) The receipt in intrastate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the sale thereof in such commerce for pay or otherwise.
>
> (16) Promotion for personal gain of any unnecessary or inefficacious drug, device, treatment, procedure or service.

Section 3: NOTICE TO RESPONDENT

The charges in this document affect the public health, safety and welfare. The Program Manager of the Commission directs that a notice be issued and served on Respondent as provided by law, giving Respondent the opportunity to defend against these charges. If Respondent fails to defend against these charges, Respondent shall be subject to discipline, pursuant to RCW 18.130.180 and the imposition of sanctions under 18.130.160.

DATED this 5th day of February, 2003.

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

Lisa Noonan
Disciplinary Manager

Keith Armstrong WSBA # 23795
Assistant Attorney General Prosecutor

FOR INTERNAL USE ONLY. INTERNAL TRACKING NUMBERS: Program No. 2001-08-0007MD

CONFIDENTIAL SCHEDULE

Geoffrey S. Ames, MD - Program Number 2001-08-0007MD

This information is confidential and is NOT to be released without the consent of the individual or individuals named herein. RCW 42.17.310(1)(d)

PATIENT ONE [redacted]

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