

No. 50022-1-II

COURT OF APPEALS, DIVISION II
OF THE STATE OF WASHINGTON

KING COUNTY CITIZENS AGAINST FLUORIDATION
a nonprofit corporation,
Appellant,

v.

WASHINGTON STATE PHARMACY QUALITY
ASSURANCE COMMISSION, an administrative agency,
Respondent.

BRIEF OF APPELLANT

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I. INTRODUCTION

Appellant, King County Citizens Against Fluoridation (“Citizens”), petitioned the Respondent, Washington State Pharmacy Quality Assurance Commission (“Commission”), for a new rule clarifying that fluoridating additives and fluoridated waters using those additives (whether bottled or public) are drugs under state laws when the intended use is prevention of tooth decay disease. (AR19-89¹) The Commission denied Citizens’ petition finding and concluding only that:

fluoridating substances used in drinking water, including bottled water, are not drugs. *Protect the Peninsula’s Future v. City of Port Angeles*, 175 Wn.App. 201, 304 P.3d 914 (2013), *rev. denied*, 178 Wn.2d 1022, 312 P.3d 651 (2013). *See also*, RCW 18.64.011(12), 69.04.008, 69.04.009, and 69.41.010(9).

(AR147-48)

The issue of whether fluoridating additives and “bottled” fluoridated waters using those additives are drugs under state law when the intended use is prevention of tooth decay disease, is an issue of first impression in Washington State.

The issue of whether fluoridating additives and municipal public fluoridated waters using those additives are drugs was addressed in *Protect the Peninsula’s Future v. City of Port Angeles* (“*Protect the Peninsula’s Future*”), 175 Wn.App. 201, 304 P.3d 914 (2013), *rev. denied*, 178 Wn.2d 1022, 312 P.3d 651 (2013). Citizens provides new evidence, not considered by the *Protect the Peninsula’s Future* Court, to rebut that Court’s conclusion that there was “binding precedent” in *Kaul v. City of Chehalis* (“*Kaul*”), 45

¹ AR19-89 refers to the Administrative Record provided to this Court at pages 19 to 89. CP refers to Clerk’s Papers and RP refers to the Verbatim Report of 2-10-17 Proceedings.

Wn.2d 616, 625, 277 P.2d 352 (1954) that fluorides² are not drugs. (See *Protect the Peninsula's Future* at 214-16 and 220)

If this Court agrees, based on the new evidence, that such “binding precedent” does not exist, then this Court should overrule, clarify, or distinguish *Protect the Peninsula's Future*. This Court should then rely on the plain language in unambiguous state statutes to conclude that fluoridated waters (bottled or public) and their fluoridating additives are drugs when the intended use is “prevention of disease.”

Alternatively, if this Court finds that such “binding precedent” exists, Citizens intends to file a Petition for Review with the State Supreme Court to overrule, clarify, or distinguish *Kaul* and *Protect the Peninsula's Future* and, if necessary, *City of Port Angeles v. Our Water-Our Choice!* (“*City of Port Angeles*”), 170 Wn.2d 1, 259 P.3d 598 (2010). The Supreme Court should then rely on the plain language in unambiguous state statutes to conclude that fluoridated waters (bottled or public) and their fluoridating additives are drugs when the intended use is “prevention of disease.” Pursuant to RAP 13.4(b)(4), such a Petition should be accepted for review because there is substantial public interest in knowing if public fluoridated waters and their fluoridating additives are drugs. There are over 3 million people in Washington State who are being served fluoridated water mostly by municipal water providers. (CP95:14-23³, AR149-53)

² In *Protect the Peninsula's Future* at 206, Note 1, the Court states it uses the term “fluorides” to refer to the Cities’ fluoride compounds and fluoridated drinking waters.

³ 14-23 in CP95:14-23 refers to lines 14-23 on page 95 of the Clerk’s Papers.

This Court should find that the Commission's denial of Citizens' Petition was "contrary to law" and/or "arbitrary or capricious" pursuant to RCW 34.05.570(4)(c)(ii) and (iii). This Court should remand to the Commission for it to take action consistent with this Court's Order. This Court should also reverse the portion of that Order at CP164-65 that strikes Paragraphs 11, 12, 13, 14, 15, and 16 of the Petition for Judicial Review. This Court should correct the errors in the trial court's Findings of Fact, Conclusions of Law, and Final Order at CP172-75, and reverse that court's decision to affirm the Commission's denial of the Petition for Rulemaking.

II. ASSIGNMENTS OF ERROR

A. Errors Of The Superior Court's Findings Of Fact, Conclusions Of Law, And Final Order At CP172-75

- No. 1.** Error in failure to find in CP172-75 that "*bottled*" fluoridated waters and their fluoridating additives are drugs under state laws when the intended use is mitigation, treatment, or prevention of tooth decay disease.
- No. 2.** Error in failure to find in CP172-75 that "*public*" fluoridated waters and their fluoridating additives are drugs under state laws when the intended use is mitigation, treatment, or prevention of tooth decay disease.
- No. 3.** Error in Finding of Fact 1.2 on CP173 in that the December 11, 2015 presentation was at a Commission meeting and not a Commission hearing.
- No. 4.** Error in Finding 1.3 on CP173 in citation to *Protect the Peninsula's Future* as being to 175 Wn.App. 2013 instead of 175 Wn.App. 201.
- No. 5.** Error in Finding 1.5 on CP173-74 that *Kaul v. City of Chehalis*, 45 Wn.2d 616, 277 P.2d 352 (1954) "held that fluoridating substances added to

drinking water are not drugs” and error in characterizing this alleged holding as “not dicta.”

No. 6. Error in Conclusion 2.3 on CP174 because said Finding 1.5 is an inaccurate characterization.

No. 7. Error in Conclusions 2.4, 2.5, 2.6, 2.7 on CP174-75 and in the Order on CP175 because *Kaul* and *Protect the Peninsula's Future* are irrelevant to bottled water, and because *Kaul* is misinterpreted by *Protect the Peninsula's Future*.

B. Error Of The Superior Court's Order At CP164-65

No. 8. Error in striking paragraphs 11 to 16 of Citizens' Petition for Judicial Review.

C. Errors Of The Commission's Decision At AR147-48

No. 1. Error in denying Petition regarding bottled drinking water because of a misinterpretation regarding RCW 69.04.008 and 69.04.009, because *Protect the Peninsula's Future* is irrelevant, and because, by the unambiguous plain language of RCW 69.04.009, former RCW 18.64.011(12), and former RCW 69.41.010(9), fluoridating additives and bottled water using those additives are drugs when the intended use is mitigation, treatment, or prevention of tooth decay disease.

No. 2. Error in denying Petition regarding public drinking water because of a misinterpretation of *Kaul* by *Protect the Peninsula's Future* and by the Commission, and because, by the unambiguous plain language of RCW 69.04.009, former RCW 18.64.011(12), and former RCW 69.41.010(9), fluoridating additives and public water using those additives are drugs when

the intended use is mitigation, treatment, or prevention of tooth decay disease.

No. 3. Error in failing to find that fluoridated waters (bottled or public) and their fluoridating additives are drugs in intrastate commerce when the intended use is mitigation, treatment, or prevention of tooth decay disease.

III. MAJOR ISSUES BEFORE THE COURT

No. 1. Are “bottled” fluoridated waters and their fluoridating additives, drugs under state law when the intended use is mitigation, treatment, or prevention of tooth decay disease? (Superior Court (“SC”) Errors 1 and 4-7; Commission (“C”) Errors 1 and 3.)

No. 2. Are “public fluoridated waters and their fluoridating additives, drugs under state law when the intended use is mitigation, treatment, or prevention of tooth decay disease? (SC Errors 2 and 4-7; C Errors 2 and 3.)

No. 3. Did the Superior Court abuse discretion when it struck from the Petition for Judicial Review allegations supporting standing (as required by RCW 34.05.530), exhaustion of administrative remedies (as required by RCW 34.05.531), and substantial prejudice (as required by RCW 34.05.570(1)(d)) when these allegations that were only required for judicial review were based on alleged facts not in the administrative record? (SC Errors 3 and 8.)

No. 4. Should the Commission’s denial of Appellant’s Petition for Rulemaking be remanded to the Commission for further proceedings? (SC Errors 1-2 and 4-7; C Errors 1-3.)

IV. STATEMENT OF THE CASE

Appellate King County Citizens Against Fluoridation (“Citizens”) submitted a Petition for Rulemaking to the Washington State Pharmacy Quality Assurance Commission (“Commission”) on October 2, 2015. (CP172:20-24) The Rulemaking Petition (AR19-89) requested that the Commission adopt a new rule to clarify that fluoridated waters (bottled and/or public) and their fluoridating additives are drugs pursuant to state statutes when the intended use is mitigation, treatment and/or prevention of dental caries disease (tooth decay, cavities). (AR19-89)

The Commission considered the Petition at its December 11, 2015 meeting⁴ during which Citizens’ attorney had 25 minutes to explain the request, present documents, make arguments, and engage in a dialogue with members of the Commission. (CP173:10-12; CP92-112) The Commission’s attorney argued:

there is a Court of Appeals decision [*Protect the Peninsula’s Future* (CP 103-04)] that has already applied the law and said fluoridating substances in drinking water are not drugs.

(CP107:17-20) Appellant’s attorney responded expressing an intent “to take this up to the Court of Appeals or Supreme Court.” (CP107:22-24)

A motion was made and seconded at the meeting to deny the Petition based on the *Protect the Peninsula’s Future* Court of Appeals decision. (CP108:12-17) The Commission passed the motion with one “no” vote. (CP110:14 to 111:2)

⁴ Not at an adjudicative hearing. (See RCW 34.05.010(1))

By letter dated January 26, 2016, the Commission's decision was communicated in writing to Citizen's attorney. (CP173:16-17) The Commission's decision states:

The Commission denies your petition for rulemaking because fluoridating substances used in drinking water, including bottled water, are not drugs. *Protect the Peninsula's Future v. City of Port Angeles*, 175 Wn.App. 201, 304 P.3d 914 (2013), *rev. denied*, 178 Wn.2d 1022, 312 P.3d 651 (2013). See also, RCW [former]18.64.011(12)⁵, 69.04.008, 69.04.009, and [former] 69.41.010(9)⁶.

(AR148)

Citizens timely filed and served a petition for judicial review under RCW 34.05.570(4) (CP4-90). (CP173:23-24) Paragraphs 1 to 18 in Section VI of the judicial petition provided "FACTS DEMONSTRATING THAT THE PETITIONER IS ENTITLED TO OBTAIN JUDICIAL REVIEW" citing to the requirement in RCW 34.05.546(6) that a judicial petition must set forth "Facts to demonstrate that the petitioner is entitled to obtain judicial review."

The Commission argued in its Response Brief (without filing a motion) that Paragraphs 8 to 17 in said Section VI should be stricken from the Petition because the Commission claimed that these paragraphs "were neither raised nor supported at the administrative hearing⁷." (CP186) Citizen's filed and served the First Declaration of Julie Simms along with Citizens' Motion to Supplement the Record with that Declaration at the same

⁵ The same language is in current RCW 18.64.011(14).

⁶ The same language is in current RCW 69.41.010(10).

⁷ The Commission held a meeting but not an adjudicative hearing. (See RCW 34.05.010(1)) No opportunity for a hearing is required for a Petition for Rulemaking. (RCW 34.05.330(1))

time that Citizen's filed and served its Reply Brief. (CP160) Citizens' argued that said Paragraphs 8 to 17 should not be stricken and that, "A trial court abuses discretion if it excludes supplemental facts necessary to satisfy prerequisites to judicial review." (CP 154-55) Nevertheless, the trial court denied Citizens' Motion to Supplement the Record with the First Declaration of Julie Simms and struck Paragraphs 11-16 in said Section VI of the judicial petition. (CP164-65)

After reviewing the record, hearing the arguments of the parties and otherwise being fully advised on the premises, the trial court on February 10, 2017 entered a Final Order with Findings of Fact and Conclusions of Law that affirmed the Commission's denial of Citizens' Petition for Rulemaking. (CP172-75) On February 24, 2017, Citizens filed and served its Notice of Appeal to Court of Appeals, Division II. (CP 170-75) In the Argument section of this brief, Citizens' will show why the Commission's January 26, 2016 decision should not be affirmed and show why the trial court should not have stricken Paragraphs 11 to 16 in Section VI of the judicial petition.

V. ARGUMENT

A. Standard Of Review

Judicial review of agency actions other than the validity of rules or adjudicative orders is governed by RCW 34.05.570(1) and (4). In reviewing an administrative action, this Court sits in the same position as the superior court and applies the APA standards directly to the agency's administrative record. (*Alpine Lakes Protection Soc. v. Washington State Forest Practices Bd.*, 135 Wn.App. 376, 389, 144 P.3d 385 (2006)) Superior court findings are not relevant in appellate review of an agency action; however, where the

superior court takes additional evidence under RCW 34.05.562, as it is authorized to do under RCW 34.05.570(4)(b), the appellate court will look to the superior court record. (*Seattle Bldg. and Const. Trades Council v. Apprenticeship and Training Council*, 129 Wn.2d 787, 799, 920 P.2d 581 (1996)) Citizens has the burden to show that the agency action is invalid. (RCW 34.05.570(1)(a)) The validity of agency action shall be determined in accordance with the standards in RCW 34.05.570(4)(c). (RCW 34.05.570(1)(b)) Citizens asks this Court to grant relief because the agency action reported in the agency letter dated January 26, 2016 (AR147-48) is “arbitrary or capricious” or “outside the statutory authority of the agency or the authority conferred by a provision of law.” (RCW 34.05.570(4)(c)(ii) and (iii))

An action is “arbitrary or capricious” if it is “willful and unreasoning, and taken without regard to the attending facts or circumstances.” (*Children's Hosp. and Medical Center v. Washington State Dept. of Health*, 95 Wn.App. 858, 871, 975 P.2d 567 (1999)) An action that is “outside the statutory authority of the agency or the authority conferred by a provision of law” is “contrary to law.” (*Id.* at 863-64)

1. Principles Of Statutory Interpretation

Statutory interpretation is a matter of law that is reviewed *de novo*. (*Jametsky v. Olsen*, 179 Wn.2d 756, 761, 317 P.3d 1003 (2014)) The primary goal of statutory interpretation is to determine and give effect to the legislature's intent. (*Id.* at 762) To determine legislative intent, the Court first looks to the plain language of the statute. (*Id.*) The Court considers the

language of the provision in question, the context of the statute in which the provision is found, and related statutes. (*State v. Jacobs*, 154 Wn.2d 596, 600, 115 P.3d 281 (2005))

To discern the plain meaning of undefined statutory language, the Court gives words their usual and ordinary meaning and interprets them in the context of the statute in which they appear. (*Id.*) "Related statutory provisions must be harmonized to effectuate a consistent statutory scheme that maintains the integrity of the respective statute." (*Koenig v. City of Des Moines*, 158 Wn.2d 173, 184, 142 P.3d 162 (2006))

If the plain meaning of a statute is unambiguous, the Court must apply that plain meaning as an expression of legislative intent without considering extrinsic sources. (*Jametsky*, 179 Wn.2d at 762) A Court does not give deference to an agency interpretation of a statute where the language of the statute is unambiguous. (*Children's Hosp. and Medical Center v. Washington State Dept. of Health*, 95 Wn.App. 858, 869, 975 P.2d 567 (1999)) The Court does not rewrite unambiguous statutory language under the guise of interpretation. (*Cerrillo v. Esparza*, 158 Wn.2d 194, 201, 142 P.3d 155 (2006)) And a Court does not add language to an unambiguous statute even if it believes the legislature "intended something else but did not adequately express it." (*Kilian v. Atkinson*, 147 Wn.2d 16, 20, 50 P.3d 638 (2002))

2. Standards For Abuse Of Discretion

A trial court abuses its discretion when its exercise of discretion is manifestly unreasonable or based upon untenable grounds or reasons. (*Davis v. Globe Mach. Mfg. Co., Inc.*, 102 Wn.2d 68, 77, 684 P.2d 692 (1984))

B. The Commission Is The Agency That The Legislature Designates To Administer And Implement Drug Statutes

The Commission is the agency that the Legislature designates to administer and implement drug statutes. RCW 18.64.001 created the Commission and RCW 18.64.005 lists its powers and duties. For example, RCW 18.64.005(7) (AR34) states that the Commission shall:

Promulgate rules for the . . . distribution, wholesaling, and manufacturing of drugs . . . for the protection and promotion of the public health, safety, and welfare.

The word “‘distribute’ means the delivery of a drug . . . other than by administering or dispensing.” (RCW 18.64.011(12)⁸; CP161) The Commission shall also “enforce all laws placed under its jurisdiction” and “assist the regularly constituted enforcement agencies of this state in enforcing all laws pertaining to drugs.” (RCW 18.64.005(1) and (6); AR 34)

Chapter 69.04 RCW is titled “Intrastate Commerce in Food, Drugs, and Cosmetics. The purpose of this chapter is:

to enact state legislation (1) which safeguards the public health and promotes the public welfare by protecting the consuming public from (a) potential injury by product use . . . and (2) which is uniform, as provided in this chapter, with the federal food, drug, and cosmetic act . . . and (3) which thus promotes uniformity of such law and its administration and enforcement, in and throughout the United States.

