95770-3

No. 50022-1-II

COURT OF APPEALS, DIVISION II
OF THE STATE OF WASHINGTON

KING COUNTY CITIZENS AGAINST FLUORIDATION,
a nonprofit corporation,
Petitioner,

v.

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

PETITION FOR REVIEW

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A. IDENTITY OF PETITIONER

The Petitioner is King County Citizens Against Fluoridation ("Citizens"), a nonprofit corporation.

B. CITATION TO COURT OF APPEALS DECISION

King County Citizens Against Fluoridation v. Washington State Pharmacy Quality Assurance Commission, 50022-1-II. A copy of the March 27, 2018 unpublished Opinion of is provided in Appendix 1 hereto.

C. ISSUES PRESENTED FOR REVIEW

1) Should the denial of Citizens' Petition for rule-making by the Washington State Pharmacy Quality Assurance Commission ("Commission") be remanded to the Commission for further proceedings because the Commission's decision is arbitrary and capricious?

2) Should this Court clarify that based on the administrative record ("AR") and law, that the rejection in *Kaul v. City of Chehalis* (*"Kaul"*), 45 Wn.2d 616, 625, 277 P.2d 352 (1954) of the Kaul assignment of error regarding "sell drugs" did not reach the issue of whether the City of Chehalis fluoridated water was a drug under the statutory definition of drugs in former RCW 69.04.009?

3) Should this Court find that in reasonable consideration of the facts and circumstances including the Brief of Appellant Arthur Kaul in the administrative record of the Commission, that the only possible interpretation of *Kaul* at 625 is that the *Kaul* Court did not consider or decide on the merits whether public fluoridated waters and their fluoridating additives are drugs when "intended solely for use in the prevention of tooth decay" disease?

4) Should this Court find that in reasonable consideration of the administrative record, *Kaul* at 625, and *Protect Peninsula's Future v. City of Port Angeles* ("*Protect Peninsula's Future*"), 175 Wn.App. 201, 304 P.3d 914 (Div. 2 2013) that the Commission could not reasonably rely, as it did, on the dicta in *Protect Peninsula's Future* at 216 that "*Kaul 's* decision [is] that fluorides in drinking water are not drugs under Washington law"?

5) Should this Court find, based on the administrative record and law, that the Commission made a "willful and unreasoning decision taken without regard to the facts and/or circumstances" when it denied the rule-making petition for bottled waters making claims they will prevent tooth decay disease which are drug claims under RCW 69.04.009?

6) Should this Court find, based on the administrative record and law, that the Commission made a "willful and unreasoning decision taken without regard to the facts and/or circumstances" when it denied the rule-making petition for piped public fluoridated waters making claims they will prevent tooth decay disease which are drug claims under RCW 69.04.009?

D. STATEMENT OF THE CASE

1. Statement of the Procedural History of the Case

Citizens did substantial research on the meaning of the cryptic statement in *Kaul* at 625 regarding sale[1] of City of Chehalis public fluoridated waters:

> Appellant's remaining assignments of error . . . that the city is not engaged in selling drugs . . . as defined by statute [is] not well taken.

(*Kaul* at 625.) The *Kaul* Opinion[2] does not quote the relevant assignment of error and does not identify the relevant statute. It was uncontested in *Kaul* "[t]hat the addition of fluoride to the Chehalis water supply is intended solely for use in prevention of tooth decay" (*Kaul* at 618; AR103) and that tooth decay "is a common disease of mankind" (*Kaul* at 620; AR103).

Citizens also reviewed the statement in *Protect Peninsula's Future*[3] that:

> *Kaul*'s decision [is] that fluorides in drinking water are not drugs under Washington law.

(*Protect Peninsula's Future* at 216.) Citizens went to the Washington State Law Library and got the Briefing Before the *Kaul* Court and researched the relevant statutes in effect in 1954 when *Kaul* was decided. There was only one possible interpretation of this cryptic statement in *Kaul* at 625. The *Kaul* Court rejected Appellant Kaul's assignment of error but it did not consider or decide whether selling public fluoridated waters is selling drugs when the intent is to prevent tooth decay disease.

