

NO. 35144-7

COURT OF APPEALS, DIVISION II
STATE OF WASHINGTON

STATE OF WASHINGTON,

Respondent/ Plaintiff,

vs.

Joyce M. Tasker
Appellants/Defendants.

11/21/06
Kz

ON APPEAL FROM THE SUPERIOR COURT OF
THURSTON COUNTY, THE HON. GARY TABOR

OPENING BRIEF OF APPELLANTS

Joyce M. Tasker, Pro Se
2279 Marble Valley Basin Rd'
Colville WA 99144-9575
(509) 684-5433

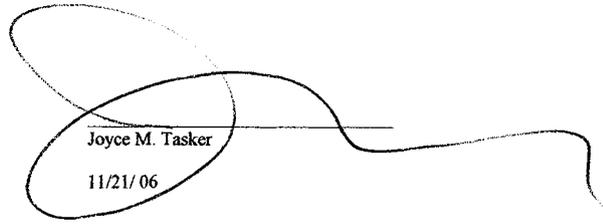
CERTIFICATE OF SERVICE

Appellant served this Opening Brief of Appellant by arranging
for its delivery or mailing to the addresses set forth below on this date.
The brief was also e-mailed to the AAG.

Richard McCartan
Assistant Attorney General
PO Box 40109
2425 Bristol Court S.W.
Olympia, WA 98504-109-

Joyce M. Tasker

11/21/06



US Express 11/21/06

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**COURT OF APPEALS, DIVISION II OF THE STATE OF
WASHINGTON**

In the Matter of the

No. 35144-7

Unlicensed Practice of Medicine

Appellant Opening Brief

and Veterinary Medicine

Joyce M. Tasker, Appellant

v

State of Washington, Respondent

Introduction

This appeal is a question of law and legislative intent not a question of fact. Because this is on appeal from a Summary Judgment, all facts asserted and substantiated here must be taken as true.

The Department of Health (DOH) is not operating according to law or according to legislative intent. It is prosecuting appellant and many safe unregulated healthcare practitioners as practicing various professions without a license in the same manner as practitioners who actually often do harm the public[SD1]. (RCW 18.71.011)

The arguments and law urged by DOH confirm precisely what DOH denies – that this case does not arise from concerns about unsafe conduct or the unlawful practice of a profession requiring state licensure. The aim of this action, as of the two other actions (*Kline v State of Washington*, No. 56886-8-1 and *Geoffrey S. Ames v Washington State Health Department Medical Quality Assurance Commission, No24896*) proceedings DOH wants this Court to be aware of, is to suppress the use

of electrodermal testing (EDT /CEDS) – no matter what kind of practitioner is using it and no matter how candid he/she may be about its acceptance or non-acceptance by establishment health care and its validation by conventional researchers. DOH pursues Tasker even though it can prove no harm to anyone from its use and cannot disprove the benefits reported by clients.

As the Court will see, the conduct DOH claims to be unsafe is simply the practice of offering and giving nutritional, dietary and homeopathic products and recommendations for Over-The-Counter products as a clerk in a store would do (an activity the FDA regulates) that are based in part on use of EDT/CEDS. DOH apparently expects this Court to believe that DOH did not error when it ignore the applicability of RCW 18.120.010 and failed to produce any evidence of harm. The DOH implies falsely that Tasker is practicing medicine and veterinary medicine because such licensed professionals allegedly may engage in similar everyday activities. Ignoring the obvious point that no reasonable person would draw such an improbable inference, the record established that Tasker expressly and repeatedly, in writing, states to her clients that she is not a licensed health professional and that her biofeedback does not take the place of care by a physician. Tasker's device measures meridian energy aka Oriental Medicine a form of medicine that is exempt from regulation

Excerpt from RCW 18.120.010:

(2) It is the **intent** [legislative intent] of this chapter that no regulation shall, after July 24, 1983, be imposed upon any health profession except for the exclusive purpose of protecting the public interest. All bills introduced in the legislature to regulate a health profession for the first time should be reviewed according to the following criteria. A health

profession should be regulated by the state only when:

(a) Unregulated practice can clearly harm or endanger the health, safety, or welfare of the public, and the potential for the harm is easily recognizable and not remote or dependent upon tenuous argument;
[Emphasis added.]

By doing this, DOH knowingly and without authority takes Tasker's property rights, the right to practice a profession; and even vital income and lives of Tasker's beloved dogs. Further DOH deprives consumers of their fundamental constitutional right to choose their own healthcare options.

DOH does not have the authority to act in contravention of a state statute or legislature when administering its provisions. If the legislative intent is clear and "plain on its face," the agencies must administer the law according to the legislative intent. The agencies cannot adopt administrative rules or administrative practices that conflict with the statutes' intent.