Chapter 69.04 RCW relies on the Director of the department of agriculture to adopt regulations for the efficient enforcement of the “food” provisions of this chapter. (RCW 69.04.006; 69.04.730) It requires the Commission to:

to carry out all the provisions of this chapter pertaining to drugs and cosmetics, with authority to promulgate regulations for the efficient enforcement thereof.

⁸ AR31 contains the same definition under former RCW 18.64.011(10).

(RCW 69.04.730)

C. **The Commission Is The Agency That Determines If A Substance Is A Drug In Intrastate Commerce**

Fundamental to the Commission's powers is the power to apply the statutory definitions of drugs to determine whether particular substances are drugs under the Commission's regulatory authority. There are three relevant statutory definitions of drugs:

"Drugs" means:

(b) Substances intended for use in the . . . mitigation, treatment, or prevention of disease in human beings or other animals;

(c) Substances (other than food) intended to affect the structure or any function of the body of human beings or other animals; or

(d) Substances intended for use as a component of any substances specified in (a), (b), or (c) of this subsection.

(RCW 18.64.011(14)⁹; CP161) Nearly identical definitions are provided in RCW 69.04.009(2), (3), and (4) (CP162) and RCW 69.41.010(10)(b), (c) and (d)¹⁰ (CP163).

D. **In The Challenged Decision, the Commission Determined That Fluoridating Substances Used In Drinking Water Are Not Drugs**

In the challenged decision, the Commission determined that fluoridating substances used in drinking water are not drugs:

⁹ AR31 contains the same definition under former RCW 18.64.011(12).

¹⁰ AR33 contains the same definition under former RCW 69.41.010(9).

The Commission denies your petition for rulemaking because fluoridating substances used in drinking water, including bottled water, are not drugs. *Protect the Peninsula's Future v. City of Port Angeles*, 175 Wn.App. 201, 304 P.3d 914 (2013), *rev. denied*, 178 Wn.2d 1022, 312 P.3d 651 (2013). *See also*, RCW 18.64.011(12)¹¹, 69.04.008, 69.04.009, and 69.41.010(9)¹².

(AR148) The Commission did not address whether fluoridated waters would be drugs when the intended use is mitigation, treatment, or prevention of tooth decay disease. (*See Id.*)

E. Under A Plain Meaning Analysis Of Relevant Unambiguous Statutes, Fluoridated Waters (Bottled And/Or Public) And Their Fluoridating Additives Are Drugs When Intended For Use In The Mitigation, Treatment, And/Or Prevention Of Tooth Decay Disease

Citizens' Petition to the agency fundamentally asks the Commission to rule or find that fluoridated drinking water (bottled or public) is a drug "if" it is intended for use in the mitigation, treatment, and/or prevention of tooth decay disease in human beings. The requested determination follows from the unambiguous plain language of RCW 69.04.009:

"drug" means: . . . (2) articles intended for use in the . . . mitigation, treatment, or prevention of disease in human beings.

(CP162) It also follows from the unambiguous plain meaning of similar statutory language in RCW 18.64.011(14):

"Drugs" means: . . . (b) Substances intended for use in the . . . mitigation, treatment, or prevention of disease in human beings.

(CP161) It further follows from the unambiguous plain meaning of the similar statutory language in RCW 69.41.010(10):

"Drug" means: . . . (b) Substances intended for use in the . . . mitigation, treatment, or prevention of disease in human beings.

¹¹ Former RCW 18.64.011(12) has been renumbered to 18.64.011(14). (AR31; CP161)

¹² Former RCW 69.41.010(9) has been renumbered to 69.41.010(10). (AR33; CP163)

(CP163)

If this Court concludes that bottled and/or public fluoridated drinking waters are drugs if the intended use is mitigation, treatment, and/or prevention of tooth decay disease in human beings, then this Court should also conclude that the fluoridating additives used to make these fluoridated waters are also drugs. This follows from the unambiguous plain meaning of the statutory language in RCW 69.04.009:

“drug” means: . . . (2) articles intended for use in the . . . mitigation, treatment, or prevention of disease in human beings . . . and (4) articles intended for use as a component of any article specified in . . . (2).

(CP162; emphasis supplied) It also follows from the unambiguous plain meaning of the nearly identical statutory language in RCW 18.64.011(14)¹³:

“Drugs” means: . . . (b) Substances intended for use in the . . . mitigation, treatment, or prevention of disease in human beings . . . or (d) Substances intended for use as a component of any substance specified in . . . (b).

(CP161; emphasis supplied) It also follows from the unambiguous plain meaning of the nearly identical statutory language in RCW 69.41.010(10):

“Drug” means: . . . (b) Substances intended for use in the . . . mitigation, treatment, or prevention of disease in human beings . . . and (d) Substances intended for use as a component of any article specified in . . . (b).

(CP163; emphasis supplied)

Therefore under a unambiguous plain meaning analysis of the relevant statutes, fluoridated drinking waters (bottled or public), and the component

¹³ RCW 18.64.011 states, “The definitions in this section apply throughout this chapter” and Chapter 18.64 RCW in sections 001 to 005 creates and defines the power and duties of the Commission to regulate drugs.

fluoridating additives, are both drugs when the intended use is mitigation, treatment, and/or prevention of tooth decay disease in human beings.

The same conclusion is reached with another version of the analysis. When fluoridating additives are intended for use in the mitigation and/or prevention of tooth decay disease, then, under the unambiguous plain language of RCW 69.04.009(2), 18.64.011(14)(b), and 69.41.010(10)(b), the fluoridating additives are drugs. NSF, an author of NSF/ANSI Standard 60¹⁴ and who tests and certifies fluoridating additives, states: “Fluoride is added to water for . . . preventing and reducing [mitigating] tooth decay.” (AR35) The fluoridating additives are simply delivered in the bottled or public drinking water. Under this alternative analysis, this Court should find that the fluoridating additives are drugs when intended for use in the mitigation, treatment, and/or prevention of tooth decay disease.

F. The Commission’s Action To Deny Citizen’s Petition To The Agency Was Contrary To Law And Arbitrary Or Capricious

Citizen’s Petition to the agency did not request that the Commission find or rule that fluoridated drinking waters and their fluoridating additives are always drugs. Instead, Citizen’s Petition to the agency requested that the Commission find or rule that such waters and substances are drugs “when the intended use is to aid in the prevention, mitigation, and/or prophylactic treatment of dental caries disease (tooth decay, cavities).” (AR21)

¹⁴ Also referred to as ANSI/NSF Standard 60. WAC 246-290-220(3) states: “Any treatment chemicals, with the exception of commercially retailed hypochlorite compounds such as unscented Clorox, Purex, etc., added to water intended for potable use must comply with ANSI/NSF Standard 60.” This applies to Group A public waters and all bottled waters. (WAC 246-290-020(2); WAC 16-165-130(12)(a))

Most literature claims fluoridated waters, and fluoridating additives used to make fluoridated waters, are intended for the prevention of tooth decay disease. (e.g. *Kaul v. City of Chehalis*, 45 Wn.2d 616, 618, 277 P.2d 352 (1954) (“addition of fluoride . . . is intended solely for use in prevention of tooth decay” which “is a very common disease of mankind”)) The U.S. Public Health Service recommends addition of fluoride to community water supplies “for dental caries prevention.” (AR37) NSF reports that certified fluorides are added to water for “preventing and reducing [mitigating] tooth decay.” (AR35; *supra* at 15)

The Federal Food and Drug Administration (“FDA”) defines an anticaries drug as a drug that aids in the prevention and prophylactic treatment of dental cavities (decay, caries). (21 CFR 355.3(c)) Some literature states that added fluoride reduces [mitigates] tooth decay disease. (AR35) The specific language proposed in the Rulemaking Petition was intended to capture all claims that would make fluoridated water, and its fluoridating additives, drugs under the unambiguous plain language of state drug laws.

Because the unambiguous plain language of state drug laws make a substance a drug when the substance is intended for use in the mitigation, treatment, and/or prevention of tooth decay disease, the Commission’s ruling on Citizen’s Petition to the agency should be found to be “contrary to law” and “arbitrary or capricious.” By not acting consistent with the unambiguous plain language of the state’s drug laws, the Commission acted contrary to law. By willfully and unreasonably, failing to consider the phrase in the Petition for Rulemaking, “when the intended use is to aid in the prevention,

mitigation, and/or prophylactic treatment of dental caries disease (tooth decay, cavities)”, the Commission acted in an arbitrary or capricious manner.

Citizens requests that this Court conclude that fluoridated drinking waters (bottled and/or public), and their fluoridating additives are drugs under RCW 69.04.009, 18.64.011(14), and 69.41.010(10) when the intended use is to aid in the prevention, mitigation, and/or prophylactic treatment of dental caries disease (tooth decay, cavities). With this conclusion, this Court should remand the matter back to the Commission for further proceedings consistent with this Court’s Order.

G. Analysis Of Prior Caselaw Regarding Fluoridation

1. *Kaul v. City of Chehalis* (“*Kaul*”), 45 Wn.2d 616, 277 P.2d 352 (1954)

The first Washington case to address fluoridation was *Kaul v. City of Chehalis* (“*Kaul*”), 45 Wn.2d 616, 277 P.2d 352 (1954). (See AR101-13 ignoring the eleven West Headnotes which are not part of the Opinion) *Kaul* focuses on the issue of whether the City of Chehalis has police power to fluoridate the City water supply and concludes in a 5 to 4 decision that such police power is valid. The issue in the instant case is not whether municipal water purveyors have police power to fluoridate. Instead, the instant issue is whether public water purveyors that fluoridate must comply with relevant state drug laws.

The *Kaul* Court mentions some laws where compliance is required for water purveyors who fluoridate including the requirement for approval of the water system by the State Department of Health. (*Kaul* at 620; AR103) Other laws where compliance is required are not mentioned such as

requirements to comply with zoning and building permit laws. The *Kaul* Court does not explicitly state whether or not there must be compliance with state drug laws and regulations.

There is no analysis or discussion in the majority Opinion in *Kaul* regarding whether or not public water purveyors that fluoridate must comply with relevant state drug laws and regulations. There is no citation to any state or federal definition of drugs. At the end of the *Kaul* decision the *Kaul* majority describes several remaining trial court conclusions that *Kaul* challenged with assignments of error with one being “that the city is not engaged in selling drugs.” The decision did not elsewhere address these assignments of error but disposes of all of them with the following cryptic statement:

We have considered these assignments of error. It would add nothing to discuss them in detail. They are not well taken.

(*Kaul* at 625; AR106) But the question remains as to why *Kaul*’s assignment of error on this issue was rejected by the *Kaul* Court. The Rulemaking Petition includes (as new evidence) all of the Appellate Court briefing in the *Kaul* case. (Appellant’s Brief at AR46-69; Respondents’ Brief at AR70-89) This briefing answers the question as to why the “selling drugs” argument was “not well taken” by the *Kaul* Court. As stated in the Rulemaking Petition:

While the Brief of Appellant [Kaul] assigns error to the trial court conclusion that the City was not selling drugs [AR57], the Brief of Appellant fails to argue this assignment of error. (See [AR46-69].) “If a party fails to support assignments of error with legal arguments, they will not be considered on appeal.” (*Howell v. Spokane & Inland Empire Blood Bank*, 117 Wn.2d 619, 624, 818 P.2d 1056 (1991).) So the proper interpretation of the *Kaul* Court’s cryptic statement quoted above, is that Kaul failed to support this assignment of error with legal argument, so it was not considered on appeal and “not well taken” for this reason.

(AR24)

The relevant Kaul assignment of error is:

The [trial] court erred in entering Conclusion of Law IV stating that the City in carrying out the provisions of Ordinance No. 653-A is not engaging in selling drugs as defined in [former] RCW 18.64.010 or practicing medicine, dentistry, or pharmacy as defined in [former] RCW 18.71.010, 18.64.010, and 18.32.020, as said Conclusion does not follow from the Findings of Fact entered by the trial court.

(AR57) Appellant Kaul argued to the trial court that the City was “engaging in selling drugs as defined in [former] RCW 18.64.010” and when the trial court ruled against him on this issue, he assigned an error to that ruling. But as Citizens stated in its Rulemaking Petition, Appellant Kaul “failed to support this assignment of error with legal argument.” Appellant Kaul did supply legal argument supporting the portion of this assignment of error involving “practicing medicine, dentistry, or pharmacy” (AR62-64) but simply did not support with legal argument the portion of this assignment of error involving “selling drugs as defined in [former] RCW 18.64.010.”

Perhaps the most obvious demonstration that “selling drugs as defined in RCW 18.64.010” was not argued is found on AR48 where it states that a citation to [former] “RCW 18.64.010” only appears on page 17 (AR57) of Kaul’s Brief. AR57 only mentions [former] RCW 18.64.010 in the relevant

assignment of error. (*See supra* at 19) No other part of Kaul's Brief mentions [former] RCW 18.64.010. Because Kaul never supports his assignment of error based on [former] RCW 18.64.010, the Respondents' Brief also never mentions this statute. (AR71)

The Brief of Appellant has five major subsections under the heading, "ARGUMENT FOR APPELLANT":

1. No Hearing Before Passage of Ordinance as Required by Statute.
2. Ordinance Contemplates Misappropriation of funds.
3. Ordinance Contemplates Unlawful Practice of Medicine, Dentistry, and Pharmacy.
4. Ordinance Unconstitutional Under Due Process Clause.
5. Ordinance Falls Within Constitutional Prohibition Against Exercise of Police Power Outside of City.

(AR58-69) The only one of these subsections to mention "drug" or "drugs" is Subsection 3. Said Subsection 3 consists of three subsections:

- (a) Medicine.
- (b) Dentistry.
- (c) Pharmacy.

Only subsections "Medicine" and "Pharmacy" mention "drug" or "drugs"

Those subsections state in full:

(a) *Medicine.*

[Former] RCW 18.71.010 reads, insofar as pertinent as follows:

"The practice of medicine * * * consists of the use of drugs * * * in or upon human beings * * *".

[Former] RCW 18.71.020 reads, insofar as pertinent, as follows:

"Any person who practices * * * medicine * * * without having a valid, unrevoked certificate * * * shall be guilty of a misdemeanor. * * *".

Both Sec. 201(g) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. 321(g)(1) read, insofar as pertinent, as follows:

"The term 'drug' means * * * (2)¹⁵ articles intended for use in the * * * prevention of disease in man * * *".

¹⁵ Subsection (2) is now subsection (B) in current 21 U.S.C.A. 321(g)(1). The remainder of the quoted language is unchanged today.

Tooth decay is a disease (Finding of Fact VII (Tr. 33)).
The addition of fluoride to the Chehalis Municipal Water System is intended solely for use in prevention of tooth decay. (Finding of Fact VII (Tr. 33)).
The Chehalis Municipal Water System is the only practical source of supply available to Appellant and all other users for domestic purposes including drinking (Finding of Fact V (Tr. 33)).
Operation of the fluoridation equipment is under the supervision of the City Engineer. (St. 43 and 44).
Hence fluoridation is the use of a drug on human beings and constitutes the unlawful practice of medicine.

...
(c) *Pharmacy.*

[Former] RCW 18.64.020 reads in part:

“It shall be unlawful for any person to compound or dispense drugs * * * unless he is a registered pharmacist, or places a registered pharmacist in charge thereof.”

[Former] RCW 18.64.250 reads in part:

“Every person shall be guilty of a misdemeanor * * * who * * * wilfully and knowingly violates any provision of this chapter.”

Appellant at time of trial and for eight years prior thereto was a resident of the City of Chehalis and used and paid for water for said period from the Municipal Water System of said City (Finding of Fact I (Tr. 33)).

Fluoridation is, therefore, likewise the unlawful practice of pharmacy.

(AR62-64) There is no legal argument regard “selling drugs as defined in [former] RCW 18.64.010” in these two subsections, which are the only subsections in the “ARGUMENT” Section of the Kaul Brief that mention “drug” or “drugs.” As stated in the Rulemaking Petition at AR 24: the Brief of Appellant fails to argue this assignment of error. (*See* AR46-69.) “If a party fails to support assignments of error with legal arguments, they will not be considered on appeal.” (*Howell v. Spokane & Inland Empire Blood Bank*, 117 Wn.2d 619, 624, 818 P.2d 1056 (1991).) So the proper interpretation of the *Kaul* Court’s cryptic statement quoted above (*supra* at 18), is that Kaul

failed to support the “selling drugs” assignment of error with legal argument, so it was not considered on appeal and “not well taken” for this reason.

The cryptic statement at the end of the *Kaul* majority Opinion also states that the assignments of error regarding “practicing medicine . . . or pharmacy as defined by statute . . . are not well taken.” (*Kaul* at 625; AR106) Regarding pharmacy, Appellant Kaul argued that the City was practicing pharmacy because former RCW 18.64.020¹⁶ allows only a pharmacist “to compound or dispense drugs.” But the words “compound” and “dispense,” while not defined at the time either in chapter 18.64 RCW or in any other statute, are implied by former RCW 18.64.250¹⁷ to only apply to the filling of physicians’ prescriptions. The Chehalis Ordinance did not involve physicians’ prescriptions and so the City was not practicing pharmacy even if fluoridated water and fluoridating additives are drugs.