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[1] "Sale" is a means of "distribution." (Trial Court Report of Proceedings ("RP2") at 34.)
[2] AR102-06 not including West Headnotes.
[3] AR92-100 not including West Headnotes.

Citizens then looked at the language quoted above from *Protect Peninsula's Future* at 216 and concluded that this language was only dicta[4] and that no Washington appellate court had decided on the merits if selling public fluoridated waters with the claim of prevention of tooth decay disease was selling drugs. (Brief of Appellant at 45-46.)

Citizens assembled the facts and circumstances that prove beyond a doubt that the question of whether fluoridated water is a drug when intended to prevent tooth decay disease has not been decided by this state's appellate courts. Citizens put these facts and circumstances into a October 2, 2015, Petition for New State Administrative Rule (AR19-89) that it filed with the Commission. In summary, the Petition asked the Commission to adopt a rule to:

> clarify that fluoridation chemical additives and fluoridated drinking waters (bottled and/or [from] public water systems, that are fluoridated with such additives) are drugs [under state statutes] when the intended use is . . . prevention [of] tooth decay [disease].

(AR1.)

The Department of Health prepared the Commission SBAR analysis on November 16, 2015. (AR1-7.) Citizens' responded. (AR15-18.) Citizens was given twenty five (25) minutes to present its request at the December 11, 2015 Commission meeting. (CP92-93.) The Commission voted at that meeting and issued its written decision on January 26, 2016 which states:

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[4] The quoted sentence is not necessary to *Protect Peninsula's Future*'s decision in that case. (*Protect Peninsula's Future* at 214-17.) The trial court did not abuse discretion because, without Appellant Kaul's briefing in that record, *Kaul* at 625 could be interpreted to hold that public fluoridated waters were not drugs. When the quoted sentence is removed from the paragraph where it occurs in *Protect Peninsula's Future* at 216, the paragraph still reaches the same conclusion. (*See Protect Peninsula's Future* at 215, Note 11.)

> 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 (CP4-90)[7] under RCW 34.05.570(1) and (4). On February 10, 2017, the trial court entered a Final Order with Findings of Fact and Conclusions of Law that affirmed the Commission's denial of Citizens' rule-making Petition. (CP172-75.) On February 24, 2017, Citizens filed and served its Notice of Appeal to Court of Appeals, Division II. (CP170-75.) The Brief of Appellant included Appendix A which provided copies of relevant statutes. A copy of that Appendix A is attached hereto.[8]

On March 27, 2018, Court of Appeals, Div. II issued its unpublished Opinion without oral argument. A copy of that Opinion is provided in Appendix 1 hereto. (*Supra* at 1.)

2. <u>Statement of the Facts of the Case</u>

As stated previously (*supra* at 3), the cryptic statement in *Kaul* at 625 is:

> Appellant's remaining assignments of error . . . that the city is not engaged in selling drugs . . . as defined by statute [is] not well taken

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[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] "CP" refers to Clerk's Papers.
[8] Pages in Appendix A hereto are referred to as A[page number].

The Brief of Appellant Kaul identifies the "selling drugs" assignment of error:

> 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 (emphasis supplied).) 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 rule-making Petition, Appellant Kaul "failed to support this assignment of error with legal argument." (AR24)

Perhaps the most obvious demonstration that "selling drugs as defined in [former] 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. Said page 17 (AR57) only mentions [former] RCW 18.64.010 in the relevant assignment of error. No other part of Kaul's Brief mentions [former] RCW 18.64.010. The Brief of Appellant at 20-23 further develops the fact that Appellant Kaul did not argue the "selling drugs" assignment of error.