Assignment of Errors

- (1) The DOH erred by failing to consider or apply the plain meaning of the terms of RCW 18.120.010, which is the only statute that controls the healthcare practice of unlicensed healthcare practitioners.
- (2) The DOH erred by failing to have substantial evidence to support its findings of fact upon which it made its findings. There is no evidence in the record that Tasker provided any healthcare that

was inherently unsafe and/or caused harm to any patient or is of a type that is limited only to licensed healthcare practitioners.

(3) The DOH erred by failing to follow procedures and failing to correctly interpret statutory language. Legislative intent set out in RCW 18.120.010 is undermined by DOH in its investigation and prosecution of Tasker as well as by the lower courts(in Kline and Ames), both of which have interpreted the term "harm" used in the statute to include economic harm and/or the substitution of unlicensed health care for allopathic healthcare treatments. The statute clearly intends to only protect the public from physical harm.

(4) The DOH erred by failing to provide notice of violations of state law. Tasker was never notified of any law outside of RCW18.120.010 that she was required to comply with.

(5) The DOH erred by failing to comply with the terms of WAC 296-21-280, which authorizes unlicensed/non-physicians to use biofeedback tools to treat disease.

(6) The DOH erred by failing to give Federal regulations, which have the same preemptive effect as federal statutes, their preemptive effect on state statutes and state court orders.

(7) The DOH erred by asserting it has jurisdiction on Tribal land.

Tasker's activities on Tribal land are exempt from State law.

(8) The DOH erred by finding that it can regulate truthful statements made by Tasker and clients on the Internet. Internet speech is protected as freedom of speech over the airways.

(9) The DOH erred by pursuing a bad faith prosecution by using biased professional witnesses who are not qualified experts, as required by American Medical Association and Washington State Medical Association, but rather are representatives of special interests who benefit from the prosecution of Tasker and whose stated aim is to eradicate alternatives to conventional medicine.

Related Issues

Did the court error in its ruling in regards to legislative intent?

Does RCW 18.120.010 regulate the practice of safe healthcare?

Did the court correctly interpret statutory language?

Should the court have applied RCW 18.120.010 to Tasker as the controlling statute for her EDT/CEDS practice?

Should the law of lenity apply if it is upheld Tasker was practicing medicine and veterinary medicine?

Can the state enforce a cease and desist v. Tasker on Sovereign Tribal land and does a state cease and desist order preempt federal device regulation on federalized tribal lands?

Can the court base its order on testimony of alleged "expert" witnesses

who do not qualify as experts according to the American Medical or Washington State Medical Association standards?

Can the state forward the agenda of a special interest group by using the groups' board member as a witness to prosecute Tasker?

Can a state agency regulate freedom of speech by Tasker or testimonials by others on Tasker's Internet sites?

Should the State have regulated Tasker's profession v. prosecute?

Can a cease and desist order rest on the speculation that Tasker might cause harm at some future date?

Did the court abuse its discretion by imposing a \$10,000.00 fine when the state has brought no evidence of harm?

Did the court abuse its discretion by fining Tasker for operating on Federalized Tribal land?

Did the court violate Tasker's right to Due Process and Equal Treatment?

Facts

Tasker uses safe (CP 664) FDA approved biofeedback equipment (CP 663-666, ADR 1861-1873) that does not require licensure by the Federal Government nor the State of Washington (RCW18.120.010) (ADR 1428-1430,1434,1438-1440). A release stating that Tasker is not a licensed health care professional has always been provided to clients. (CP 679-683) Tasker's clients access physicians and veterinarians and other health professionals (ADR 1855-1856, CP 686-689). Tasker identifies non-audible sound frequencies (ADR 657) records them and the clients feeds them back to his/herself thereby completing a biofeedback loop. (CP 663, 679-680, ADR 1861-1862,1905, 1909-1911) There have never been any allegations or complaints of harm (ADR 1824-1826) vs Tasker or her technology. Tasker operated legally under RCW 18.120.010. In spite of that DOH began a prosecution of Tasker for practicing medicine without a license. Tasker also practiced on Federalized Tribal land with specific direction from Bonnie King, DOH supervisor. (CP 701)

Tasker maintains that due to lack of harm, her EDT/CEDS activities are legal and lawful in the state of Washington and on Tribal land. In spite of of Tasker's safe practice permitted under RCW 18.120.010, the DOH repeatedly contacted Tasker with challenges to her practice.

In a good faith effort Tasker constantly tried to placate the DOH by changing the language on her Internet site (www.energieswork.com) and moving her practice to Tribal sovereign land.