Regarding medicine, Appellant Kaul argued that the City was practicing medicine because former RCW 18.71.010¹⁸ defines the practice of medicine as using “drugs * * * in or upon human beings.” (AR62) But there was no practitioner at the City actually using the drug “in or upon human beings.” The Chehalis Ordinance did not involve direct action “in or upon human beings” and so the City was not practicing medicine even if

¹⁶ The relevant portion of former chapter 18.64 in effect when *Kaul* was decided is provided as Attachments A1 - A6 hereto.

¹⁷ Former RCW 18.64.250 in effect when *Kaul* was decided connects the words “compound” and “dispense” to the filling of physician’s prescriptions. (*See* Attachments A5 - A6 hereto (“physicians’ prescriptions are compounded and dispensed”) Appellant Kaul in his assignment of error regarding pharmacy cites to [former] RCW 18.64.010. (AR57) In 1935 c 98 s. 6, the last portion of former RCW 18.64.010 was recodified in 1935 to former RCW 18.64.250. (Attachments A2 and A5 - A6 hereto)

¹⁸ Former chapter 18.71 in effect when *Kaul* was decided is provided as Attachments A7 - A15 hereto.

fluoridated water and fluoridating additives are drugs. Instead, the City was manufacturing, distributing, and selling these drugs which was not and is not the practice of pharmacy or medicine. (*See supra* at 20-23)

So Appellant Kaul was correct that the City was “selling drugs” but this assignment of error was “not well taken” by the *Kaul* majority only because Kaul did not argue this assignment of error. Whether or not fluoridated water and fluoridating additives are drugs would not affect any element of the majority Opinion in *Kaul*.

There is no basis in *Protect the Peninsula’s Future v. City of Port Angeles*, 175 Wn.App. 201, 215, 304 P.3d 914 (2013), *rev. denied*, 178 Wn.2d 1022, 312 P.3d 651 (2013) for the *Protect the Peninsula’s Future* Court’s conclusion that: “a holding that fluoridated waters are drugs would have resulted in a different outcome” in *Kaul*. (See AR97) The only arguments made by Appellant Kaul that were at all related to whether or not fluoridated waters are drugs were his arguments regarding practice of pharmacy or medicine. As demonstrated above, the City of Chehalis should not have been found to be practicing pharmacy or medicine whether or not the fluoridated waters were found to be drugs. If *Kaul* would have found that the City of Chehalis was “selling drugs,” it would not have affected any outcomes of the *Kaul* majority including that the City had police power to fluoridate and that none of Kaul’s constitutional rights were violated. The only effect of a ruling that the City was selling drugs would have been a requirement for the City to comply with relevant drug laws and regulations.

When *Kaul* was decided there was no definition of drugs in chapters 18.64¹⁹ or 18.71²⁰ or 69.41²¹ RCW. However, former RCW 69.04.009, in effect when *Kaul* was decided, did provide the only state statutory definition of drugs:²²

The term “drug” means (a) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (b) *articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease* in man or other animals; and (c) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (d) *articles intended for use as a component of any article specified in the clause (a), (b), or (c)*; but does not include devices or their components, parts, or accessories.

(1945 c. 257 s. 10 (emphasis supplied); Attachment A25 hereto). The *Kaul* majority Opinion quoted the unchallenged Finding of Fact VII which found “dental caries, commonly referred to as tooth decay, is a very common disease of mankind” and “the addition of fluoride to the Chehalis water supply is intended solely for use in prevention of tooth decay.” (AR103; *Kaul* at 618) Had this matter been argued in *Kaul*, the unambiguous plain language in former RCW 69.04.009

The term “drug” means . . . articles intended for use in the . . . prevention of disease in man [and any] component of any [such] article . . .

¹⁹ The relevant portion of former chapter 18.64 RCW in effect when *Kaul* was decided is provided as Attachments A1 - A6 hereto. RCW 18.64.011 which first defines “drugs” in chapter 18.64 RCW was first adopted in 1963. (CP161)

²⁰ Former chapter 18.71 RCW in effect when *Kaul* was decided is provided as Attachments A-7 - A15 hereto. Chapter 18.71 RCW does not define “drug” or “drugs”.

²¹ Chapter 69.41 RCW was first created in 1973 and was not in effect when *Kaul* was decided. RCW 69.41.010 which first defines “drug” in chapter 69.41 was first adopted in 1973 (1973 1st ex.s. c 186 s. 1) (Attachments A16 - A22 hereto; CP 163)

²² The relevant part of former Chapter 69.04 in effect when *Kaul* was decided is provided as Attachments A23- A30 hereto. It includes a definition of “drugs” in RCW 69.04.009 and a definition of “sale” in RCW 69.04.005. “Sale” includes manufacture and delivering.

along with uncontested Finding of Fact VII (AR82-83) should have led to the conclusion in 1954 that fluoridated waters and fluoridating additives intended for use in the prevention of tooth decay disease are drugs. The broad definition of “sale” in former RCW 69.04.005 (Attachment A24 hereto) if argued in *Kaul* should have led to the conclusion in 1954 that the City of Chehalis was “selling drugs.” Only because these statutes were not identified and this issue was not argued could the *Kaul* Court have reached its conclusion that the assignment of error to “the city is not engaged in selling drugs” was “not well taken.” (See *Kaul* at 625; AR106)

Appellate *Kaul* cited to a federal definition of the term “drug” (AR62) but did not make an argument that this definition was relevant in intrastate commerce. But *Kaul*’s specific assignment of error was to the trial court conclusion that the City “is not engaged in selling drugs as defined in [former] RCW 18.64.010.” (AR 57) Former RCW 18.64.010 did not have a definition of “selling” or “sale” or “drugs” when *Kaul* was decided. (Attachment A2 hereto) This may be why Appellant *Kaul* abandoned this assignment of error in his legal argument.

If this Court agrees that the assignment of error regarding “selling drugs as defined in [former] RCW 18.64.010” was not argued by Appellant *Kaul* and likely found “not well taken” for that reason, then the issue of whether certain fluoridated waters and their fluoridating additives are drugs is an issue of first impression for this Court.²³ Citizens’ intent is that the

²³ This Court should overrule, clarify, or distinguish *Protect the Peninsula’s Future* at 215-16 and 220 to the degree that the *Protect the Peninsula’s Future* Court assumed *Kaul* was “binding precedent” “that fluorides in drinking water are not drugs under Washington law.”

Commission and this Court clarify that when fluoridated drinking waters meet the state statutory definitions of a drug (i.e. if it is an article or substance “intended for use in the . . . mitigation, treatment, or prevention of disease”) then such fluoridated waters and their fluoridating additives must comply with state drug laws and regulations. The Commission has jurisdiction to regulate the manufacturing and distribution of drugs and to participate in enforcement of all drug laws. (*Supra* at 11)

2. *City of Port Angeles v. Our Water-Our Choice!* (“*City of Port Angeles*”), 170 Wn.2d 1, 239 P.3d 589 (2010)

City of Port Angeles (AR120-30), in another 5 to 4 decision, found two City of Port Angeles local initiatives filed in 2006 (*City of Port Angeles* at 5; AR122) attempted to interfere with implementation of the Port Angeles existing public water fluoridation program first adopted in 2003, and therefore the initiatives were administrative in nature. (*Id.* at 13-15; AR126-27) The Court found local administrative matters are not subject to initiative or referendum. (*Id.* at 8; AR123)

The majority analysis correctly found that the POW initiative for Port Angeles would make it a crime to “*add* any substance to a public drinking water supply . . . which is intended as a medication for humans,” with exceptions for substances to make water safe or potable, and substances approved by the federal Food and Drug Administration (“FDA”) for use in public water systems. (*Id.* at 6; AR122) The majority in footnote 1 states in dicta, “The FDA exception is essentially meaningless since the Environmental Protection Agency [“EPA”], not the FDA regulates public

drinking water systems” and the majority referenced the 1979 MOU between FDA and EPA for this conclusion. (*Id.*)

Counsel Gerald Steel requested clarification from the EPA Administrator in 2012 as to whether the EPA regulates medications (drugs) added to public drinking water. (AR39-40) The EPA Administrator directed Steven M. Neugeboren to respond on her behalf. (*Id.*) Mr. Neugeboren is the Associate General Counsel in charge of the Water Law Office of the EPA. The Water Law Office is responsible for providing interpretations of the Safe Drinking Water Act (“SDWA”) for the EPA Administrator. Mr. Neugeboren states:

Under the Safe Drinking Water Act (SDWA), EPA is the lead federal agency with responsibility to regulate the safety of public water supplies. EPA does not have responsibility for substances added to water solely for preventative health care purposes, such as fluoride, other than [to meet maximum contaminant limits.] The Department of Health and Human Services (HHS), acting through the FDA, remains responsible for regulating the addition of drugs to water supplies for health care purposes.

(*Id.*)

Therefore EPA’s interpretation of the SDWA which it administers is that this Act does not affect the responsibility of the FDA “for regulating the addition of drugs to water supplies for health care purposes.” (AR39-40) Substantial weight is given to EPA’s interpretation of the SDWA. (*King County v. Central Puget Sound Growth Management Hearings Bd.*, 142 Wn.2d 543, 553, 14 P.3d 133 (2000)) The *City of Port Angeles* Court at 6, Note 1, misinterprets the role of the EPA with regard to the addition of medications (drugs) to public drinking water systems.

The majority in *City of Port Angeles* left the issue open as to whether fluoridation chemical additives are medicines (drugs).

The petitioners also argue that the decision [sic - “initiative”] was legislative because there was no prior law regarding medicines in public waters. However, the trial court did not find that fluoride was a medicine, and [petitioners] did not assign error to that lack of finding. The factual predicate for this argument is not provided by the record before us, and we do not reach it.

(*City of Port Angeles* at 12, Footnote 6; AR125) The *City of Port Angeles* Court did not reach the issue of whether fluoridating additives and fluoridated waters are drugs. If the Supreme Court believed this issue was settled law under *Kaul*, the *City of Port Angeles* Court surely would have so stated.

3. *Protect the Peninsula’s Future v. City of Port Angeles* (“*Protect the Peninsula’s Future*”), 175 Wn.App 201, 304 P.3d 914 (2013), *rev denied*, 178 Wn.2d 1022, 312 P.3d 651 (2013)

A Court of Appeals, Division II case, *Protect the Peninsula’s Future*, addressed a fluoridation-related issue. (AR90-100) The major issue in *Protect the Peninsula’s Future* was whether RCW 69.41.060 authorizing civil action in rem for issuance of a warrant directing a peace officer to search designated premises for legend drugs, and to seize such drugs if found, created a private cause of action that could be pursued by citizens instead of just by the prosecuting attorney. (*Id.*)

After the opposing party had responded to petitioners’ pleadings in the trial court, petitioners requested leave of the trial court to amend their complaint by adding a request that the trial court declare that the Cities’ fluoridated waters and fluoridating additives are drugs. (*Id.* at 214; AR97)

The trial court denied the motion on the grounds that it would be futile given that the trial court interpreted *Kaul* to include a decision that fluoridated public waters and their fluoridating additives were not drugs. (*Id.* at 214-15; AR97) The *Protect the Peninsula's Future* Court upheld the trial court denial, finding that the trial court had not abused discretion. (*Id.* at 215-16; AR97-98) The Appellant's and Respondents' briefing that was before the *Kaul* Court was not in the record before the *Protect the Peninsula's Future* trial court or Court of Appeals. (AR25) Without the benefit of the *Kaul* Court briefing, the *Protect the Peninsula's Future* Court assumed that the *Kaul* Court had actually ruled on the merits and found public fluoridated waters and their fluoridating additives were not drugs.

The *Protect the Peninsula's Future* Court supported its interpretation that *Kaul* found public fluoridated waters and their fluoridating additives were not drugs by concluding that “a holding that fluoridated waters are drugs would have resulted in a different outcome.” (*Id.* at 215; AR97) However, the *Protect the Peninsula's Future* Court fails to support this conclusion and fails to give any reason why this holding would result in any different outcome. (*See Id.* at 90-100) Citizens' analysis herein shows this Court that no different outcome would result. (*Supra* at 23)

Citizens herein (*supra* at 19-23) demonstrates that Appellant *Kaul's* Brief (AR46-69) shows conclusively that *Kaul* abandoned the assignment of error regarding “selling drugs as defined in RCW 18.64.010” by not supporting that assignment with legal argument. *Howell v. Spokane & Inland Empire Blood Bank*, 117 Wn.2d 619, 624, 818 P.2d 1056 (1991) provides that a Court will not consider an assignment of error if it not

supported with legal argument. (*Supra* at 18-19) Citizens demonstrates that, contrary to the *Protect the Peninsula's Future* Court's conclusion, a holding that fluoridated waters are drugs would not have resulted in a different outcome in *Kaul*. (*Supra* at 23)

a. Request To Overrule, Clarify, Or Distinguish
Protect the Peninsula's Future

Citizens asks this Court to overrule, clarify, or distinguish *Protect the Peninsula's Future* at 215-16, 220, and generally, to the degree that the *Protect the Peninsula's Future* Court found *Kaul* was “binding precedent” “that fluorides in drinking water are not drugs under Washington law.” The unambiguous plain language of state statutory definitions of “drug” and “drugs” when *Kaul* was decided and today require the conclusion that fluoridated waters and their fluoridating additives are drugs when the intended use is mitigation, treatment, or prevention of tooth decay disease.

i. An Issue Of First Impression For This Court

If *Kaul* did not decide the “selling drugs” issue, it is an issue of first impression for this Court. This Court should find that the unambiguous plain language of the definitions of “drug” and “drugs” in state statutes makes fluoridated waters (bottled and public), and their fluoridating additives, drugs if they are intended for use in the mitigation, treatment, or prevention of tooth decay disease.

ii. This Court Should Remand To The Commission

The major issue before this Court is the determination of whether fluoridated waters (bottled and public) and their fluoridating additives are

drugs when the intended use is mitigation, treatment, or prevention of tooth decay disease. If this Court agrees with Citizens that such substances and articles are drugs, then this Court should remand to the Commission.

iii. The Trial Court Did Not Abuse Discretion

The *Protect the Peninsula's Future* Court found that petitioners did not show that the trial court abused discretion when he denied petitioners' motion to amend their complaint. It is a high burden to show abuse of discretion. A trial court abuses its discretion when its decision is manifestly unreasonable or based on untenable grounds or reasoning. (*Warner v. Regent Assisted Living*, 132 Wn.App. 126, 136, 130 P.3d 865 (2006)) If a trial court is not obviously²⁴ unreasonable, it is not an abuse of discretion. If a trial court uses plausible²⁵ reasoning, it is not an abuse of discretion. So the issue before the *Protect Peninsula's Future* Court was not whether public fluoridated waters and their fluoridating additives were or were not drugs if the intended use was to prevent tooth decay disease, but rather it was whether the trial court abused discretion when he found the proposed amendment was futile. The Supreme Court "denied review" likely because it could only find that the trial court did not abuse discretion and it would not be able to reach the issue of whether fluoridated waters, and their fluoridating additives, were drugs when intended for use in the prevention of tooth decay disease.

²⁴ Dictionary definition of "manifest" is "obvious."

²⁵ Dictionary definition of "untenable" is "indefensible."

iv. The Commission Has Primary Jurisdiction

In *Protect the Peninsula's Future*, the Cities argued that “whether the fluorides are drugs is an issue falling within the primary jurisdiction of the Board of Pharmacy [now the Commission].” (*Protect the Peninsula's Future* at 216, Footnote 13; AR98) The Cities’ argument prompted the Citizens’ Petition to the Commission and then to this Court.

b. The Kaul Court Would Not Have Decided On The Merits That Public Fluoridated Waters And Their Fluoridating Additives Were Not Drugs Without Any Analysis Or Citation To Statute

If the *Kaul* Court intended to decide on the merits the issue of whether public fluoridated water and their fluoridating additives were or were not regulated by state drug laws and regulations, it is inconceivable to Citizens, and should be inconceivable to this Court, that the *Kaul* Court would have sought to resolve this immensely important issue with no analysis, no logic, no legal argument or explanation, but only with a cryptic statement that the “selling drugs” assignment was “not well taken.” If the *Kaul* Court intended to decide this issue on the merits only with such a cryptic statement, Citizens believes it would have been judicial malfeasance. Citizens prefers to believe in the *Kaul* Court’s credibility and prefers the explanation that the “selling drugs” issue was “not well taken” because “selling drugs” was never argued in the Brief of Appellant (AR46-69) and because it had no effect on the other decisions made in *Kaul*.

In *Kaul*, unchallenged finding VII was:

That dental caries, commonly referred to as tooth decay, is a very common disease of mankind. . . . That the addition of fluoride to the Chehalis water supply is intended solely for use in prevention of tooth decay.

