# Appendix D

# Additional Laws, Court Cases and Ethics

### I. Laws

#### A. RCW 57.08.012

- 1) RCW 57.08.012 authorizes, and the public expects, pharmaceutical grade fluoride will be added to water. RCW 57.08.012 does not authorize the addition of lead, arsenic, cadmium, radium, and other known hazardous substances contained in the industrial waste product currently added to public water. Expecting a 100% pure substance is unrealistic; however, we can do better than the scrubbings of the Chinese phosphate fertilizer companies. Hydrofluorosilicic acid does not meet EPA maximum contaminant level goals for substances such as arsenic and lead. And to no surprise, measured blood lead levels in children are higher in communities using hydrofluorosilicic acid. Pharmaceutical grade chemicals must be used for the treatment of humans.
- 2) RCW 57.08.012 does not negate the contracting of professional services provided for in RCW 57.08.005. It is reasonable for the voters and public to expect the dispensing of a poison as a legend drug should be both FDA approved substances as required in this petition.
- RCW 57.08.012 does not designate dosage. Those who 3) promote fluoridation forget that concentration is not dosage. Not everyone drinks the average amount of water. The amount (parts per million) of fluoride to be added to water must be determined based on the desired daily "dosage" of fluoride (an amount to optimize benefits and minimize risks) less the current exposure for that specific individual. Currently fluoride is arbitrarily added to achieve 1 ppm of fluoride in water without regard to desired dosage or determinations of current exposure. The World Health Organization recommends fluoride exposure from all sources be determined and the Washington Department of Health said they have not made a determination as to the exposure of fluoride for individuals in Washington. Is 1 ppm the correct dosage considering significant increases in fluoride exposure from post-harvest fumigant (SF Dowagro's Profume), fluoride pesticides, fluoride dental and medical products, etc? Or would 0.6 or 0.4 ppm be a more reasonable exposure level? FDA approval will review dosage and current exposure.
- 4) RCW 57.08.012 does not permit an unauthorized drug or substance be used. Neither the FDA nor any countries drug regulatory agency has authorized fluoride or fluoridation substances such as hydrofluorosilicic acid be used/dispensed or put in public water systems for the prevention of tooth decay.

- 5) RCW 57.08.012 does not supersede the Federal Constitution's right to "life" or that the Washington State Constitution was "established to protect and maintain individual rights." (Article I section 1) Freedom not to be medicated is protected by law. Water districts have the right to fluoridate, but they have the responsibility to get each patient's consent.
- 6) RCW 57.08.012 does not spell out how the use of police powers to medicate everyone maybe stopped or who is the legal intermediary. If the Water District Commissioners have the electors vote and a majority are in favor, can the Water District based on new evidence stop the fluoridation or is it required to go back to the electors and educate each elector on the hazards? Who pays for health damages from the fluoridation? Who pays and provides for other water sources when voters chose to follow the Centers for Disease Control's recommendation not to use fluoridated water for their baby's formula? And who is liable for the cancer death's and reduced IQ? Who is providing informed consent and who is the legal intermediary?
- 7) RCW 57.08.012 does not negate the normal and usual protocol for individual consent in research and experiments or the "practice" of medicine and dentistry. The act of fluoridation is not a passive social experimental observation and the practice of medicine is always and experiment. Fluoridation internationally is not the "standard of care." The practice of medicine and clinical care should hold standards of protection for patients and freedom of choice similar or higher than those of an experiment. The medical ethics of an experiment should be insisted upon when an unregulated, unmonitored, unevaluated and unsupervised experiment/practice removes an individual's freedom of choice.

#### B. RCW 69.41.060 Search and Seizure

"If, upon the sworn complaint of any person, it shall be made to appear to any judge of the superior or district court that there is probable cause to believe that any legend drug is being used, manufactured, sold, bartered, exchanged, given away, furnished or otherwise disposed of or kept in violation of the provisions of this chapter, such judge shall, with or without the approval of the prosecuting attorney, issue a warrant directed to any peace officer in the county, commanding the peace officer to search the premises designated and described in such complaint and warrant, and to seize all legend drugs there found, together with the vessels in which they are contained, and all implements, furniture and fixtures used or kept for the illegal manufacture, sale, barter, exchange, giving away, furnishing or otherwise disposing of such legend drugs and to safely keep the same, and to make a return of said warrant within three days, showing all acts and things done thereunder, with a particular statement of all articles seized and the name of the person or persons in whose possession the same were found, if any, and if no person be found in the possession of said articles, the returns shall so state. A copy of said warrant shall be served upon the person or persons found in possession of any such legend drugs, furniture or fixtures so seized, and if no person be found in the possession thereof, a copy of said warrant shall be posted on the door of the building or room wherein the same are found, or, if there be no door, then in any conspicuous place upon the premises.

This petition is reasonable because fluoride is a legend drug and a judge SHALL, under 69.41.060, issue a warrant to search the premises of the water supplier and seize the fluoride along with all the related property.

The term "person" is defined in 69.41.010 (15) and RCW 18.64.011(15) "Person" means individual, corporation, **government or governmental subdivision or agency**, business trust, estate, trust, partnership or association, or any other legal entity.

RCW 18.64.011(14) "Legend drugs" means any drugs which are required by any applicable federal or state law or regulation to be dispensed on prescription only or are restricted to use by practitioners only.

(15) "Manufacture" means the production, preparation, propagation, compounding, or processing of a drug or other substance or device or the packaging or repackaging of such substance or device, or the labeling or relabeling of the commercial container of such substance or device, but does not include the activities of a practitioner who, as an incident to his or her administration or dispensing such substance or device in the course of his or her professional practice, prepares, compounds, packages, or labels such substance or device

RCW 18.64.255 Authorized practices.