Arguments

A. RCW18.120.010 Controls Safe Healthcare Practice

RCW 18.120.010 allows the practice of unlicensed health care:

(regulates safe healthcare)

Excerpt from RCW 18.120.010:

(2) It is the **intent** [legislative intent] of this chapter that no regulation shall, after July 24, 1983, be imposed upon any health profession except for the exclusive purpose of protecting the public interest. All bills introduced in the legislature to regulate a health profession for the first time should be reviewed according to the following criteria. A health profession should be regulated by the state only when:

(a) Unregulated practice can clearly harm or endanger the health, safety, or welfare of the public, and the potential for the harm is easily recognizable and not remote or dependent upon tenuous argument;

[Emphasis added.]

The statute goes on to state that if harm exists, the healthcare profession should be regulated - not prosecuted.

The Department of Health and the Attorney General's Office are prosecuting safe unlicensed healthcare professionals, practicing within RCW 18.120.010 (18.120 allows all individuals to enter into a health

profession without licensing absent state's proof of harm and they also authorize substantially increasing the scope of practice for licensed healthcare practitioners in violation of legislative intent.

One of the fictions used to justify these investigations and prosecutions is a claim of harm from the alternative treatment because it delays a person getting treatment (pharmaceuticals) by a licensed physician. Such "delay" does not "clearly harm or endanger" a person, nor does such purported harm rise to the standard set out in 18.120 which is "easily recognizable. Instead, the fictions are excellent examples of speculative harm that is both "remote" and "dependent upon tenuous argument," all in violation of RCW 18.120.010(2)(a).

In RCW 18.120.010 the legislature insists on hard evidence of harm not manufactured or speculative harm. See RCW 18.120.010 (healthcare should not be regulated unless "the potential for harm is easily recognizable and not remote or dependant on tenuous argument"). In Tasker the lower courts and the DOH have only speculated on some future possibility of an undefined harm. But, if the statute and the legislative intent (stated in the statute) behind it are to be followed, then Tasker would have had to cross the safety line in order to violated 18.12.010 and be prosecuted. There is no such evidence in this case and is a material disputed fact. Under RCW 18.120.010 a showing of easily recognizable harm is the basis for a cease and desist order not whims or RCW 18.71.011. These whims have inflicted easily recognizable harm on Tasker and her beloved dogs. There has never been any even alleged case of harm caused by Tasker or her technology. Absent evidenced harm,

Tasker is operating legally in compliance with the statute that controls her profession, RCW18.120.010.

As a matter of law, the failure of the DOH to provide any evidence of harm, means there has been no violation of RCW 18.120.010 which is the applicable law in this case.

In *Kline v State of Washington, No. 56886-8-1* the court did not consider or apply RCW18.120.010, WAC 296-21-280 nor did the court benefit from the transcript of the legislative intent recorded during the enactment of the current definition of the practice of medicine. In Kline the court found that there was no harm in performing EDT/CEDS. In Tasker the same lack of demonstrated harm is true. The lack of harm clearly brings Tasker under RCW 18.120.010.

The lower court's logic (in fact, speculation) was that Tasker might cause harm in the future. This opinion violates Tasker's statutory right to practice under RCW 18.120.010 absent any proof of harm.

The safety record of Tasker's technology is documented in Kline. DOH has not provided any evidence of harm in all the years of litigation versus Kline, Tasker, Ames or any other medical doctor or practitioner they have intimidated out of practice or prosecuted for use of EDT/CEDS devices.

Even Washington State pharmacy law is constrained by RCW 18.120.010 (CP 695-696)

Although Tasker has always believed she is using her technology to record inaudible sounds/frequencies and deliver them back to client from whom

they came in compliance with FDA biofeedback regulations, (CP 663 ADR 1861-1862, 1903), the state has says Tasker is using her device “off label”. Practitioner often use devices for “off label” purposes. This is not a violation of the Food, Drug and Cosmetic Act. The fact that a device has not been cleared for a particular use does not mean it is unsafe.

Buckman Company v. Plaintiff

Legal Committee, 531 U.S. 341, 350, 121S.Ct. 1012, 1019 (2001)

recognizes wide spread “off label” use. Washington State speaks to this in WAC 296-21-280 and statutorily provides for it in RCW 18.120.010, the controlling law for safe unregulated health professions.

The state’s citation: Griffith v Department of Motor Vehicles, 23 Wn.app. 722 predates RCW 18.120.010, deals with physical childbirth and fails to confront legislative intent.

B. SAFETY: Class II devices Used By Tasker

1. Orion is Classified by FDA as Biofeedback (CP 663) (this is the same un-regulated technology permitted by WAC 296-21-280 for use by non-M.D.’s to treat disease and receive L&I reimbursement for the Procedure.