(AR103; *Kaul* at 618) Former RCW 69.04.009, in effect when *Kaul* was decided, made articles drugs if “intended for use in the . . . prevention of disease in man” or if a component of such articles. Citizen’s believes that based on the above finding and RCW 69.04.009, the *Kaul* Court, if it reached this issue, would have found the City fluoridated water and its fluoridating additive to be drugs.

c. It Is An Issue Of First Impression Whether Public Fluoridated Waters And Their Fluoridating Additives Are Drugs Under Drug Definitions Adopted After *Kaul* Was Decided

The definition of “drugs” in chapter 18.64 RCW was first adopted in 1963.²⁶ The definition of “drug” in chapter 69.41 RCW was first adopted in 1973.²⁷ These definitions are both different than the definition of drug in former RCW 64.04.009 that was in effect when *Kaul* was decided in 1954.

The new definition in RCW 18.64.011(14) defines “drugs” to include:

(b) Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or animals;. . . or (d) Substances intended for use as a component of any substances specified in . . . (b).

RCW 18.64.011 states, “The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.” (CP161) RCW 18.64.001 in the same chapter creates the Commission and RCW 18.64.005,

²⁶ See *supra* at 24, Note 19.

²⁷ See *supra* at 24, Note 21.

also in the same chapter gives the Commission its powers and duties including that:

The Commission shall:

...
Promulgate rules for the dispensing, distribution, wholesaling, and manufacturing of drugs . . . for the protection and promotion of the public health, safety, and welfare.

Because *Kaul* could not have applied the new definition of drugs in RCW 18.64.011(14), it is an issue of first impression for this Court with regard to this statutory definition as to whether fluoridated waters (bottled and public) and their fluoridating additives are drugs when the intended use is mitigation, treatment, or prevention of tooth decay disease.

Clearly both fluoridated waters and their fluoridating additives are substances. The unambiguous plain language of RCW 18.64.011(14) makes such substances drugs when the intended use is mitigation, treatment, or prevention of tooth decay disease. Under this statute all fluoridated waters and their fluoridating additives are not necessarily drugs. They are only drugs when the intended use is mitigation, treatment, or prevention of tooth decay disease or when they are a component of a substance intended to mitigate, treat, or prevent disease. However, the common purpose of fluoridation is to prevent tooth decay disease. (*Supra* at 16)

The relevant part of the definition of “drug” in RCW 69.41.010(10) (CP163) is nearly identical to the unambiguous plain language in RCW 18.64.011(14) (CP161) and under this new definition (implemented after *Kaul* was decided) this Court should also conclude that fluoridated waters (bottled and public) and their fluoridating additives are drugs when the intended use is mitigation, treatment, or prevention of tooth decay disease or

when they are a component of an article intended to mitigate, treat, or prevent disease. This conclusion cannot be defeated by simple citation to *Kaul* and *Protect the Peninsula's Future*.

4. ***Parkland Light & Water Co. v. Tacoma-Pierce County Bd. of Health ("Parkland")*, 151 Wn.2d 428, 90 P.3d 37 (2004)**

Parkland (AR114-19) involves a dispute over a resolution passed by a local Board of Health that required water districts and certain private water purveyors to fluoridate their water. The *Parkland* Court found that the resolution conflicted with authority in RCW 57.08.012 that gives water districts power to decide if they want to fluoridate their water. (*Parkland* at 430, AR115) The resolution was voided in its entirety. (*Id.* at 434; AR117)

While *Parkland* provides that water districts can make the decision to fluoridate, it does not address which other laws and regulations must be followed when water districts implement fluoridation. Certainly Washington State Board of Health regulations regarding group A public water systems must be followed as well as local zoning and building codes. (*See supra* at 17-18) It remains an open question as to whether drug laws and regulations must be followed when water districts implement fluoridation. Because RCW 57.08.012 gives water districts authority to decide to fluoridate does not excuse such water districts from having to comply with other applicable laws and regulations. A property owner has a right to decide to build on his property, but that does not excuse the property owner from having to get a building permit.

A relatively small fraction of the fluoridated population in Washington State gets its water from water districts. (AR15; AR 149-53)

Municipal water providers (that are not water districts) are by far the main providers of fluoridated waters in Washington State. (*Id.*)

H. Bottled Fluoridated Water In Intrastate Commerce Is A Drug When The Intended Use Is Mitigation, Treatment, And/Or Prevention Of Tooth Decay Disease

Whether bottled fluoridated water in Washington intrastate commerce is a drug when the intended use is mitigation, treatment, and/or prevention of tooth decay disease is an issue of first impression. The caselaw on fluoridated water in Washington only addresses public fluoridated water. (*Kaul; Protect the Peninsula's Future; City of Port Angeles; Parkland*) However, Citizens' analysis is the same.

1. Under The Unambiguous Plain Language Of State Statutes, Bottled Fluoridated Waters Are Drugs When Intended For Use In The Mitigation, Treatment, And/Or Prevention Of Tooth Decay Disease

State statutes make articles and substances drugs when:

intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings

(RCW 18.64.011(14)(b) at CP161; RCW 69.04.009(2) at CP162; and RCW 69.41.010(10)(b) at CP163) The articles and substances that are bottled fluoridated waters intended for use in the mitigation, treatment, and/or prevention of tooth decay disease are therefore drugs under the unambiguous plain language of the cited three state statutes.

2. Under The Unambiguous Plain Language Of State Statutes, Fluoridating Additives Are Drugs When They Are A Component Of Bottled Fluoridated Waters That Are Intended For Use In The Mitigation, Treatment, And/Or Prevention Of Tooth Decay Disease

When identified articles or substances are drugs because they are “intended for use in the mitigation, treatment, and/or prevention of disease” then other articles or substances are drugs when “intended for use as a component” of the identified articles or substances. (RCW 18.64.011(14)(d) at CP161; RCW 69.04.009(4) at CP162; and RCW 69.41.010(10)(d) at CP163) The articles and substances that are fluoridating additives “intended for use as a component” of bottled fluoridated waters intended for use in the mitigation, treatment, and/or prevention of tooth decay disease are therefore also drugs under the unambiguous plain language of the cited three state statutes.

3. Because Such Bottled Fluoridated Waters Are Also Foods Does Not Exempt Them From Being Drugs

Because drinking waters, including such bottled waters, are also foods under RCW 69.04.008²⁸, does not exempt them from being drugs. The Commission argues in its Responding Brief before the trial court that:

RCW 69.04.009(3) defines “drug” to specifically exclude food. Similarly, “food” is excluded from the definition of “drug” in RCW 18.64.011(14) and RCW 69.41.010(10)(c). The Commission has no authority over food. Under RCW 69.04.008, articles used for drink for people or other animals and components of any such article are regulated as “food.” Therefore, drinking water, including bottled water, are “food,” excluded from the definition of “drug” under RCW 69.04.009(3), RCW 18.64.011(14), and RCW 69.41.010(10)(c).

²⁸ RCW 69.04.008 is Attachment A31 hereto.

(CP187:8-16; footnotes excluded) There are four alternative definitions for drugs in RCW 18.64.011(14) and only one of those four alternative definitions specifically excludes “food” from being a drug. (RCW 18.64.011(14)(c); CP161) The other three alternative definitions in RCW 18.64.011(14) do not exclude “food” from also being a drug. RCW 18.64.011(14) states in full:

"Drugs" means:

- (a) Articles recognized in the official United States pharmacopoeia or the official homeopathic pharmacopoeia of the United States;
- (b) Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals;
- (c) Substances (other than food) intended to affect the structure or any function of the body of human beings or other animals; or
- (d) Substances intended for use as a component of any substances specified in (a), (b), or (c) of this subsection, but not including devices or their component parts or accessories.

The legislature included the phrase “other than food” in subsection (c) but omits that phrase in subsections (b) and (d). Citizens’ analysis is based on the language in subsections (b) and (d). Where the legislature includes particular language in one section of a statute, but omits it in another, the exclusion is presumed intentional:

The legislature is deemed to intend a different meaning when it uses different terms, and a court will not read into a statute the language that it believes was omitted. In accordance with these rules, where the legislature includes particular language in one section of a statute but omits it in another, the exclusion is presumed intentional.

(*State v. Lynch*, 178 Wn.2d 487, 505, 309 P.3d 482 (2013) (citations and punctuation omitted)) RCW 18.64.011(14) must be interpreted to make a food also a drug when a substance satisfies the conditions in subsections (b) or (d). Therefore, the Commission misinterprets the law when it states, “‘food’ is excluded from the definition of ‘drug’ in RCW 18.64.011(14).”

Similar analysis is appropriate for the definitions of “drug” in RCW 69.04.009 (CP162) and RCW 69.41.010(10) (CP163). In RCW 69.04.009, the legislature included the phrase “other than food” in subsection (3) but omits that phrase in subsections (2) and (4). Citizens’ analysis is based on the language in subsections (2) and (4). In RCW 69.41.010(10), the legislature included the phrase “other than food, minerals or vitamins” in subsection (c) but omits that phrase in subsections (b) and (d). Citizens’ analysis is based on the language in subsections (b) and (d). In all of these statutes, Citizens’ analysis relies upon drug definition subsections that allow a food to also be a drug.

4. Under Similar Laws In Other States, Appellate Courts Have Found That A Food Is A Drug If It Is Intended For Use In The Mitigation, Treatment, Or Prevention Of Disease

In most states the terms “food” and “drug” are defined similarly to the Washington State definitions. For example, the State of Alaska defines drug:

"drug" means an article recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary; an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animal; an article other than food, intended to affect the structure or function of the body of man or animal; and an article intended for use as component of an article specified in this paragraph but does not include devices or their components, parts, or accessories;

(AS 17.20.370(8)); and defines food:

"food" means an article used for food or drink for man or animal, chewing gum, and articles used for components of either of them;

(AS 17.20.370(11)).

The Alaska Supreme Court found:

Under the statute, however, the terms food, and drug, are not mutually exclusive. A food may be a drug so long as it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. For example, in *United States v. 250 Jars of U.S. Fancy Pure Honey*, the court determined that honey was a drug under the similar federal act because of claims made by its distributor that it was "a panacea for various diseases that have plagued man from time immemorial." 218 F.Supp. 208, 211 (E.D.Mich.1963), aff'd, 344 F.2d 288 (6th Cir.1965).

(*Ross Laboratories, Div. of Abbott Laboratories v. Thies*, 725 P.2d 1076, 1080 (1986))

5. Under Similar Laws, Federal Courts Have Found That A Food Is A Drug If It Is Intended For Use In The Mitigation, Treatment, Or Prevention Of Disease

Chapter 69.04 RCW is titled Intrastate Commerce in Food, Drugs, and Cosmetics. RCW 69.04.001 provides the purpose of this chapter:

This chapter is intended to enact state legislation (1) which safeguards the public health and promotes the public welfare by protecting the consuming public from (a) potential injury by product use; . . . and (2) which is uniform, as provided in this chapter, with the federal food, drug, and cosmetic act; . . . and (3) which thus promotes uniformity of such law and its administration and enforcement, in and throughout the United States.

Therefore, purposes of chapter 69.04 RCW are to be uniform with the federal food, drug, and cosmetic act ("FDCA") and promote uniformity of food and drug laws and their administration and enforcement, in and throughout the United States. In light of that purpose it is appropriate to look at federal court interpretations of language in the FDCA that is similar to RCW 69.04.009.

A long line of federal court cases has found that articles normally regulated as "foods" will also be regulated as "drugs" if the intended use is to mitigate, treat, and/or prevent a disease:

The word “drug” is defined in 21 U.S.C. § 321(g)(1)(B) to include:

articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals

...

Thus, it is the intended use of an article which determines whether or not it is a “drug,” and even the most commonly ingested foods and liquids are “drugs” within the meaning of the [FDCA] if their intended use falls within the definition of § 321(g)(1)(B).

(*Gadler v. United States*, 425 F.Supp. 244, 246-47 (D.Minn. 1977); see *Nutrilab, Inc. v. Schweiker*, 713 F.2d 335, 336 (7th Cir. 1983); see also *Bradley v. United States*, 264 F.79 (5th Cir., 1920) where the Court specifically found bottled water to be a “drug” when it was intended to treat disease.)

In the determination of whether an article is a drug under federal law, the only question under the [FDCA] is whether the intended use of the product is to prevent disease, not whether the product actually prevents disease.

(*United States v. Bowen*, 172 F.3d 682, 686 (9th Cir. 1999)) Intent “may be derived or inferred from [any] relevant source.” (*National Nutritional Foods Ass’n v. Mathews*, 557 F.2d 325, 334 (2nd Cir. 1977))

The basis for finding that a food is a drug under federal law when the intended use is to prevent disease is found in the definition of a drug itself:

The term “drug” means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). . . .

(21 USC 321(g)(1)²⁹) In 21 USC 321(g)(1), Congress included the phrase “other than food” in clause (C) but omits that phrase in clauses (B) and (D). Therefore, Congress intended that clauses (B) and (D) not exclude foods.

[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.

(*Russello v. United States*, 104 S.Ct. 296, 464 U.S. 16, 23, 78 L.Ed.2d 17 (1983)) Clauses (B) and (D) in 21 USC 321(g)(1) are substantively identical to the state law provisions that Citizens relies upon in: RCW 69.04.009(2) and (4); RCW 18.64.011(14)(b) and (d); and RCW 69.41.010(10)(b) and (d).

There are two sentences in 21 USC 321(g)(1) after Clause (D) that are not quoted above. (*See* Attachment A32-33 hereto) These sentences which were added in 1994 (Pub. L. 103-417) reference health-related food claims allowed by 21 USC 343(r) and provide that a food or dietary supplement is not a drug solely because of such a claim. Such food claims are not allowed to state that foods or dietary supplements are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of a disease or the item becomes a drug. (*Infra* at 43-44) There are not similar statutes in Washington state.

Fluorides could qualify as dietary supplements under 21 USC 321(ff)³⁰. Dietary supplements can be either food or drugs but not both. Dietary supplements in 21 USC 321(ff) are foods unless they qualify as drugs under 21 USC 321(g). (21 USC 321(ff)(postscript))

²⁹ 21 USC 321(g)(1) is provided in Attachments A32 - A33 hereto.

³⁰ 21 USC 321(ff) is provided in Attachments A34 - A35 hereto.

A dietary supplement is deemed to be " food," [21 USC] 321(ff), which is defined in part as "articles used for food or drink for man or other animals," *Id.* § 321(f)(1), *except* when it meets the definition of a "drug," which is defined in part as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals."

(*Alliance for Natural Health U.S. v. Sebelius*, 714 F.Supp.2d 48, 50 (D.D.C. 2010) (emphasis supplied))

I. **The FDA Has Determined That Fluoridated Drinking Water Is Both A Food And A Drug When It Is Supplied As Bottled Water With A Claim That It Is Intended For Use In The Prevention Of Tooth Decay Disease**

As previously stated (*supra* at 40), purposes of chapter 69.04 RCW are to be uniform with the federal food, drug, and cosmetic act ("FDCA") and promote uniformity of food and drug laws and their administration and enforcement, in and throughout the United States. Under both federal and state law, bottled water is a food. (RCW 69.04.008; 21 USC 321(f)) A request was made to the FDA to determine if fluoridated drinking water is also a drug when it is supplied as bottled water with a claim that "this drinking water is intended for use in the prevention of tooth decay disease." (AR44-45)

The FDA Center for Food Safety and Applied Nutrition ("CFSAN") which has federal jurisdiction over "food" responded that the claim "is not an authorized claim on food labeling under [21 USC 343(r)] Section 403r of the Act." (AR44; *see supra* at 42) The FDA states the "proposed product (if marketed with your proposed claim) would be a drug as that term is defined in [21 USC 321(g)(1)(B)] Section 201(g)(1)(B) of the [FDCA]." (*Id.*) The FDA Center for Drug Evaluation and Research ("CDER") has federal jurisdiction over "drugs."

The FDA then stated:

However, the fact that your proposed product (if marketed with your proposed claim) would be a drug under the Act does not mean that your product is not also a food. To the contrary, the definitions of “food” and “drug” under the Act are not mutually exclusive. *See, e.g. Nutrilab v. Schweiker*, 713 F.2d 335, 336 (7th Cir. 1983). It is commonplace for FDA to take regulatory action with respect to food products that are promoted for conditions that cause the products to be drugs as well as foods.

(AR45) Under 21 USC 321(g)(1)(D), the fluoridating additives used as a component of such bottled fluoridated drinking waters would also be drugs.

J. Under The Unambiguous Plain Language Of State Drug Laws, Fluoridated Waters (Bottled And/Or Public) And Their Fluoridating Additives Are Drugs When Intended For Use In The Mitigation, Treatment, And/Or Prevention Of Tooth Decay Disease

Under the unambiguous plain language of state drug laws, fluoridated waters (bottled and/or public) and their fluoridating additives are drugs when intended for use in the mitigation, treatment, and/or prevention of tooth decay disease. Bottled and public drinking waters are food under both state and federal law. But under both state and federal law, food can also be a drug because the definitions of “food” and “drug” are not always mutually exclusive.

The *Kaul* Court found Appellant Kaul’s assignment of error regarding “selling drugs as defined in [former] RCW 18.64.010” not well taken. (AR57; *Kaul* at 625; AR106) But the *Kaul* Court did not explicitly reach the issue of whether the City of Chehalis fluoridated waters and their fluoridating additives were or were not drugs. Instead the *Kaul* Court found this assignment of error “not well taken” because Appellate Kaul did not argue the “selling drugs as defined in [former] RCW 18.64.010” issue and no

outcome of the *Kaul* 5 to 4 decision would have changed whether or not the City was required to comply with drug laws and regulations. The *City of Port Angeles* Court did not find that *Kaul* was settled law on the issue of selling drugs.