"Nothing in this chapter shall operate in any manner:

(1) To restrict the scope of authorized practice of any practitioner other than a pharmacist, duly licensed as such under the laws of this state. **However, a health care entity shall comply with all state and federal laws and rules relating to the dispensing of drugs and the practice** of pharmacy; or"

# II. Court Cases

Doe vs Rumsfeld, 2003.

"The central question before this Court is whether AVA is an "investigational" drug or a drug unapproved for its use against inhalation anthrax. Upon consideration of plaintiffs' motion for a preliminary injunction, the opposition, the reply, and oral arguments, as well as the statutory and case law governing the issues, and for the following reasons, it is, by the Court, hereby **ORDERED** that the Motion for a Preliminary Injunction is **GRANTED**. In the absence of a presidential waiver, defendants are enjoined from inoculating service members without their consent."

<sup>&</sup>lt;sup>1</sup> Page 2 2003 U.S. Dist. LEXIS 22990, \*3

The similarities between fluoridation and AVA are striking. The intent of both AVA and fluoridation are to prevent disease. Both were given without patient consent. Neither drug is approved for the purpose given. The FDA had not approved either AVA or fluoridation. In 1970 the NIH, then charged with approving biologic drugs, had approved AVA but not fluoridation. A licensed health care provider administered the AVA but not fluoridation. In 1985 the Federal Register published a rule recommended by the independent Biologics Review Panel that AVA be classified as safe, effective, and not misbranded. Fluoridation has not been reviewed by an independent panel. The AVA label does not specify which method of anthrax exposure it protects against and neither does the fluoridation label. . . which does not exist. Although testing has been done with AVA, it still is not FDA approved. Fluoridation has not been approved.

# **Ethics**

The ethics of Title 45 of the Federal Code states, ". . . provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence."

And the University of Washington, "... no informed consent ... may include any exculpatory language through which the subject ... is made to waive or appear to waive any of the subject's legal rights. . . the sponsor, the institution or its agents from liability for negligence." http://www.washington.edu/research/hsd/hsdman4.html

Fundamental declarations of medical ethics were laid down in 1947 after the Nurenberg trials.

1. The subject must give his or her voluntary consent, knowing the nature, direction, purpose, inconveniences, and hazards of the experiment.

Fluoridation does not provide for voluntary consent of all subjects.

2. The experiment should be necessary both in yielding fruitful results for the good of society and in the sense that the information cannot be gained without experiment.

When asked, the Washington Department of Health said they did not have any information on results of fluoridation in Washington State. And preliminary results indicate fluoridation is not yielding fruitful results either with a reduction of dental decay or reduced dental expenses.

3. The anticipated results justify doing the experiment.

Both efficacy and safety are in dispute. See Appendix E. The FDA needs to justify the experiment.

4. All unnecessary physical and mental suffering must be avoided.

See Appendix J.

5. There should be no prior reason to believe that death or injury will occur.

Historically, warnings of death or injury were ignored. Certainly fluorosis injury is well known. Current evidence gives plenty of reason to "believe" that death or injury will occur. Absolute proof is not required, simply to believe injury will occur is cause to stop the experiment or continue under the authorization of the FDA.

6. The degree of risk shall not exceed the humanitarian importance of the problem.

Fluoridation no longer appears to reduce tooth decay. See Appendix E. Without significant benefit any risk is excessive. See Appendix J.

7. Preparations should be made and adequate facilities provided against the remote possibility of adverse effects.

This code of ethics is concerned about the "remote possibility of adverse effects" not simply violent sickness or death. There is undisputed evidence adverse effects of dental fluorosis are occurring and plenty of evidence many are harmed with other diseases.

8. Those who conduct the experiment shall exercise the highest degree of skill and care and be scientifically qualified.

Fluoridation is done by water district board members most of whom have minimal scientific training and are not qualified. Most voters are not scientifically qualified. The FDA needs to review the evidence and approve the drug.

9. The subject must always be free to bring the experiment to an end.

The fluoridation experiment does not permit the subject bringing it to an end.

10. The investigator must terminate the experiment if its continuation may be detrimental to the patient."

The level of proof only needs to be to the level of "may be detrimental to the patient" and not to higher levels of probably will be detrimental or proof of harm.

Fluoridation should be both clinical research combined with a professional standard of care. The doctor must be free to use a new therapeutic measure if in his/her judgment it would alleviate suffering, but it must include obtaining the patient's freely given consent with full explanation, unless legal incapacity. At all times the doctor must be the protector of life and a legal intermediary.

Washington Supreme Court, Kaul v Chehalis, 1953.

The 5-4 split decision has strong dissenting opinions and should be carefully read. In part:

"Medication, in lay understanding, includes prophylaxis or preventive measures when applied to the individual. We hear much of preventive medicine. "The practice of medicine . . . consists of the use of drugs or medical preparations in or upon human beings, . . ." RCW 18.71.010. The Federal food, drug and cosmetic act defines the term "drugs" as ". . . articles intended for use in the diagnosis, cure, mitigation, treatment, or *prevention* of disease in man. . . ." (Italics mine.) 21 U. S. C. A. (Sup.), § 321(g). [\*\*\*29] I do not believe that respondent city would seriously contend that the prescribing of drugs for preventive purposes does not constitute practicing medicine. If, however, it is the position of respondent city and its experts that, while giving a preventive prescription is practicing medicine, the prescription, when filled, is not medicine and, when used, is not medication, they are dealing in refinements which escape the lay mind and which are not reflected in current terminology."