2. Asyra is Classified by FDA as Galvanic Skin Device (This is the same unregulated technology used in lie detector tests (aka galvanic skin response) and biofeedback both legally performed by non-MD’s.)

The use of Tasker's devices and recommendations for Over-The-Counter do not violate RCW 18.120.010 which is the controlling statute for safe healthcare practice in Washington State.

Biofeedback (EDT/CEDS) is not a regulated activity. It is inherently safe. (CP 667-668, ADR 1863-1868)

Products (products any retailer can recommend and sell) are inherently protected by and allowed by RCW18.120.010 and FDA. Tasker's activities do not rise to the standard of the practice of a licensed form of health care such as medicine or veterinary medicine. Tasker's device is based on Oriental Medicine and exempt from regulation. (ADR 563)

C. Legislative Intent Mandates How to Administer Statutes

Legislative intent of RCW 18.71.011 exempts drugless healing/healers and approves diagnosis by drugless healers.

(ADR 528-531,631-643)

Legislative intent is a critical part of correctly interpreting and applying a statute. The subject of statutory construction and the proper use of legislative history for both state and federal purposes is covered in the preeminent American law treatise in this area, Sutherland on Statutory Construction. In the construction of a statute the intention of the Legislature ... is to be pursued, if possible. A statute is ambiguous if: (1) it "is reasonably susceptible of different conclusions or interpretations." Coastal Barge Corp.v. Coastal Zone Indus. Control Bd., Del. Supr., 492

A.2d 1242, 1246 (1985); or (2) a literal interpretation of the words would lead to an unreasonable or absurd result that could not have been intended.

DiStefano v. Watson, Del. Supr., 566 A2d. 1,4 (1989). As the Supreme Court recently reiterated in Jackson v. Multi-Purpose Criminal Justice Facility, Del. Supr., 700 A.2d 1203, 1205 (1997):

(ADR 522-532, 563, 588-592, 631-635, 1230-1238)

Legislative Intent see also: Supreme Court of the State of Washington
Docket # 75934-1

HEATHER ANDERSEN ET AL VS KING COUNTY ET AL

The most obvious defect in DOH's interpretive method is its insistence on interpreting the language on which it focuses as if it existed by itself, assuming that to be the proper way to determine the "plain meaning" of the statute. But its refusal to consider each statute in the context of the other statutes implicated by its lawsuit directly ignores what modern – and Supreme Court-approved – linguistic theory requires. *State v. J.P.*, 149 Wash.2d 444, 450, 69 P.3d 318, 320 (2003) ("The plain meaning of a statute may be discerned 'from all that the Legislature has said in the statute and related statutes which disclose legislative intent about the provision in question.'")

Thus, for example, and contrary to accepted principles of statutory interpretation, DOH does not attempt to harmonize and reconcile the protections afforded practitioners, nutritionists and health food stores in RCW 18.36A.050, 18.118.110 and 18.06.010(1)(k), RCW 18.120.010 with the language of RCW 18.71.011 and RCW 18.92. *E.g.*, *In re Estate of Black*, 153 Wn.2d 152, 164, 102 P.3d 796, 802 (2004) ("Statutes relating to the same subject are construed together and, in 'ascertaining legislative purpose ... are to be read together as constituting a unified whole, to the end that a harmonious, total statutory scheme evolves.'")

By failing to do so, DOH in effect reads those protections out of the statutes. And, most interestingly, it does not deny that its reading would have that effect.

It does not deny that to deprive such practitioners of the right to make assessments and to recommend remedies to clients who come to them would deprive these practitioners of any meaningful function provided to them under RCW 18.120.010

The fact that scores of health care providers have been practicing for years without regulatory action by DOH is strong evidence of the meaning of that statutory scheme which DOH does not really attempt to rebut except by insisting that “diagnose” means any assessment and any test, “advice” means any advice of any kind and “condition, physical or mental” means any state or circumstance which could be described in English as a “condition” no matter the consequences or the affected parties’ expectations. The long practice of providing these unregulated health care therapies and services under RCW 18.120.010 is evidence that this statute controls safe healthcare—evidence that may be better than a dictionary—of the meaning of the relevant statutes to those most concerned with them. See *Murray v. Board of Appeals of Barnstable, supra*.

RCW18.71.011 appears to conflict with RCW18.120.010.

RCW18.71.011 appears to be in disharmony with RCW18.120.010 and 18.120’s legislative intent. Therefore, 18.71.011 is not plain on its face and can't be given meaning without its' legislative intent being considered and brought into evidence.