The *Protect the Peninsula's Future* Court did not have the benefit of the *Kaul* Briefing when it assumed that the *Kaul* Court decided the “selling drugs” issue on the merits and assumed *Kaul* was binding precedent and assumed that a holding that fluoridated waters are drugs would have resulted in a different outcome. As addressed in this brief, the *Protect the Peninsula's Future* Court was wrong on all of these assumptions. Citizens requests that this Court overrule, clarify, or distinguish *Protect the Peninsula's Future* and then decide whether fluoridated waters (bottled and/or public) and their fluoridating additives are drugs based on the unambiguous plain language of this state's statutory drug definitions.

This Court should consider how the Alaska Supreme Court and how federal courts have interpreted similar statutes and also how the EPA has interpreted the Safe Drinking Water Act which it administers and how the FDA has concluded that bottled fluoridated waters under its jurisdiction are food and drugs when there is a claim that the waters are intended for use in the prevention of tooth decay disease.

- 1. This Court Should Consider Whether The *Protect The Peninsula's Future* Discussion About *Kaul* Being Binding Precedent Is Just Dicta**

Citizens has requested that this Court overrule, clarify, or distinguish the *Protect the Peninsula's Future* Court's discussion that *Kaul* is “binding precedent” “that fluorides in drinking water are not drugs under Washington

law.” One way to address this request is to find that this discussion in *Protect the Peninsula’s Future* is just dicta. A statement is dicta when it is not necessary to the court’s decision in a case. (*Protect the Peninsula’s Future* at 215; AR97)

This discussion was not necessary to the decision in *Protect the Peninsula’s Future* because the relevant issue before that Court was whether the trial court abused its discretion. (*Id.* at 214; AR97) Certainly if the *Protect the Peninsula’s Future* Court can assume that *Kaul* is such binding precedent, then the trial court did not abuse discretion when it concluded similarly. The trial court used plausible reasoning that was not obviously unreasonable and so did not abuse discretion whether or not the fluorides in drinking water are or are not actually drugs under state statutes. (*See supra* at 31) The discussion of whether the *Kaul* Court actually decided whether or not the fluorides in the drinking are or are not actually drugs was not necessary to the decision that the trial court did not abuse discretion and so that discussion can fairly be called dicta.

K. The Trial Court In The Instant Case Abused Discretion When He Struck Paragraphs 11-16 From The Judicial Petition

In the Statement of Case (*supra* at 7-8) Citizens explains that RCW 34.05.546(6) requires that a judicial petition must set forth “Facts to demonstrate that the petitioner is entitled to obtain judicial review.” Section III of this brief (*supra* at 5), identifies as major issue No. 3:

Did the Superior Court abuse discretion when it struck from the Petition for Judicial Review allegations supporting standing (as required by RCW 34.05.530), exhaustion of administrative remedies (as required by RCW 34.05.531), and substantial prejudice (as required by RCW 34.05.570(1)(d)) when these allegations that were only required for judicial review were based on alleged facts not in the administrative record? (SC Errors 3 and 8.)

As has been noted (*supra* at 7, Note 7) there is no requirement for a hearing for a Petition for Rulemaking (RCW 34.05.330(1)) and so there was no adjudicative hearing provided by the Commission. Citizens had a 25 minute opportunity to present its Rulemaking Petition and request that the Commission enter rulemaking proceedings. (*Supra* at 6) Citizens had no requirement when presenting its Rulemaking Petition to show that it was qualified for judicial review if its Rulemaking Petition was denied. If the Petition were granted there would be no need for judicial review.

However, when Citizens filed its judicial petition it was required for the first time to show that it had judicial standing as required by RCW 34.05.530, that it had exhausted administrative remedies as required by RCW 34.05.531, and that it met substantial prejudice requirements in RCW 34.05.570(1)(d). Citizens included allegations in paragraphs 1-18 in Section VI of its judicial petition to demonstrate that it was entitled to judicial review. (CP6-8) Citizens did not limit its allegations to facts already in the Administrative Record.

The Commission's Responding Brief to the trial court argued that Paragraphs 8 to 17 in judicial petition section VI should be stricken because the Commission claimed allegations were made that provide new evidence outside the administrative record. (CP186) Citizens considered the

Commission's request to strike said paragraphs 8-17 to be an initial move to challenge Citizen's entitlement to obtain judicial review. Citizen's responded as if the Commission's challenge was similar to a summary judgment motion. Citizens filed a Motion to Supplement the Record with the First Declaration of Julie Simms. In that motion, Citizens argues that:

Petition Paragraphs 8-17 and the First Declaration of Julie Simms are not intended to supplement the administrative record on the merits, but rather are intended to show that Petitioner satisfies prerequisites for judicial review and relief.

(Motion to Supplement at 2) Citizens' trial Reply Brief argues that:

These supplemental facts are allowed by RCW 34.05.562(1)(c) because they are "material facts not required to be determined on the agency record" and because they relate to the validity of the agency action because a finding of invalidity requires judicial review prerequisites to be satisfied.

(CP154)

Citizens then argued that a trial court abuses discretion if it excludes supplemental facts necessary to satisfy prerequisites to judicial review and provided the following quote from *The City of Burlington v. Washington State Liquor Control Bd.* ("*Burlington*"), 187 Wn.App. 853, 866-67, 351 P.3d 875 *rev. denied* 184 Wn.2d 1014, 360 P.3d 818 (2015):

A party seeking review of an agency action may submit additional evidence to demonstrate standing particularly where, as here, no hearing occurred at the administrative level. Typically, judicial review of an agency action is limited to the administrative record. Because the [Petitioner] was not required to demonstrate standing for judicial review at the administrative level, and because the [Agency] denied the [Petitioner] an adjudicative hearing, the administrative record is limited on evidence of standing. We conclude that the trial court should have considered the [Petitioner's] supplemental declarations, because the evidence went only to the question of standing for judicial review and not to the merits.

(CP154-55)

In Citizens' Opening Brief, Citizens argued that because there was no summary judgment motion, the allegations in said Paragraphs 1-18 were presumed to embrace the facts necessary to support standing, substantial prejudice and exhaustion. (CP117)

Citizens has alleged in its judicial Petition that it meets the judicial requirements for standing (RCW 34.05.530), substantial prejudice (RCW 34.05.570(1)(d)), and exhaustion (RCW 34.05.534). (*Supra* at [CP116]) Generally with regard to standing, substantial prejudice, and exhaustion, the Court should "presume that general allegations [in the judicial petition] embrace those specific facts that are necessary to support the claim." (*Lujan v. Defenders of Wildlife*, 112 S.Ct. 2130, 504 U.S. 555, 561, 119 L.Ed.2d 351, 60 U.S.L.W. 4495 (1992)) Allegations must be supported by affidavits or other evidence if a challenge is made by summary judgment motion. (*Id.*) No challenge was made by summary judgment motion.

(CP117)

To date, the Commission has not challenged that Citizens' does not meet the requirements for judicial review, so it appears that the First Declaration of Julie Simms is not yet necessary and Citizen's has not objected to the denial in CP164-65 of Citizens' Motion to Supplement the Record with that Declaration. But Citizens does challenge that the trial court abused discretion when he struck paragraphs 11-16 from Section VI of the judicial petition because Citizens "was not required to demonstrate standing for judicial review at the administrative level" and there was no "adjudicative hearing." (*See* CP164-65)

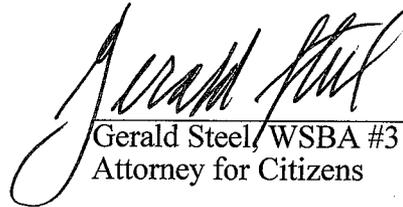
VI. CONCLUSION

Pursuant to RCW 34.05.574, Citizens requests reinstatement of Paragraphs 11-16 in Section VI of the judicial petition and:

- 1) That this Court rule that fluoridated waters (bottled and public) and their fluoridating additives are drugs in intrastate commerce when intended for use in the mitigation, treatment and/or prevention of tooth decay disease;
- 2) That this Court overrule, clarify, or distinguish the *Protect the Peninsula's Future* Court's discussion that *Kaul* is "binding precedent" "that fluorides in drinking water are not drugs under Washington law";
- 3) That this Court set aside the Commission's action provided at AR147-48 because the Commission's action was arbitrary, capricious and/or contrary to law and that this Court remand to the Commission for it to take action consistent with this Court's Order; and
- 4) Provide such other relief as this Court may deem proper.

Dated the 10th day of July, 2017.

Respectfully submitted,


Gerald Steel, WSBA #31084
Attorney for Citizens

APPENDIX A

No. 50022-1-II

ATTACHMENTS

PAGES

A1 - A6	Former Ch. 18.64 RCW (1951 with amendments to 1959) Relevant Portion
A7 - A15	Former Ch. 18.71 RCW (1951 with amendments to 1959)
A16 - A22	RCW 69.41.010 and 173 1 st ex.s. c 186
A23 - A30	Former Ch. 69.04 RCW (1951 with amendments to 1959) Relevant Portion
A31	RCW 69.04.008
A32 - A33	21 USC 321(f) and (g)
A34 - A35	21 USC 321(ff)

REVISED CODE *of* WASHINGTON

Containing on initial publication all statutes in force to and including the laws enacted by the second extraordinary session of the Legislature, which adjourned September 4, 1951.

Published under authority of chapter 155, Laws of 1951, and chapter 7, Second Extraordinary Session Laws, 1951.

VOLUME 2

- Title 14 Aeronautics
- 15 Agriculture and marketing.
- 16 Animals, estrays, brands and fences.
- 17 Weeds, rodents and pests.
- 18 Businesses and professions.
- 19 Business regulations—Miscellaneous.
- 20 Commission merchants.
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- 24 Nonprofit corporations and associations.
- 25 Partnerships.
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- 27 Libraries, museums and historical activities.
- 28 Public schools and colleges.

18.64.001: State board of pharmacy—Creation—Members—Meetings—Powers and duties. See chapter 43.69.

18.64.010 Definitions. [(i) 1931 c 56 § 1, part; 1927 c 253 § 1, part; 1923 c 180 § 3, part; RRS § 10126-3, part. (ii) 1935 c 98 § 6, part; 1909 c 213 § 7, part; 1899 c 121 § 13, part; 1891 c 153 § 13, part; RRS § 10138, part.] Now codified in RCW 18.64.080 and 18.64.250.

18.64.020 Licensing required. It shall hereafter be unlawful for any person to compound or dispense drugs, medicines or poisons, or to institute any pharmacy, store or shop for wholesaling or retailing, compounding or dispensing drugs, medicines or poisons, unless such person shall be a registered pharmacist or shall place in charge of said pharmacy store or shop a registered pharmacist except as hereinafter provided. [1899 c 121 § 1; RRS § 10126. Prior: 1891 c 113 § 1. Formerly RCW 18.67.010, part.]

Persons licensed under prior laws: 1923 c 180 § 6: The director of licenses shall on application issue a certificate of registered pharmacist without examination to a regularly licensed physician and surgeon of the state of Washington: *Provided*, That a physician and surgeon to be entitled to registration as a pharmacist without examination under the provisions of this act shall make application to the director of licenses within six months of the taking effect of this act.

1923 c 180 § 10: Unregistered persons who furnish affidavits from two or more registered pharmacists of the state of Washington that they

have five or more years continuous experience in pharmacy prior to the enactment of this act and who are actually engaged in pharmacy in the state of Washington at the time of the enactment of this act, shall have opportunity of passing the examination as provided in section three for registered pharmacists within one year after the date this act takes effect: *Provided*, That time spent by such applicant in the medical department of the army, navy, or marine corps of the United States during the world war shall for the purpose of this act be considered time spent in a pharmacy.

18.64.030 Licensing—Exemptions. [1935 c 98 § 6, part; 1909 c 213 § 7, part; 1899 c 121 § 13, part; RRS § 10138, part. Prior: 1891 c 153 § 13, part.] Now codified in RCW 18.64.250.

18.64.040 Fee for certificate—Graduates and licentiates—Examination fee—Shopkeeper's license—Failure to pay—Penalty. Every person claiming registration as a graduate in pharmacy or as a licentiate of some other state board, shall, before a certificate be granted, pay the sum of ten dollars, and every applicant for registration by examination under this chapter shall pay the sum of ten dollars before the examination be attempted: *Provided*, That in case the applicant fails to pass a satisfactory examination he shall have the privilege of a second examination without any charge any time within one year. Every shopkeeper not a pharmacist, desiring to secure the benefits and privileges of this chapter, is hereby required to secure a shopkeeper's license, and he or she shall pay the sum of five dollars for the same, and annually thereafter the sum of five dollars for renewal of the same; and shall at all times keep said license or the current renewal thereof conspicuously exposed in the shop to which it applies. In event such shopkeeper's license fee re-

the general fund of the state. [1935 c 98 § 10; RRS § 10145-2. Formerly RCW 18.64.050, part.]

18.64.060 Pharmacist and assistant pharmacist applicants—Eligibility. A person making application to the state of Washington for a certificate of registered pharmacist shall be over twenty-one years of age, or as registered assistant pharmacist shall be over eighteen years of age, and shall satisfy the board of pharmacy that he or she is able to read, write and speak the English language, and shall furnish affidavits from not less than two reputable citizens that he or she is of good moral character, not addicted to the use of alcoholic liquors or to the use of any narcotic drug or drugs. [1923 c 180 § 2; RRS § 10126-2.]

Reviser's note: See note following chapter digest.

18.64.065 Certificate of pharmacist or assistant pharmacist—Persons qualified. No person shall be granted a certificate of registered pharmacist or registered assistant pharmacist by the board of pharmacy except by examination, by graduation, by having been registered by examination in another state as hereinafter provided, or by being a duly licensed physician and surgeon in the state of Washington. [1923 c 180 § 1; RRS § 10126-1. Prior: 1899 c 121 § 2; 1891 c 153 § 2. Formerly RCW 18.64.070, part.]

Reviser's note: See note following chapter digest.

18.64.070 Certificate by graduation—Requirements. To be granted a certificate of registered pharmacist by the board of pharmacy, by graduation, a person shall furnish evidence of having had twelve months' practical experience in a pharmacy, as that term is defined in RCW 18.64.080, and of having graduated from not less than a three year course of the University of Washington college of pharmacy or the Washington State College school of pharmacy. [1927 c 253 § 2; 1923 c 180 § 4; RRS § 10126-4. Prior: 1899 c 121 § 3; 1891 c 113 § 3. FORMER PART OF SECTION: 1923 c 180 § 1; 1899 c 121 § 2; RRS § 10126-1, now codified as RCW 18.64.065.]

Reviser's note: See note following chapter digest.

18.64.080 Certificate by examination—Prerequisites—Examinations—Subjects—Grades required. To be granted a certificate of registered pharmacist by the board of pharmacy by examination, a person shall furnish suitable evidence that he or she is a graduate of a college of pharmacy maintaining not less than a two year course, recognized by the board of pharmacy, or that he or she shall have had, prior to the taking effect of this chapter, at least twelve years' service in the medical department of the United States navy, and attained the rating of chief pharmacist's mate, or pharmacist's mate first class and in addition thereto shall have had subsequent to said naval service at least six months' continuous experience in the

practice of pharmacy wherein the prescriptions of medical practitioners were compounded or that he or she shall have had prior to the taking effect of this chapter, and not otherwise, at least fifteen years' continuous experience in the practice of pharmacy wherein the prescriptions of medical practitioners were compounded and was so engaged in this state at the time this chapter took effect: *Provided, however,* That experience gained before the age of fifteen years shall not be counted or computed, or that he or she is a regularly licensed physician and surgeon in the state of Washington, and shall pass an examination in the subjects of pharmacy, materia medica, chemistry, toxicology and posology, compounding of prescriptions, identification of drugs, and the laws relating to the practice of pharmacy in the state of Washington, with a general average of not less than seventy-five percent and a grade of not less than sixty percent in any one subject: *Provided,* That physicians and surgeons as herein defined shall be required to pass an examination only in the subjects of pharmacy, compounding of prescriptions, and the laws relating to the practice of pharmacy in the state of Washington with a grade in each subject and a general average as defined in this section: *Provided,* That before a certificate of registered pharmacist is issued, graduates of two year courses of recognized colleges of pharmacy shall be required to present evidence of having had at least twenty-four months of practical experience in a pharmacy and graduates of three year courses of recognized colleges of pharmacy shall be required to furnish evidence of having had at least twelve months of practical experience in a pharmacy. Graduates of four and five year courses of recognized colleges of pharmacy or of colleges of medicine shall not be required to present evidence of practical experience as defined by this chapter. Practical experience shall be defined as experience in a pharmacy where drugs and medicines are compounded and dispensed, and where prescriptions of regularly licensed physicians are compounded. Recognized colleges of pharmacy as defined by this chapter shall be such colleges, schools or departments of pharmacy whose entrance requirements and courses of study are approved by the board of pharmacy. [1931 c 56 § 1; 1927 c 253 § 1; 1923 c 180 § 3; RRS § 10126-3. Formerly RCW 18.64.010, part, 18.64.080 and 18.64.090, part.]

