STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504

RE: Geoffrey S. Ames, MD
Docket No.: 02-06-A-1012MD
Document: 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	)	STATEMENT OF CHARGES
Respondent.	)	

FILED
JUL 10 2002
Adjudicative Clerk Office

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 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."

ORIGINAL

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).

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 1.12 constitute unprofessional conduct in violation of RCW 18.130.180(7), which provides in part:

> (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.

//

//

//

//

//

//

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 9th day of July, 2002.

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

Lisa Pigott
~~Marcella E. Jansen~~ Lisa Pigott
Disciplinary Manager

Jim McLaughlin
Jim McLaughlin WSBA #27349
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]

ORIGINAL