RCW18.120.010 is plain on its face and does not have a conflicting intent.

RCW18.120.010 must be taken plain on its face because its' legislative intent is stated clearly within its text.

In order to harmonize the RCW18.71.011 with its' intent and with RCW18.120.010 one must bring forth and evidence the legislative intent behind RCW18.71.011. Once that is done, RCW18.71.011 harmonizes with its' underlying legislative intent and cannot lead to absurd results and is in harmony with RCW18.120.011. RCW 18.71.011 can no longer be taken plain on its' face, as interpreted by DOH, because that produces absurd results and lacks harmony with other statutes and legislative intent. (i.e. rendering RCW 18.120.010 meaningless.)

RCW states that it applies to all health professions not regulated before 1983. Therefore the statute includes Tasker's practice.

EDT/CEDS is non-invasive and safe. Even after 35 years of use there is not even one *alleged* safety complaint v this biofeedback/galvanic response technology. It is based on Oriental Medicine (ADR 563)

Over-the Counter products are not considered prescriptions. If they were, then the store shelves across the state would have to be emptied and clerks would be prosecuted for suggesting OTC remedies. Therefore EDT/CEDS does not come under any state regulatory provisions. (ADR 1429-1430, CP 695-696)

According to RCW 18.120.010, if EDT/CEDS ever posed a real life bona-fide safety issue it would be incumbent upon the State to regulate not prosecute.

Many activities mentioned in the Uniform Disciplinary Act (ADR 1430-1431) performed by licensed professionals as in medicine and veterinary

medicine and countless other licensed professions do not require a license.

Many activities mentioned in the UDA in reference to a licensed profession are performed legally by unlicensed citizens. (ADR 551, 563, 1429-1430)

The UDA exempts unspecified professions. (ADR 551,570)

RCW 18.120.011 is plain and clear when it states: “ It is the intent of this chapter that no regulation shall, after July 24, 1983, be imposed upon any health profession except for the exclusive purpose of protecting the public interest.”

RCW 18.71.011 as interpreted by DOH, ALJ and Superior Court in their decisions is unconstitutionally vague.

Applying RCW 18.71 and 18.92 to prohibit Tasker’s activities conflicts with the long standing maxim that courts have a duty “to avoid rendering a statute unconstitutional by interpretation if an alternate interpretation may render it constitutional” Marriage of Ways, 85 Wn.2d 693, 703, 538 P.2d 1225 (1975) Under the court’s sweeping interpretation of 18.71 and 18.92 virtually any conduct utilizing common medical terminology or non-prescription products or dietary advice would constitute unlicensed practice Applying these statutes in such a sweeping manner renders them unconstitutionally vague and relies on Michigan vs. Washington legislative intent and statutes. People v. Rogers, 249 Mich.App.77,641 N.W.2d 595 (2001) (CP 588-593)

The legislative intent clearly exempts alternative/drugless healing from inclusion in the definition of the practice of medicine. (ADR 1239-1243)

Excerpt from 1975 legislative hearing transcript:

"Now because of that, I'm convinced we have to have alternatives to the medical profession. And I don't want to see anything in here that we think . . . that I get all these assurances now but later on to be interpreted to mean fine they can practice the drugless healing arts so long as they don't diagnose or prescribe or anything. I'm just concerned that people have options in health care and that they have some alternatives other than the medical profession. And Senator Day maybe if I can stand ____ put a question to the floor to establish ____ of everything we have just said, why we can cover ourselves as far as legislative intent." (ADR 631-646)

The Department of Health, Attorney General and even the lower courts are defining "harm" to include the delay of allopathic treatments such as pharmaceuticals. In fact, "alternative" treatments or "nontraditional" treatments contemplate use of natural agents other than pharmaceuticals whenever feasible. To interpret harm in this manner completely undermines the legislature's intent to allow "... alternatives to the medical profession" The interpretations of the plain meaning of the statute is in conflict with the legislative intent.

The ALJ Cease and Desist order ruling that the definition of the practice of medicine extends to activities based on non-medical theories is over reaching and unconstitutional. The Superior Court decision that Tasker must cease and desist in the face of the speculation of some future possibility of harm is a breach with regulatory requirement. Further, if any

harm had been established (which is not the case in Tasker),
RCW18.120.010 mandates that in the presence of real life harm, the state
is to regulate v. prosecute.

D. Rule of Lenity (statutory construction and notice of law)

The law of lenity applies to Tasker if the court finds she violated law.