Reviser's note: See note following chapter digest.

18.64.090 Registration of pharmacists of other states. The board of pharmacy shall grant a certificate of registered pharmacist to any person who furnishes proof that he or she is a registered pharmacist by examination in good standing in another state: *Provided,* That the applicant meets the qualifications set forth in RCW 18.64.060, the education and experience requirements of RCW 18.64.080, and passes an examination in the laws relating to the practice of phar-

18.64.246 Prescriptions—Labels. To every box, bottle, jar, tube or other container of a prescription which is dispensed there shall be fixed a label bearing the name and address of the pharmacy wherein the prescription is compounded, the corresponding serial number of the prescription, the name of the prescriber, his directions, name of patient, date and initials of the registered pharmacist who has compounded the prescription. [1939 c 28 § 2; RRS § 6154-2. Formerly RCW 18.67.080.]

18.64.247 Penalty for violation of RCW 18.64.245, 18.64.246. Any person violating or failing to comply with the requirements of RCW 18.64.245 and 18.64.246 shall be guilty of a misdemeanor. [1939 c 28 § 3; RRS § 6154-3. Formerly RCW 18.67.091.]

18.64.250 Penalty for violations—Exceptions. Any person not a registered pharmacist and not having continuously and regularly in his employ a duly licensed and registered pharmacist within the full meaning of this chapter, who shall retail, compound or dispense medicines, or who shall take, use or exhibit the title of registered pharmacist, shall be deemed guilty of a misdemeanor, and upon conviction thereof shall be fined in any sum not to exceed fifty dollars; and each and every day that such prohibited practice continues shall be deemed a separate offense. Every place in which physicians' prescriptions are compounded or dispensed shall be deemed to be a pharmacy, drug store or dispensary, and the same shall at all times be under the personal supervision of a duly licensed and registered pharmacist; and any person who shall permit the compounding and dispensing of prescriptions, or vending of drugs, medicines or poisons in his store or place of business, except upon the supervision of a registered pharmacist, or any registered pharmacist or shopkeeper registered under this chapter while continuing in business, who shall fail or neglect to procure annually his renewal of registration, or any person who shall wilfully make any false representations to procure registration for himself or any other person, or who shall violate any of the provisions of this chapter wilfully and knowingly, shall be deemed guilty of a misdemeanor, and upon conviction thereof shall be fined in any sum not to exceed fifty dollars; and each day that such prohibited practice continues shall be deemed a separate offense: *Provided*, That nothing in this chapter shall operate in any manner to interfere with the business of any physician and surgeon, duly licensed as such under the laws of this state, in regular practice, or prevent him from administering to his patients such medicines as he may deem proper, nor with selling proprietary medicine or medicines placed in sealed packages, nor with the exclusive wholesale business of any dealer except as hereinafter provided, nor prevent shopkeepers, itinerant vendors, peddlers or salesmen from dealing in and selling the commonly used medicines, or patent and proprietary medicines, if such

medicines are sold in the original packages of the manufacturer, or in packages put up by a registered pharmacist in the manner provided by the state board of pharmacy, if such shopkeeper, itinerant vendor, salesman or peddler shall have obtained a license as hereinabove provided; but any person who shall take or use or exhibit in or upon any place of business, or advertise in a newspaper, telephone or other directory, by radio, or in any manner the title of pharmacist, assistant pharmacist, druggist, pharmacy, drug store, medicine store, drug department, drugs, drug sundries, or any title or name of like description or import, or display or permit to be displayed upon said place of business the characteristic pharmacy show bottles or globes, either colored or filled with colored liquids, without having continuously and regularly employed in his shop, store, or place of business a pharmacist duly licensed and registered under this chapter, shall be guilty of a misdemeanor, and each and every day that such prohibited practice continues shall be deemed a separate offense. [1935 c 98 § 6; 1909 c 213 § 7; 1899 c 121 § 13; RRS § 10138. Formerly RCW 18.64.250, 18.64.010, 18.64.030, 18.67.030, 18.67.040 and 18.67.130. FORMER PART OF SECTION: 1909 c 213 § 13; RRS § 10146, now codified as RCW 18.64.280.]

Acting without license: RCW 9.37-.030.

18.64.260 Enforcement provisions—Disposition of fines. All suits for the recovery of the several penalties prescribed in this chapter shall be prosecuted in the name of the state of Washington in any court having jurisdiction, and it shall be the duty of the prosecuting attorney of the county wherein such offense is committed to prosecute all persons violating the provisions of this chapter upon the filing of proper complaint. All penalties collected under the provisions of this chapter shall inure to the school fund of the county in which suit was prosecuted and judgment obtained. [1909 c 213 § 9; 1899 c 121 § 17; RRS § 10142.]

Reviser's note: This section apparently superseded as to disposition of fines and penalties by RCW 10.82.070 requiring fines to be paid to the current state school fund; see Slayden v. Carr, 94 Wash. 412, 162 Pac. 529.

18.64.270 Responsibility for drug purity—Adulteration—Penalty. Every proprietor of a wholesale or retail drug store shall be held responsible for the quality of all drugs, chemicals or medicines sold or dispensed by him except those sold in original packages of the manufacturer and except those articles or preparations known as patent or proprietary medicines. Any person who shall knowingly, wilfully or fraudulently falsify or adulterate any drug or medicinal substance or preparation authorized or recognized by the pharmacopoeia of the United States or used or intended to be used in medical practice, or shall wilfully, knowingly or fraudulently offer for sale, sell or cause the same to be sold for medicinal purposes, shall be deemed guilty of a misdemeanor, and upon conviction there-

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A7

Chapter 18.71

PHYSICIANS AND SURGEONS

Sections

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- 18.71.020 Licensing required—Penalty.
- 18.71.030 Licensing exemptions.
- 18.71.040 Application fee.
- 18.71.050 Application—Eligibility requirements.
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- 18.71.900 Interchangeable terms.
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Abortion: Chapter 9.02.

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Adoption of children through hospitals, doctors, midwives, etc.: RCW 26.36.040.

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Medical disciplinary board act: Chapter 18.72.

Rebating by practitioners of healing professions prohibited: Chapter 19.58.

Regulation of practice of medicine and surgery, sale of drugs and medicines: Art. 20 § 2 state Constitution.

Reviser's note: "Director" and "director of licenses" have been substituted for "board" and "board of medical examiners" throughout this chapter, since the state board of medical examiners was abolished by 1921 c 7 § 135 and its powers and duties were transferred to the director of licenses by 1921 c 7 § 96 (RCW 43.24-.020).

AB

18.71.010 Definitions. (1) The practice of medicine and surgery consists of the use of drugs or medicinal preparations in or upon human beings, severing or penetrating the tissues of human beings, and the use of any and all other methods in the treatment of diseases, injuries, deformities, or other physical or mental conditions.

(2) "Director" means the director of licenses. [1957 c 60 § 2. Prior: 1947 c 168 § 1, part; 1919 c 134 § 3, part; 1909 c 192 § 6, part; Rem. Supp. 1947 § 10008, part; prior, 1905 c 41 § 1, part; 1901 c 42 § 1, part; 1890 p 115 § 3, part; Code 1881 § 2285, part.]

18.71.020 Licensing required—Penalty. Any person who shall practice or attempt to practice, or hold himself out as practicing medicine and surgery in this state, without having, at the time of so doing, a valid, unrevoked certificate as provided in this chapter, shall be guilty of a misdemeanor. In each such conviction the fine shall be paid, when collected, to the state treasurer, and shall constitute a special fund for the prosecution of illegal practitioners as defined in this chapter, and the director of licenses is authorized to prosecute all persons guilty of a violation of the provisions of this chapter. [1919 c 134 § 8; 1909 c 192 § 14; RRS § 10018. Prior: 1890 p 119 § 8; Code 1881 § 2290.]

Reviser's note: See note following chapter digest.

Persons licensed under prior laws: Any person who holds a license from the board of medical examiners heretofore existing, under the provisions of any laws of this state, past or present, shall be entitled to practice medi-

cine and surgery in this state the same as if issued under this act: *Provided, however,* That all licenses herein mentioned may be revoked for unprofessional conduct, in the same manner and upon the same grounds as if issued under this act. [1909 c 192 § 17.]

18.71.030 Licensing exemptions. Nothing in this chapter shall be construed to prohibit service in the case of emergency, or the domestic administration of family remedies, or the practice of midwifery; nor shall this chapter apply to any commissioned medical officer in the United States army, navy, or marine hospital service, in the discharge of his official duties; nor to any licensed dentist when engaged exclusively in the practice of dentistry; nor shall this chapter apply to any practitioner from any other state or territory in which he resides: *Provided,* That such practitioner shall not open an office or appoint a place of meeting patients or receive calls within the limits of this state. This chapter shall not be construed to apply in any manner to the practice of osteopathy or to any drugless method of treating the sick or afflicted, or to apply to or interfere in any way with the practice of religion or any kind of treatment by prayer; nor to any person now holding a license from the state board of medical examiners for any system of drugless practice. [1919 c 134 § 12; 1909 c 192 § 19; RRS § 10024.]

Administering drugs, inoculations, etc., by registered nurses permitted: RCW 18.88.290.

Reviser's note: State board of medical examiners abolished and powers

and duties transferred to director of licenses. See note following chapter digest.

18.71.040 Application fee. Every applicant for a certificate to practice medicine and surgery shall pay a fee of twenty-five dollars. [1955 c 202 § 35. Prior: 1941 c 166 § 1, part; 1913 c 82 § 1, part; 1909 c 192 § 7, part; Rem. Supp. 1941 § 10010-1, part.]

Basic sciences examination fee:
RCW 43.74.040.

18.71.050 Application—Eligibility requirements. Every such applicant must file in the office of the director with his application satisfactory testimonials as to his moral character, and a diploma issued by a medical school accredited and approved by the director, as of the time the diploma was issued therefrom, or satisfactory evidence of having possessed a diploma from a medical school accredited and approved as provided by RCW 18.71.055. The application must be sworn to before some person authorized to administer oaths, and attested by the hand and seal of such officer, if he has a seal, stating that the applicant is the person named in the diploma, that he is the lawful holder thereof, and that it was procured in the regular course of instruction and examination, without fraud or misrepresentation.

The applicant must also furnish evidence that:

(1) He has served for not less than one year as interne in a thoroughly equipped hospital, having at least twenty-five beds for each interne, devoted to the treatment of medical, surgical, gynecological and special diseases;

(2) He has had some experience in, and has a practical working knowledge of obstetrics and has attended or has participated in the attendance upon not less than six confinements;

(3) He has had some experience in, and a practical working knowledge of pathology;

(4) He can speak and write the English language. [1957 c 60 § 3. Prior: 1947 c 168 § 1, part; 1919 c 134 § 3, part; 1909 c 192 § 6, part; Rem. Supp. 1947 § 10008, part; prior, 1905 c 41 § 1, part; 1901 c 42 § 1, part; 1890 p 115 § 3, part; Code 1881 § 2285, part.]

18.71.055 Medical schools—Requirements for accreditation and approval. The director shall not accredit and approve any medical school unless it:

(1) Requires three academic years of premedical collegiate instruction which training shall include theoretical and laboratory courses in physics, biology, inorganic and organic chemistry as a prerequisite to admission;

(2) Provides a curriculum extending over a period of at least four academic years and provides adequate instruction in the following subjects: Anatomy, biochemistry, microbiology and immunology, pathology, pharmacology, physiology, anaesthesiology, dermatology, gynecology, internal medicine, neurology, obstetrics, ophthalmology, orthopedic surgery, otolaryngology, pediatrics, physical medicine and rehabilitation, preventive medicine and public

health, psychiatry, radiology, surgery and urology;

(3) Provides clinical instruction in hospital wards and outpatient clinics under guidance for third and fourth year medical students.

Approval may be withdrawn by the director at any time a medical school ceases to comply with one or more of the requirements of this section. [1957 c 60 § 4.]

18.71.060 Applications—Record. Said director shall keep an official record of all his proceedings, a part of which record shall consist of a register of all applicants for certificates under this chapter, with the result of each application. Said record shall be evidence of all the proceedings of said director which are set forth therein. [1909 c 192 § 8; RRS § 10011.]

Reviser's note: See note following chapter digest.

18.71.070 Examination. In addition to the requirements above set forth, such applicants for a certificate must be personally examined by said director as to their qualifications. The examination shall be conducted in the English language, shall be practical in character and designed to discover the applicant's fitness to practice medicine and surgery, and shall be, in whole or in part, in writing on the following fundamental subjects, to wit: Anatomy, histology, gynecology, pathology, bacteriology, chemistry, toxicology, physiology, obstetrics, general diagnosis, hygiene, practice of medicine and surgery and any other branches thereof that the director shall deem advisable. Examinations in each subject shall consist of not less than ten questions, answers to which shall be marked upon a scale of zero to ten. All applicants must obtain not less than sixty percent in any one subject: *Provided*, That applicants who can show at least ten years of reputable practice shall be granted a credit of five percent upon the general average, and five percent additional for each subsequent ten years of such practice. The examination papers shall form a part of the records of the director and shall be kept on file for a period of one year after each examination. In said examination the applicant shall be known and designated by number only, and the name attached to the number shall be kept secret until after the application has been finally voted upon. [1919 c 134 § 4; 1909 c 192 § 6; RRS § 10009.]

Reviser's note: The last two sentences of 1919 c 134 § 4 read: "The examination papers shall form a part of the records of the board and shall be kept on file by the secretary for a period of one year after each examination. In said examination the applicant shall be known and designated by number only, and the name at-

tached to the number shall be kept secret until the board has finally voted upon the application." These sentences have been changed to refer to the director of licenses as the board of medical examiners was abolished and its powers and duties transferred to the director of licenses. See note following chapter digest.

18.71.080 License—Annual renewal. Every person licensed to practice medicine and surgery in this state shall register with the

director of licenses annually, and pay an annual renewal registration fee of seven dollars, on or before the first day of July of each year, and thereupon the license of such person shall be renewed for a period of one year. Any failure to register and pay the annual renewal registration fee shall render the license invalid, but such license shall be reinstated upon written application therefor to the director, and payment to the state of a penalty of ten dollars, together with all delinquent annual license renewal fees. [1955 c 202 § 36. Prior: 1941 c 166 § 1, part; 1913 c 82 § 1, part; 1909 c 192 § 7, part; Rem. Supp. 1941 § 10010-1, part.]

18.71.090 License—Reciprocity with other states. Any applicant who has been examined and licensed under the laws of another state, which through a reciprocity provision in its laws, similarly accredits the holders of certificates from the proper authorities of this state to the full privileges of practice within its borders may, in the discretion of the director, be granted a license without examination on the payment of a fee of twenty-five dollars to the state treasurer: *Provided*, That he has not previously failed to pass an examination held in this state. He must file with the director a copy of his license certified by the proper authorities of the issuing state to be a full, true copy thereof, and must show that the standards, eligibility requirements and examinations of that state are at least equal in all respects to those of this state. [1957 c 60 § 5; 1919 c 134 § 11; RRS § 10023.]

18.71.095 Conditional certificate or license for out-of-state licensees while engaged by department of institutions. Notwithstanding any provisions of law to the contrary, the director of the department of licenses shall, upon the written request of the director of the department of institutions, issue a conditional certificate or license to practice medicine and surgery in this state to such person or persons as requested by the director of the department of institutions; who have been accepted for employment by the department as physicians or psychiatrists; who are licensed to practice medicine and surgery in another state of the United States; and who are graduates of a medical school accredited and approved in accordance with the provisions of RCW 18.71.055, as now or hereafter amended; any such license or conditional certificate to practice medicine and surgery in this state shall be issued by the director of the department of licenses, and in addition to the above requirements shall be subject to the following limitations, which shall be set forth therein:

(1) The licensee shall only practice the profession of medicine and surgery in conjunction with patients, residents, or inmates of the state institutions under the control and supervision of the director of the department of institutions.

(2) The licensee shall be subject to the jurisdiction of the med-

ical disciplinary board to the same extent as other members of the medical profession, in accordance with chapter 18.72 and in addition, the conditional license or certificate to practice medicine and surgery in the state of Washington may be revoked by the medical disciplinary board after a hearing has been held in accordance with the provisions set forth in chapter 18.72, and determination made by the medical disciplinary board that such licensee has violated the limitations set forth in subsection (1) hereof.

(3) Such license shall remain in full force and effect so long as the licensee remains an employee of the department of institutions, and his duties as such employee require him to practice the profession of medicine and surgery, unless such conditional license or certificate is revoked or suspended by the medical disciplinary board, in accordance with the provisions of chapter 18.72. [1959 c 189 § 1.]

18.71.096 ——— Limitation on issuance—Validity. The director of licenses shall not issue conditional licenses or certificates to practice medicine and surgery under the provisions of RCW 18.71.095 after July 1, 1963, but all such licenses issued under the authority of RCW 18.71.095 prior to July 1, 1963 shall remain valid and effective, subject to the provisions of RCW 18.71.095. [1959 c 189 § 2.]