Arthur Andersen LLP v United States 04-368 Supreme Court of the United States Amici Curiae 2/27/2005 Washington Legal Foundation and Chamber of Commerce of United States in Support of Petitioner:

“The court has set forth two primary reasons for the rule of lenity:
ensuring legislative supremacy and providing proper notice to the public
of what conduct is criminal.....legislatures not courts define criminal
activity.” The legislature did not intend to bring Tasker’s activities within
the scope of the Medical Practice Act. The rule of lenity is applies in this
instant case.

Lenity, a doctrine which provides that an "ambiguous criminal statute is to
be construed in favor of the accused. Where there are two rational
readings the court must turn to legislative intent. If there the court finds
ambiguity then the respondent/defendant prevails. 18.71 and 18.92 are
ambiguous when absent the intent contained in 18.120.010 and the
legislative history of 18.71. Ignorance of the law is an affirmative
defense. **Arthur Andersen LLP v United States Amici Curiae:** “ If a
statute is so expansive as to be ambiguous then lenity rules in favor of the
accused. Without lenity there is confusion and an increase in case loads.”
“Individuals and businesses need to know what they must do to comply

with the law and avoid aggressive unfair State action.” Tasker was never notified of any law outside of RCW18.120.011.

E. WAC 296-21-280

(Authorizes non-physician use of biofeedback to treat disease)

(CP 579-582, 600-602, 703-705)

“Procedures listed in the fee schedules are for use by medical doctors, osteopathic physicians, licensed psychologists and other qualified providers as determined by department policy”. The WAC lists medical conditions that L&I will pay for when providers who are not licensed physicians treat disease with biofeedback. ALJ and Superior Court orders are inconsistent with this WAC and with FDA understanding that EDT/CEDS “records” frequencies (aka EMF’s) and loops them back to the person from which they came. The WAC acknowledges that biofeedback devices are exempt from licensure. This is consistent with the FDA

Tasker’s devices are classified by the FDA as biofeedback and galvanic skin response devices that detect electromagnetic fields/sine waves.

Electromagnetic fields are ubiquitous. They are not capable of regulation. They are vibrational resonances that are **non-material, non-physical, non-chemical** vibrations that move in and out of living and inanimate objects and throughout the universe. (CP 703-704) Appellant

has not crossed the line into physical diagnosis treatment or prescribing. Electromagnetic fields are nature of everything from diseases to colors to cell phone signals and emotions. They are detectable and recordable by Class II FDA approved biofeedback devices such as Orion and Asyra.

(CP 663)

Just like a thermometer or blood pressure device recording a value, (whether by an M.D., store keeper or a neighbor) no state oversight is required or provided for in the UDA for the recording of values (nor in the material realm such as lab techs testing for physical values) of sine/sound wave/energy field recordings (sound waves).

These energy fields emanate from and exist in the physical forms of everything. In CEDS reonances are used in a biofeedback loop. They are recorded from the body and looped back to the same body from whom they came. Nothing is changed. There has simply been an informational biofeedback loop completed. A recording of non-audible frequencies is simply recorded and played back to the same client through the signal being imprinted into a tincture.

The American Medical Students Association concurs that biofeedback does not require licensing (ADR 691-694, 1901-1904)

F. Federal regulations have the same preemptive effect as federal statutes.

86 Wn. App. 898, WUTZKE v. SCHWAEGLER

[No. 16089-1-III. Division Three. July 24, 1997.]

“[5] Medical Treatment - Products Liability - Federal Preemption – Medical Devices - Factors. Whether a state law requirement is preempted by 21 U.S.C. § 360k(a), under which a state may not establish or continue a different or additional requirement relating to the safety or effectiveness of a medical device, depends upon whether (1) the state law requirement was developed specifically with respect to medical devices, (2) there is a federal requirement specific to the medical device, and (3) the state law requirement is different from or in addition to the federal requirement.

“Federal regulations have the same preemptive effect as federal statutes.”

Berger, 115 Wn.2d at 270.

The MDA preemption statute, § 360k, provides that a state may not establish or continue a different or additional "requirement" relating to the safety or effectiveness of a medical device:

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement,

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter. 21 U.S.C. § 360k (1994). «4»”

There is no state law regulating biofeedback devices. The FDA has

regulated Tasker's device as a Class II biofeedback device.

The FDA (and WAC 296-21-280) does not require licensure to operate Tasker's device.

In fact, according the WAC 296-21-280, unlicensed, non-physicians can treat diseases with biofeedback devices.

There is no Washington law regulating biofeedback. The only regulation is the WAC which is consistent with FDA and allows non-physician use even to treat disease.

The state has brought no evidence let alone the heavy burden that it preempts in any way the supremacy of the FDA Class II device regulation.

The Federal Government separates medicine as practiced by physicians from alternative practices including energetic medicine and biofeedback. (ADR 1244-1248)

G. Tribal land and Tasker's activities thereon exempt from state law

Attorney General's opinion dated 6/8/2006 (CP 706-730)

According to the AG letter of opinion dated 6/8/06 the state cannot exercise its laws on tribal property when Federal statutes (and regulations) preempt. There is no controlling Washington state interest in Tasker's use of her device on Federalized Tribal land. The FDA regulations prevail. The state has no issue with Tasker "escaping" WA law in Idaho. The state agrees Tasker can freely use her device outside of Washington State. Therefore, based on the AG letter that opines that WA law is not exercisable in Federalized tribal sovereign land. As far as DOH is

concerned Tasker should be free to use her device on tribal land. AG opinion 6/8/06 clearly defies the courts position that the cease and desist order is enforceable on tribal land. The state has no issue with Tasker “escaping” Washington law in Idaho. The state agrees Tasker can freely use her device outside of Washington State. It follows then that Tasker can use her device in Sovereign Nations such as Canada and on Sovereign Tribal land without interference from Washington State. Therefore, based on the AG letter that opines that Washington law and Washington court orders are not exercisable on federalized tribal sovereign land. Federal regulations preempt state especially in the absence of any state regulation except a WAC that permits treatment of medical conditions by non-physicians..

WUTZKE v. SCHWAEGLER

In 1992 Chief Justice Marshall gave back sovereignty to the Indian nations. Sovereignty took away the states’ mistaken concept it could exercise its’ authority over activities within another sovereign nation. The AG/DOH citations dated 1972 and 1980 are therefore obsolete and do not attend to the 1992 retrocession which nullified them. The Colville Federalized Reservation where Tasker used EDT/CEDS states its’ intent: *“To exercise its inherent sovereignty over Indian trust lands wherever situated and over all lands in which the Tribes hold a security interest of any sort.”*

The State of Washington Secretary of State acknowledges the absolute sovereignty of the Colville Nation (where Tasker practiced beginning in the Spring of 2005) by registering the Colville Tribal Services and Colville Tribal Enterprises Corporation as a Foreign Corporations. (CP 698-701)Washington

Department of Health recognizes the absolute sovereignty of the Tribal lands. Governor Gregoire concurs. (CP 701, ADR 607-609)

The state has erred in trying to prevent Tasker's device use on Tribal land and going so far as to exert a fine on her activities on Tribal land.

H. Freedom of Speech Over the Airways

U.S. 8th Circuit Court of Appeals HORNELL BREWING CO. v
SETH BIG CROW United States Court of Appeals for the eighth
Circuit NO. 97-1242

This case states that Internet speech is the same as network speech and is protected by the Constitution. The state cannot restrict Tasker's Internet speech which is broadcast from Arizona. *"We find this contention specious. Advertising outside the Reservation and on the Internet does not fall within the rubric of directly affecting the health and welfare of the Tribe. The Internet is analogous to the use of the airwaves for national broadcasts over which the Tribe can claim no proprietary interest, and it cannot be said to constitute non-Indian use of Indian land."* The reverse is also true and Tasker's site broadcast from an Arizona location is coming over the airways and is analogous to national broadcasts over which Washington State can claim no interest.

Tasker does claim the use of biofeedback, galvanic /electrical response (as in

lie detector and biofeedback tests) and the detection and transfer of

vibrational/frequency information from the client back to the client. This is corroborated by the sworn client statements provided to the DOH and AG. (ADR 1813-1818) Previously posted Internet Testimonials complied with FDA requirements at that time. (ADR 652)

Current content on Tasker's Internet site are at www.energieswork.com

I. Bad-faith Prosecution and Special Interest Influence

The State engaged in bad-faith prosecution by knowingly using biased professional witnesses who are not qualified experts, as required by the American and Washington State Medical Associations, but rather are representatives of special interests who benefit from the prosecution of Appellant. (ADR 1239-1243, 1826-1829, 1850-1854)

Quackbuster special interest group board member, Harriet Hall M.D.,(retired for over 10 years) was hired by Washington Department of Health as an "expert" witness in this EDT/CEDS case. Dr. Hall not only has no experience in alternative healthcare, but she does not have the years of practice experience in EDT/CEDS required to be an expert witness in the case. Hall was paid by the Washington Department of Health for her "expert" testimony on EDT/CDES/Biofeedback against Tasker's EDT/CEDS/biofeedback use. Hall's credentials made it clear she is an activist for a special interest group (ADR 1848-1854) and is not qualified according to the standards of the Washington State Medical

Board (and the AMA). (ADR 1889-1899, CP 595-599)

Dr. Linda Crider, a pocket-pet veterinarian in Spokane WA with no experience in EDT/CEDS, was used as a veterinary expert on veterinary EDT/CEDS and biofeedback. (Tasker's experts, Levy, Clark, Tiller and Sherman are bona-fide experts on biofeedback and/or EDT/CEDS) (ADR1239-1243, 1889-1899, 1901-1904)

Dr. Crider does not qualify as an expert in veterinary EDT/CEDS or biofeedback. On the contrary Tasker brought world renowned experts in EDT/CEDS/Biofeedback such as William Tiller and Jim Clark who both testified that EDT/CEDS is biofeedback.