18.71.100 Applicability of health regulations. All persons granted licenses or certificates under this chapter, shall be subject to the state and municipal regulations relating to the control of contagious diseases, the reporting and certifying to births and deaths, and all matters pertaining to public health; and all such reports shall be accepted as legal. [1909 c 192 § 18; RRS § 10022.]

Public health and safety: Title 70.
Vital statistics: Chapter 70.58.

18.71.110 Unprofessional conduct. [1915 c 65 § 1; RRS § 10015.]
Repealed by 1955 c 202 § 47. Later enactment, see RCW 18.72.030.

18.71.120 Refusal of license—Reinstatement procedure. The director must refuse a certificate to any applicant guilty of unprofessional conduct: *Provided*, That any person whose license has been suspended or revoked under the provisions of chapter 18.72 may apply to the board for reinstatement at any time and the board may hold hearings on any such petition and may order reinstatement and impose terms and conditions thereof and issue a certificate of reinstatement to the director of licenses. [1955 c 202 § 38. Prior: 1919 c 134 § 7, part; 1909 c 192 § 11, part; 1905 c 41 § 1, part; RRS § 10014, part.]

"Unprofessional conduct": RCW
18.72.030.

18.71.130 Revocation of license—Grounds. [1919 c 134 § 7, part; RRS § 10014, part.] Deleted by 1955 c 202 §§ 37, 39. Later enactment, see chapter 18.72.

18.71.140 Refusal of license—Hearing required. Before refusal of a license upon the ground of unprofessional conduct a hearing must be had before the medical disciplinary board. Such hearing shall be governed by the procedure set forth in chapter 18.72 and the applicant shall have all the rights accorded to an accused license holder under such chapter, including the right to appeal from an adverse decision. [1955 c 202 § 40. Prior: 1919 c 134 § 7, part; 1909 c 192 § 11, part; 1905 c 41 § 1, part; RRS § 10014, part.]

“Unprofessional conduct”: RCW 18.72.030.

18.71.150 Same—Default—Reference to hearing committee. [1919 c 134 § 7, part; RRS § 10014, part.] Deleted by 1955 c 202 §§ 37, 41. Later enactment, see chapter 18.72.

18.71.160 Same—Hearing—Generally. [1919 c 134 § 7, part; RRS § 10014, part.] Deleted by 1955 c 202 §§ 37, 42. Later enactment, see chapter 18.72.

18.71.170 Refusal or revocation of licenses—Hearing—Recalcitrancy of witnesses. [1919 c 134 § 7, part; RRS § 10014, part.] Deleted by 1955 c 202 §§ 37, 43. Later enactment, see chapter 18.72.

18.71.180 Same—Record of refusal. In case of the refusal of a license, the medical disciplinary board shall file a brief and concise statement of the grounds and reasons therefor in the office of the director of licenses, which, together with the decision of the hearing committee of the medical disciplinary board, in writing, shall remain of record therein. [1955 c 202 § 44. Prior: (i) 1919 c 134 § 7, part; RRS § 10014, part. (ii) 1909 c 192 § 12; RRS § 10016.]

18.71.190 False personation—Penalty. Every person filing for record, or attempting to file for record, the certificate issued to another, falsely claiming himself to be the person named in such certificate, or falsely claiming himself to be the person entitled to the same, shall be guilty of a felony, and, upon conviction thereof, shall be subject to such penalties as are provided by the laws of this state for the crime of forgery. [1909 c 192 § 16; RRS § 10019.]

False personation: RCW 9.37.010.

18.71.900 Interchangeable terms. The words “certificates” and “licenses” shall be known as interchangeable terms in this chapter. [1909 c 192 § 21.]

18.71.910 Repeal—1909 act. All acts, or parts of acts, in any wise conflicting with the provisions of this act, are hereby repealed. [1909 c 192 § 22.]

Physicians, Surgeons 18.71.930

18.71.920 Repeal—1957 act. All acts and parts of acts to the extent that the same are in conflict herewith are hereby repealed. [1957 c 60 § 6.]

18.71.930 Severability—1957 act. If any section, sentence, clause, or phrase of this act should be held to be invalid or unconstitutional, the invalidity or unconstitutionality thereof shall not affect the validity or constitutionality of any other section, sentence, clause or phrase of this act. [1957 c 60 § 7.]

RCW 69.41.010**Definitions.**

As used in this chapter, the following terms have the meanings indicated unless the context clearly requires otherwise:

- (1) "Administer" means the direct application of a legend drug whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by:
 - (a) A practitioner; or
 - (b) The patient or research subject at the direction of the practitioner.
- (2) "Commission" means the pharmacy quality assurance commission.
- (3) "Community-based care settings" include: Community residential programs for persons with developmental disabilities, certified by the department of social and health services under chapter **71A.12** RCW; adult family homes licensed under chapter **70.128** RCW; and assisted living facilities licensed under chapter **18.20** RCW. Community-based care settings do not include acute care or skilled nursing facilities.
- (4) "Deliver" or "delivery" means the actual, constructive, or attempted transfer from one person to another of a legend drug, whether or not there is an agency relationship.
- (5) "Department" means the department of health.
- (6) "Dispense" means the interpretation of a prescription or order for a legend drug and, pursuant to that prescription or order, the proper selection, measuring, compounding, labeling, or packaging necessary to prepare that prescription or order for delivery.
- (7) "Dispenser" means a practitioner who dispenses.
- (8) "Distribute" means to deliver other than by administering or dispensing a legend drug.
- (9) "Distributor" means a person who distributes.
- (10) "Drug" means:
 - (a) Substances recognized as drugs in the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States, or official national formulary, or any supplement to any of them;
 - (b) Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or animals;
 - (c) Substances (other than food, minerals or vitamins) intended to affect the structure or any function of the body of human beings or animals; and
 - (d) Substances intended for use as a component of any article specified in (a), (b), or (c) of this subsection. It does not include devices or their components, parts, or accessories.
- (11) "Electronic communication of prescription information" means the transmission of a prescription or refill authorization for a drug of a practitioner using computer systems. The term does not include a prescription or refill authorization transmitted verbally by telephone nor a facsimile manually signed by the practitioner.
- (12) "In-home care settings" include an individual's place of temporary and permanent residence, but does not include acute care or skilled nursing facilities, and does not include community-based care settings.
- (13) "Legend drugs" means any drugs which are required by state law or regulation of the pharmacy quality assurance commission to be dispensed on prescription only or are restricted to use by practitioners only.
- (14) "Legible prescription" means a prescription or medication order issued by a practitioner that is capable of being read and understood by the pharmacist filling the prescription or the nurse or other practitioner implementing the medication order. A prescription must be hand printed, typewritten, or electronically generated.
- (15) "Medication assistance" means assistance rendered by a nonpractitioner to an individual residing in a community-based care setting or in-home care setting to facilitate the individual's self-administration of a

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legend drug or controlled substance. It includes reminding or coaching the individual, handing the medication container to the individual, opening the individual's medication container, using an enabler, or placing the medication in the individual's hand, and such other means of medication assistance as defined by rule adopted by the department. A nonpractitioner may help in the preparation of legend drugs or controlled substances for self-administration where a practitioner has determined and communicated orally or by written direction that such medication preparation assistance is necessary and appropriate. Medication assistance shall not include assistance with intravenous medications or injectable medications, except prefilled insulin syringes.

(16) "Person" means individual, corporation, government or governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.

(17) "Practitioner" means:

(a) A physician under chapter 18.71 RCW, an osteopathic physician or an osteopathic physician and surgeon under chapter 18.57 RCW, a dentist under chapter 18.32 RCW, a podiatric physician and surgeon under chapter 18.22 RCW, an East Asian medicine practitioner to the extent authorized under chapter 18.06 RCW and the rules adopted under RCW 18.06.010(1)(j), a veterinarian under chapter 18.92 RCW, a registered nurse, advanced registered nurse practitioner, or licensed practical nurse under chapter 18.79 RCW, an optometrist under chapter 18.53 RCW who is certified by the optometry board under RCW 18.53.010, an osteopathic physician assistant under chapter 18.57A RCW, a physician assistant under chapter 18.71A RCW, a naturopath licensed under chapter 18.36A RCW, a pharmacist under chapter 18.64 RCW, or, when acting under the required supervision of a dentist licensed under chapter 18.32 RCW, a dental hygienist licensed under chapter 18.29 RCW;

(b) A pharmacy, hospital, or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a legend drug in the course of professional practice or research in this state; and

(c) A physician licensed to practice medicine and surgery or a physician licensed to practice osteopathic medicine and surgery in any state, or province of Canada, which shares a common border with the state of Washington.

(18) "Secretary" means the secretary of health or the secretary's designee.

[2016 c 148 § 10; 2016 c 97 § 2. Prior: 2013 c 276 § 1; 2013 c 19 § 55; 2012 c 10 § 44; 2009 c 549 § 1024; 2006 c 8 § 115; prior: 2003 c 257 § 2; 2003 c 140 § 11; 2000 c 8 § 2; prior: 1998 c 222 § 1; 1998 c 70 § 2; 1996 c 178 § 16; 1994 sp.s. c 9 § 736; prior: 1989 1st ex.s. c 9 § 426; 1989 c 36 § 3; 1984 c 153 § 17; 1980 c 71 § 1; 1979 ex.s. c 139 § 1; 1973 1st ex.s. c 186 § 1.]

NOTES:

Reviser's note: (1) The definitions in this section have been alphabetized pursuant to RCW 1.08.015 (2)(k).

(2) This section was amended by 2016 c 97 § 2 and by 2016 c 148 § 10, each without reference to the other. Both amendments are incorporated in the publication of this section under RCW 1.12.025(2). For rule of construction, see RCW 1.12.025(1).

Application—2012 c 10: See note following RCW 18.20.010.

Findings—2006 c 8: "The legislature finds that prescription drug errors occur because the pharmacist or nurse cannot read the prescription from the physician or other provider with prescriptive authority. The legislature further finds that legible prescriptions can prevent these errors." [2006 c 8 § 114.]

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Findings—Intent—Part headings and subheadings not law—Severability—2006 c 8: See notes following RCW 5.64.010.

Effective date—2003 c 140: See note following RCW 18.79.040.

Findings—Intent—2000 c 8: "The legislature finds that we have one of the finest health care systems in the world and excellent professionals to deliver that care. However, there are incidents of medication errors that are avoidable and serious mistakes that are preventable. Medical errors throughout the health care system constitute one of the nation's leading causes of death and injury resulting in over seven thousand deaths a year, according to a recent report from the institute of medicine. The majority of medical errors do not result from individual recklessness, but from basic flaws in the way the health system is organized. There is a need for a comprehensive strategy for government, industry, consumers, and health providers to reduce medical errors. The legislature declares a need to bring about greater safety for patients in this state who depend on prescription drugs.

It is the intent of the legislature to promote medical safety as a top priority for all citizens of our state." [2000 c 8 § 1.]

Effective date—1996 c 178: See note following RCW 18.35.110.

Severability—Headings and captions not law—Effective date—1994 sp.s. c 9: See RCW 18.79.900 through 18.79.902.

Effective date—Severability—1989 1st ex.s. c 9: See RCW 43.70.910 and 43.70.920.

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CHAPTER 186
[House Bill No. 766]

LEGEND DRUGS--

REGULATION

AN ACT Relating to legend drugs; creating a new chapter in Title 69 RCW; repealing section 22, chapter 38, Laws of 1963, section 3, chapter 71, Laws of 1967 and RCW 69.40.064; repealing section 2, chapter 33, Laws of 1970 ex. sess. and RCW 69.40.065; and prescribing penalties.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

NEW SECTION. Section 1. As used in this chapter:

(1) "Administer" means the direct application of a legend drug whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by:

(a) A practitioner; or

(b) The patient or research subject at the direction of the practitioner.

(2) "Deliver" or "delivery" means the actual, constructive, or attempted transfer from one person to another of a legend drug, whether or not there is an agency relationship.

(3) "Dispense" means to deliver a legend drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery.

(4) "Dispenser" means a practitioner who dispenses.

(5) "Distribute" means to deliver other than by administering or dispensing a legend drug.

(6) "Distributor" means a person who distributes.

(7) "Drug" means:

(a) Substances recognized as drugs in the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States, or official national formulary, or any supplement to any of them;

(b) Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals;

(c) Substances (other than food) intended to affect the

structure or any function of the body of man or animals; and

(d) Substances intended for use as a component of any article specified in clause (a), (b), or (c) of this subsection. It does not include devices or their components, parts, or accessories.

(8) "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.

(9) "Person" means individual, corporation, government or governmental subdivision or agency, business trust, estate, trust, partnership or association, or any other legal entity.

(10) "Practitioner" means:

(a) A physician under chapter 18.71 RCW, an osteopathic physician and surgeon under chapter 18.57 RCW, a dentist under chapter 18.32 RCW, a podiatrist under chapter 18.22 RCW, a veterinarian under chapter 18.92 RCW, a registered nurse under chapter 18.88 RCW, a licensed practical nurse under chapter 18.78 RCW, or a pharmacist under chapter 18.64 RCW.

(b) A pharmacy, hospital or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a legend drug in the course of professional practice or research in this state.

NEW SECTION. Sec. 2. Legend drugs shall not be sold, delivered, dispensed or administered except in accordance with this chapter.

(1) No person shall obtain or attempt to obtain a legend drug, or procure or attempt to procure the administration of a legend drug:

(a) By fraud, deceit, misrepresentation, or subterfuge; or

(b) By the forgery or alteration of a prescription or of any written order; or

(c) By the concealment of a material fact; or

(d) By the use of a false name or the giving of a false address.

(2) Information communicated to a practitioner in an effort unlawfully to procure a legend drug, or unlawfully to procure the administration of any such drug, shall not be deemed a privileged communication.

(3) No person shall wilfully make a false statement in any prescription, order, report, or record, required by this chapter.

(4) No person shall, for the purpose of obtaining a legend drug, falsely assume the title of, or represent himself to be, a manufacturer, wholesaler, or any practitioner.

(5) No person shall make or utter any false or forged prescription or other written order for legend drugs.

(6) No person shall affix any false or forged label to a package or receptacle containing legend drugs.

NEW SECTION. Sec. 3. It shall be unlawful for any person to sell, deliver or possess any legend drug except upon the order or prescription of a physician under chapter 18.71 RCW, an osteopathic physician and surgeon under chapter 18.57 RCW, a dentist under chapter 18.32 RCW, a podiatrist under chapter 18.22 RCW, or a veterinarian under chapter 18.92 RCW: PROVIDED, HOWEVER, That the above provisions shall not apply to sale, delivery, or possession by drug wholesalers or drug manufacturers, or their agents or employees, or to any practitioner acting within the scope of his license, or to a common or contract carrier or warehouseman, or any employee thereof, whose possession of any legend drug is in the usual course of business or employment.

NEW SECTION. Sec. 4. A prescription, in order to be effective in legalizing the possession of legend drugs, must be issued for a legitimate medical purpose by one authorized to prescribe the use of such legend drugs. An order purporting to be a prescription issued to a drug abuser or habitual user of legend drugs, not in the course of professional treatment, is not a prescription within the meaning and intent of this section; and the person who knows or should know that he is filling such an order, as well as the person issuing it, may be charged with violation of this chapter. A legitimate medical purpose shall include use in the course of a bona fide research program in conjunction with a hospital or university.

NEW SECTION. Sec. 5. To every box, bottle, jar, tube or other container of a legend drug, which is dispensed by a practitioner authorized to prescribe legend drugs, there shall be affixed a label bearing the name of the prescriber, complete directions for use, the name of the drug and strength per unit dose, name of patient and date: PROVIDED, That the practitioner may omit the name and dosage of the drug if he determines that his patient should not have this information and that, if the drug dispensed is a trial sample in its original package and which is labeled in accordance with federal law or regulation, there need be set forth additionally only the name of the issuing practitioner and the name of the patient.

NEW SECTION. Sec. 6. If, upon the sworn complaint of any person, it shall be made to appear to any judge of the superior court or justice of the peace 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 justice of the peace or judge shall, with or without the approval of the prosecuting attorney, issue a warrant directed to any peace officer in the county, commanding him 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.

NEW SECTION. Sec. 7. Whoever violates any provision of this chapter shall, upon conviction, be fined and imprisoned as herein provided:

(1) For a violation of section 2 of this act, the offender shall be guilty of a felony.

(2) For a violation of section 3 of this act involving the sale, delivery or possession with intent to sell or deliver, the offender shall be guilty of a felony.

(3) For a violation of section 3 of this act involving possession, the offender shall be guilty of a misdemeanor.

(4) For a violation of section 4 of this act, the offender shall be guilty of a felony.

(5) For a violation of section 5 of this act, the offender shall be guilty of a misdemeanor.

(6) Any offense which is a violation of chapter 69.50 RCW shall not be charged under this chapter.

NEW SECTION. Sec. 8. This act shall constitute a new chapter in Title 69 RCW.

NEW SECTION. Sec. 9. The following acts or parts of acts are each repealed:

(1) Section 22, chapter 38, Laws of 1963, section 3, chapter 71, Laws of 1967 and RCW 69.40.064; and

(2) Section 2, chapter 33, Laws of 1970 ex. sess. and RCW 69.40.065.

Passed the House April 14, 1973.