(ADR 1239-1246, 1801-1804, 1853-1854 CP 600-602)

Neither of DOH's "experts" claims any expertise in EDT/CEDS. This violates American Medical Association and Washington Medical Association standards for expert testimony as well as accepted court standards. Special interest group agendas are not to be promoted by a state. In Tasker the state has furthered the agenda of a private interest group that is documented within the Hall CV and Hall's lack of qualification as an expert in biofeedback and galvanic response.

The DOH position and hiring of biased, unqualified

witnesses makes it clear to any reasonable person that these

**proceedings are an ideological attack on an alternative modality
that DOH cannot show to be unsafe. Tasker's activities are
statutorily ruled (regulated by) and protected under RCW 18.120.010.**

Tasker relied on credible experts.(ADR 1239-1243, CP 600-602)

J. Tasker's Testimony

Tasker's testimony was consistent with the opinions of the leaders in the field of EDT/CEDS, biofeedback experts and FDA. Tasker testified that non-material, non-chemical, non-physical frequencies/electromagnetic fields are recorded and she uses them in a biofeedback loop. (ADR 1905)

Tasker further stated that the testimonials that were at one time on her site were the words of clients vs her words and that those people's words are protected by the First Amendment. Smith v. Linn, 386 PaSuper. 392,563 A.2d 123 (Pa.Super. 1989) (ADR 603, CP 652)

Conclusion

**DOH has brought NO evidence that Tasker crossed the safety line
between RCW 18.120.010 and RCW 18.71.011.**

1. RCW 18.120.010 provides that unlicensed healthcare practitioners are unregulated so long as they meet the requirements of that law.
2. Only if the state presents evidence of HARM by an unlicensed practitioner can the state regulate a healthcare practice – which is to require licensing, not prosecute the practice
3. So long as an unlicensed practitioner is practicing within the parameters of RCW 18.120.010, he/she is not “practicing medicine without a license.” To the extent that RCW 18.71.011 provides otherwise (by having an overly broad definition of “practicing medicine” that includes vitamin store employees and grandmothers), it is in direct conflict with RCW 18.120.010 and the intent of that statute must prevail.

(See also Section A above)

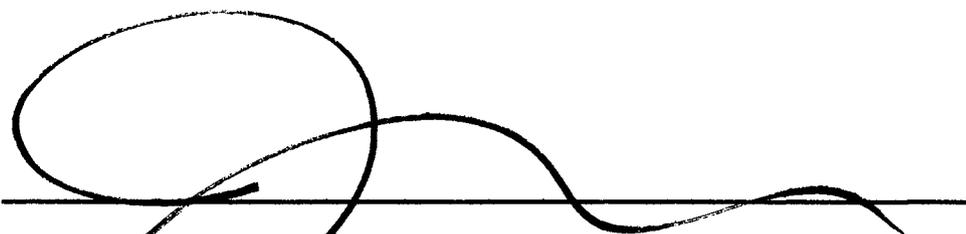
In conclusion: Under RCW 18.120.010 and WAC 296-21-280 and FDA regulations Tasker’s device and the use of it are legal and lawful in Washington State.

The state has brought no evidence of harm or violation of RCW18.120.010.

Washington State has no jurisdiction over Tasker’s EDT/CEDS activities on Federalized Tribal Land. Tasker’s Internet site cannot be constrained by the Department of Health. The state brought no credible witnesses to

this case. The state knowingly promoted the influence of a special interest group in Tasker.

Tasker requests the court reverse the decision, vacate the cease and desist order and award her reimbursement for costs and losses (costs, time and emotional).



Joyce M. Tasker, Pro Se dated: 11/ 14 /06

2279 Marble Wy. Basin Rd.
Colville WA 99114-9575
509-684-5433

*Please note that Judge Tabor
Ruling, June 26, 2006:
(RP pg. 30)*

*allowed all the Superior Court review record including exhibits
not part of the administrative record, to go forward.
Judge Tabor ordered the full record to go up on appeal.*

*(Most of the CP citations in this brief were part of the ADR.. Due to lack of
Bates Nos. pages in ADR Appellant used CP cites.)*

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