Passed the Senate April 14, 1973.

Approved by the Governor April 25, 1973.

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REVISED CODE *of* WASHINGTON

Containing on initial publication all statutes in force to and including the laws enacted by the second extraordinary session of the Legislature, which adjourned September 1, 1951.

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69.04.001 Statement of purpose. This chapter is intended to enact state legislation (1) which safeguards the public health and promotes the public welfare by protecting the consuming public from injury by product use and the purchasing public from injury by merchandising deceit, flowing from intrastate commerce in food, drugs, devices, and cosmetics; and (2) which is uniform, as provided in this chapter, with the federal food, drug, and cosmetic act; and with the federal trade commission act, to the extent it expressly outlaws the false advertisement of food, drugs, devices, and cosmetics; and (3) which thus promotes uniformity of such law and its administration and enforcement, in and throughout the United States. [1945 c 257 § 2; Rem. Supp. 1945 § 6163-51.]

Conformity with federal regulations: RCW 69.04.190 and 69.04.200.

69.04.002 Introductory. For the purposes of this chapter, terms shall apply as herein defined unless the context clearly indicates otherwise. [1945 c 257 § 3; Rem. Supp. 1945 § 6163-52.]

69.04.003 "Federal act" defined. The term "federal act" means the federal food, drug, and cosmetic act, approved on June 25, 1938. (Title 21 U. S. C. 301 et seq.; 52 Stat. 1040 et seq.) [1945 c 257 § 4; Rem. Supp. 1945 § 6163-53.]

69.04.004 "Intrastate commerce". The term "intrastate commerce" means any and all commerce within the state of Washington and subject to the jurisdiction thereof; and includes the operation of any business or service establishment. [1945 c 257 § 5; Rem. Supp. 1945 § 6163-54.]

69.04.005 "Sale". The term "sale" means any and every sale and includes (1) manufacture, processing, packing, canning, bottling, or any other production, preparation, or putting up; (2) exposure, offer, or any other proffer; (3) holding, storing, or any other possessing; (4) dispensing, giving, delivering, serving, or any other supplying; and (5) applying, administering, or any other using. [1945 c 257 § 6; Rem. Supp. 1945 § 6163-55.]

69.04.006 "Director". The term "director" means the director of the department of agriculture of the state of Washington and his duly authorized representatives. [1945 c 257 § 7; Rem. Supp. 1945 § 6163-56.]

Director of agriculture, general duties: Chapter 43.23. Supervisor of foods, feeds and drugs: RCW 43.23.080.

69.04.007 "Person". The term "person" includes individual, partnership, corporation, and association. [1945 c 257 § 8; Rem. Supp. 1945 § 6163-57.]

69.04.008 "Food". The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3)

69.04.009 Food, Drugs, Cosmetics and Poisons

articles used for components of any such article. [1945 c 257 § 9; Rem. Supp. 1945 § 6163-58.]

69.04.009 "Drugs". The term "drug" means (1) articles recognized in the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States, or official national formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any article specified in clause (1), (2), or (3); but does not include devices or their components, parts, or accessories. [1945 c 257 § 10; Rem. Supp. 1945 § 6163-59. Prior: 1907 c 211 § 2.]

69.04.010 "Device". The term "device" (except when used in RCW 69.04.016 and in RCW 69.04.040(10), 69.04.270, 69.04.690, and in RCW 69.04.470 as used in the sentence "(as compared with other words, statements, designs, or devices, in the labeling)") means instruments, apparatus, and contrivances, including their components, parts and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals. [1945 c 257 § 11; Rem. Supp. 1945 § 6163-60.]

69.04.011 "Cosmetic". The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such article; except that such term shall not include soap. [1945 c 257 § 12; Rem. Supp. 1945 § 6163-61.]

69.04.012 "Official compendium". The term "official compendium" mean the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States, official national formulary, or any supplement to any of them. [1945 c 257 § 13; Rem. Supp. 1945 § 6163-62.]

69.04.013 "Label". The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper. [1945 c 257 § 14; Rem. Supp. 1945 § 6163-63.]

69.04.014 "Immediate container". The term "immediate container" does not include package liners. [1945 c 257 § 15; Rem. Supp. 1945 § 6163-64.]

69.04.015 "Labeling". The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. [1945 c 257 § 16; Rem. Supp. 1945 § 6163-65.]

Crimes relating to labeling: Chapter 9.16.

69.04.016 "Misleading labeling or advertisement", how determined. If any article is alleged to be misbranded because the labeling is misleading, or if an advertisement is alleged to be false because it is misleading, then in determining whether the labeling or advertisement is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound, or any combination thereof, but also the extent to which the labeling or advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertisement relates under the conditions of use prescribed in the labeling or advertisement thereof or under such conditions of use as are customary or usual. [1945 c 257 § 17; Rem. Supp. 1945 § 6163-66.]

Crimes relating to advertising: Chapter 9.04.

69.04.017 "Antiseptic" as germicide. The representation of a drug, in its labeling or advertisement, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body. [1945 c 257 § 18; Rem. Supp. 1945 § 6163-67.]

69.04.018 "New drug" defined. The term "new drug" means (1) any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof; or (2) any drug the composition of which is such that such drug, as a result of investigations to determine its safety for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions: *Provided*, That no drug in use on the effective date of this chapter shall be regarded as a new drug. [1945 c 257 § 19; Rem. Supp. 1945 § 6163-68.]

Effective date: See RCW 69.04.855.

69.04.019 "Advertisement". The term "advertisement" means all representations, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of food, drugs, devices, or cosmetics. [1945 c 257 § 20; Rem. Supp. 1945 § 6163-69.]

69.04.020 "Contaminated with filth". The term "contaminated with filth" applies to any food, drug, device, or cosmetic not securely protected from dust, dirt, and as far as may be necessary by all reasonable means, from all foreign or injurious contaminations. [1945 c 257 § 21; Rem. Supp. 1945 § 6163-70.]

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.

(4) The introduction or delivery for introduction into intrastate commerce of (a) any food in violation of RCW 69.04.350; or (b) any new drug in violation of RCW 69.04.570.

(5) The dissemination within this state, in any manner or by any means or through any medium, of any false advertisement.

(6) The refusal to permit (a) entry and the taking of a sample or specimen or the making of any investigation or examination as authorized by RCW 69.04.780; or (b) access to or copying of any record as authorized by RCW 69.04.810.

(7) The refusal to permit entry or inspection as authorized by RCW 69.04.820.

(8) The removal, mutilation, or violation of an embargo notice as authorized by RCW 69.04.110.

(9) The giving of a guaranty or undertaking in intrastate commerce, referred to in RCW 69.04.080, that is false.

(10) The forging, counterfeiting, simulating, or falsely representing, or without proper authority, using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under RCW 69.04.350.

(11) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of a food, drug, device, or cosmetic, or the doing of any other act with respect to a food, drug, device, or cosmetic, or the labeling or advertisement thereof, which results in a violation of this chapter.

(12) The using in intrastate commerce, in the labeling or advertisement of any drug, of any representation or suggestion that an application with respect to such drug is effective under section 505 of the federal act or under RCW 69.04.570, or that such drug complies with the provisions of either such section. [1945 c 257 § 22; Rem. Supp. 1945 § 6163-71. Prior: 1917 c 168 § 1; 1907 c 211 § 1; 1901 c 94 § 1.]

69.04.050 Remedy by injunction. (1) In addition to the remedies hereinafter provided the director is hereby authorized to apply to the superior court of Thurston county for, and such court shall have jurisdiction upon prompt hearing and for cause shown to grant, a temporary or permanent injunction restraining any person from violating any provision of RCW 69.04.040; without proof that an adequate remedy at law does not exist.

(2) Whenever it appears to the satisfaction of the court in the case of a newspaper, magazine, periodical, or other publication, published at regular intervals (a) that restraining the dissemination of a false advertisement in any particular issue of such publication would delay the delivery of such issue after the regular time therefor, and (b) that such delay would be due to the method by which the manufacture and distribution of such publication is customarily conducted by the publisher in accordance with sound business practice, and not to any method or device adopted for the evasion of this section or to prevent or delay the issuance of an injunction or restraining order with respect to such false advertisement or any other advertisement, the court shall exclude such issue from the operation of the restraining order or injunction. [1945 c 257 § 23; Rem. Supp. 1945 § 6163-72.]

Injunctions, generally: Chapter 7-40.

69.04.060 Criminal penalty for violations. Any person who violates any provision of RCW 69.04.040 shall be guilty of a misdemeanor and shall on conviction thereof be subject to a fine of not more than two hundred dollars; but if the violation is committed after a conviction of such person under this section has become final, such person shall be subject to imprisonment for not more than thirty days, or a fine of not more than five hundred dollars, or both such imprisonment and fine. [1945 c 257 § 24; Rem. Supp. 1945 § 6163-73. Prior: 1907 c 211 § 12; 1901 c 94 § 11.]

69.04.070 Additional penalty. Notwithstanding the provisions of RCW 69.04.060, in case of a violation of any provision of RCW 69.04.040, with intent to defraud or mislead, the penalty shall be imprisonment for not more than ninety days, or a fine of not more than one thousand dollars, or both such imprisonment and fine. [1945 c 257 § 25; Rem. Supp. 1945 § 6163-74.]

69.04.080 Avoidance of penalty. No person shall be subject to the penalties of RCW 69.04.060:

(1) For having violated RCW 69.04.040(3), if he establishes that he received and sold such article in good faith, unless he refuses on request of the director to furnish the name and address of the person in the state of Washington from whom he received such article and copies of all available documents pertaining to his receipt thereof; or

(2) For having violated RCW 69.04.040(1), (3), or (4), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person in the state of Washington from whom he received such article in good faith, to the effect that such article complies with this chapter; or

(3) For having violated RCW 69.04.040(5), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person in the state of Washington from whom he received such advertisement in good faith, to the effect that such advertisement complies with this chapter; or

(4) For having violated RCW 69.04.040(9), if he establishes that he gave such guaranty or undertaking in good faith and in reliance on a guaranty or undertaking to him, which guaranty or undertaking was to the same effect and was signed by, and contained the name and address of, a person in the state of Washington. [1945 c 257 § 26; Rem. Supp. 1945 § 6163-75.]

69.04.090 Liability of disseminator of advertisement. No publisher, radio broadcast licensee, advertising agency, or agency or medium for the dissemination of an advertisement, except the manufacturer, packer, distributor, or seller of the article to which the advertisement relates, shall be subject to the penalties of RCW 69.04.060 by reason of his dissemination of any false advertisement, unless he has refused on the request of the director to furnish the name and address of the manufacturer, packer, distributor, seller, or advertising agency in the state of Washington, who caused him to disseminate such false advertisement. [1945 c 257 § 27; Rem. Supp. 1945 § 6163-76.]

69.04.100 Condemnation of adulterated or misbranded article. Whenever the director shall find in intrastate commerce an article subject to this chapter which is so adulterated or misbranded that it is unfit or unsafe for human use and its immediate condemnation is required to protect the public health, such article is hereby declared to be a nuisance and the director is hereby authorized forthwith to destroy such article or to render it unsalable for human use. [1945 c 257 § 28; Rem. Supp. 1945 § 6163-77.]

69.04.110 Embargo of articles. Whenever the director shall find, or shall have probable cause to believe, that an article subject to this chapter is in intrastate commerce, which was introduced into such commerce in violation of RCW 69.04.350 or 69.04.570, or which is so adulterated or misbranded as to label, that its embargo under this section is required to protect the consuming or purchasing public from substantial injury, he is hereby authorized to affix to such article a notice of its embargo and against its sale in intrastate commerce, without permission given under this chapter. But if, after such article has been so embargoed, the director shall find that such article does not involve a violation of this chapter, such

rector determines that an advance in medical science has made any type of self-medication safe as to any of the diseases named above, the director shall by regulation authorize the advertisement of drugs having curative or therapeutic effect for such disease, subject to such conditions and restrictions as the director may deem necessary in the interest of public health: *Provided further*, That this section shall not be construed as indicating that self-medication for diseases other than those named herein is safe or efficacious. [1945 c 257 § 90; Rem. Supp. 1945 § 6163-139.]

69.04.730 Enforcement, where vested—Regulations. The authority to promulgate regulations for the efficient enforcement of this chapter is hereby vested in the director: *Provided, however*, That the director shall designate the Washington state board of pharmacy to carry out all the provisions of this chapter pertaining to drugs and cosmetics, with authority to promulgate regulations for the efficient enforcement thereof. [1945 c 257 § 91 (vetoed); 1947 c 25 (passed notwithstanding veto); Rem. Supp. 1947 § 6163-139a.]

69.04.740 Regulations to conform with federal regulations. The purpose of this chapter being to promote uniformity of state legislation with the federal act, the director is hereby authorized (1) to adopt, insofar as applicable, the regulations from time to time promulgated under the federal act; and (2) to make the regulations promulgated under this chapter conform, insofar as practicable, with those promulgated under the federal act. [1945 c 257 § 92; Rem. Supp. 1945 § 6163-140.]

69.04.750 Hearings. Hearings authorized or required by this chapter shall be conducted by the director or his duly authorized representative designated for the purpose. [1945 c 257 § 93; Rem. Supp. 1945 § 6163-141.]

69.04.760 Hearing on proposed regulation—Notice. The director shall hold a public hearing upon a proposal to promulgate any new or amended regulation under this chapter, which requires or prohibits any practice in intrastate commerce; except in the case of a proposal to adopt an applicable regulation promulgated under the federal act. The director shall give appropriate notice of such hearing. The notice shall state the time and place of the hearing to be held not less than thirty days after the date of such notice, except in the case of an emergency found by the director. After the hearing the director shall issue an order, with respect to such proposal, which shall state the findings upon which such order is based. No regulation promulgated under this chapter, by order issued after such hearing, shall take effect prior to the ninetieth day after the date of such order, except in the case of an emergency found by the director. [1945 c 257 § 94; Rem. Supp. 1945 § 6163-142.]

RCW 69.04.008

"Food."

The term "food" means (1) articles used for food or drink for people or other animals, (2) bottled water, (3) chewing gum, and (4) articles used for components of any such article.

[1992 c 34 § 2; 1945 c 257 § 9; Rem. Supp. 1945 § 6163-58.]

NOTES:

Severability—1992 c 34: See note following RCW 69.07.170.

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§ 321. Definitions; generally.

United States Statutes

Title 21. FOOD AND DRUGS

Chapter 9. FEDERAL FOOD, DRUG, AND COSMETIC ACT

Subchapter II. DEFINITIONS

Current through P.L. 115-30

§ 321. Definitions; generally

For the purposes of this chapter-

- (a) (1) The term "State", except as used in the last sentence of section 372(a) of this title, means any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.
- (2) The term "Territory" means any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone.
- (b) The term "interstate commerce" means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.
- (c) The term "Department" means Department of Health and Human Services.
- (d) The term "Secretary" means the Secretary of Health and Human Services.
- (e) The term "person" includes individual, partnership, corporation, and association.
- (f) The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.
- (g) (1) The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections

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343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.

- (2) The term "counterfeit drug" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.
- (h) The term "device" (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is-
- (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
 - (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
 - (3) intended to affect the structure or any function of the body of man or other animals, and
which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.
- (i) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.
- (j) The term "official compendium" means the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them.
- (k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this chapter that

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- (2) acts in deliberate ignorance or reckless disregard of the truth or falsity of the information.
- (cc) For purposes of section 335a of this title, the term "high managerial agent"-
- (1) means-
- (A) an officer or director of a corporation or an association,
- (B) a partner of a partnership, or
- (C) any employee or other agent of a corporation, association, or partnership, having duties such that the conduct of such officer, director, partner, employee, or agent may fairly be assumed to represent the policy of the corporation, association, or partnership, and
- (2) includes persons having management responsibility for-
- (A) submissions to the Food and Drug Administration regarding the development or approval of any drug product,
- (B) production, quality assurance, or quality control of any drug product, or
- (C) research and development of any drug product.
- (dd) For purposes of sections 335a and 335b of this title, the term "drug product" means a drug subject to regulation under section 355, 360b, or 382 of this title or under section 262 of title 42.
- (ee) The term "Commissioner" means the Commissioner of Food and Drugs.
- (ff) The term "dietary supplement"-
- (1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:
- (A) a vitamin;
- (B) a mineral;
- (C) an herb or other botanical;
- (D) an amino acid;
- (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
- (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

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- (2) means a product that-
- (A) (i) is intended for ingestion in a form described in section 350(c)(1)(B)(i) of this title; or
 - (ii) complies with section 350(c)(1)(B)(ii) of this title;
- (B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and
- (C) is labeled as a dietary supplement; and
- (3) does-
- (A) include an article that is approved as a new drug under section 355 of this title or licensed as a biologic under section 262 of title 42 and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 342(f) of this title; and
 - (B) not include-
 - (i) an article that is approved as a new drug under section 355 of this title, certified as an antibiotic under section 357 of this title, or licensed as a biologic under section 262 of title 42, or
 - (ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public,
which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this chapter.²

Except for purposes of paragraph (g) and section 350f of this title, a dietary supplement shall be deemed to be a food within the meaning of this chapter.

- (gg) The term "processed food" means any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.

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