Appellant Kaul did not argue this assignment of error because there was no argument to be made. The "selling drugs" assignment of error also identifies the "statute" that Appellant Kaul relied upon. It is [former] RCW 18.64.010. There was only one state definition of drugs in the 1950's and that was in RCW 69.04.009. (AR32; Brief of Respondent at 12.) This statute

was put substantially in its current form in 1945. (*Compare* Appendix A25 (as part of A23 to A30) to AR32) There is no mention of former RCW 69.04.009 in the *Kaul* briefs. (AR46-69.) There is no mention of former RCW 69.04.009 in the *Kaul* Opinion or dissents. (AR101-13.) The legislature first added a definitions section in former Ch. 18.64 RCW in 1963, well after *Kaul* was decided. (AR139-41 and particularly AR141.)[9] The legislature first added a definitions section in former Ch. 69.41 RCW even later, in 1973. (AR144-46 and particularly AR 145.)[10] In the 1950's when *Kaul* was decided there was no definition of "drugs" or "selling" in the "statute" (former RCW 18.64.010) identified in Appellant Kaul's "selling drugs" assignment of error.[11]

It was a focus of the rule-making Petition and the facts and circumstances presented to the Commission in that Petition, that the "selling drugs" assignment of error was not considered or decided on the merits by the *Kaul* Court. (AR24.)

The rule-making Petition at AR25 explains that subsequent cases quoting *Kaul* (including *Protect the Peninsula's Future* later relied upon by the Commission), did not consider the original *Kaul* briefing, did not realize that *Kaul*'s cryptic statement at 625 was not a decision on the merits regarding "selling drugs," and did not themselves analyze any statutory definition of drugs to reach their decisions.

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[9] AR 141 states the definitions section of Ch. 18.64 RCW was first adopted in "1963 c 38 s. 1".

[10] AR 145 states the definitions section of Ch. 69.41RCW was first adopted in "1973 1st ex.s. c 186 s. 1". Appendix A19 to A22 is a copy of "1973 1st ex.s. c 186 s. 1".

[11] Appendix A1 to A6 provides a copy of former Ch. 18.64 RCW (including former RCW 18.64.010) from the 1950's.

The rule-making Petition went on to analyze the plain language of RCW 69.04.009 (AR32), first adopted in 1945, as well as the plain language the legislature later adopted to define drugs in [former] 18.64.011(12)[12] (AR139) and [former] RCW 69.41.010(9)[13] (AR144). (AR22-23; AR27-28.) The rule-making Petition shows that under a plain language analysis of all three current statutory definitions of drugs, bottled and piped fluoridated drinking waters, and the fluoridating additives that are a component of those waters, are drugs if the products are intended for use in the prevention of tooth decay disease. (*Id.*)

Citizens presented other facts and circumstances in its rule-making Petition:

- The Commission is the only state agency that has authority to regulate drugs:

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

(AR22 quoting RCW 18.64.005(7); *see* RCW 18.64.005(1), (5) and (6).)[14]

- WAC 246-290-220(3) requires fluoridating additives to comply with ANSI/NSF Standard 60 and NSF states fluorides are "added to water for . . . preventing . . . tooth decay." (AR23 citing to AR35.) The U.S. Public Health Service and the U.S. Department of Health and Human Services find fluoridation is "for the Prevention of Dental Caries." (AR23 citing to AR37.) Only one state statute addresses fluoridation and that statute does not state or

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[12] The same language that is in current RCW 18.64.011(14).
[13] The same language that is in current RCW 69.41.010(10).
[14] RCW 69.04.730 provides that the Commission shall "carry out all the provisions of [Ch. 69.04 RCW - Intrastate Commerce in Food, Drugs, and Cosmetics] pertaining to drugs."

imply that fluoridation need not comply with drug laws and regulations. (AR23-24)

- The addition of fluoride to public drinking water is not regulated by the federal Safe Drinking Water Act ("SDWA") or the U. S. Environmental Protection Agency ("EPA")[15]. (AR25 citing to AR36 and AR39-43.)

- The U. S. Food and Drug Administration ("FDA") has ruled that, under the federal Food, Drug, and Cosmetic Act ("FD&C Act"), bottled fluoridated municipal drinking water is a drug when it has a claim that it is intended to prevent tooth decay disease. (AR26-27 citing to AR44-45.) RCW 69.04.001 directs that state drug laws and regulations be "uniform" with the FD&C Act to "promote uniformity" throughout the States.

- The rule-making Petition ends its "justification" argument with:

> This commission should adopt the proposed rule because when fluoridation chemical additives and fluoridated drinking waters have the intended use to aid in the prevention, mitigation, and/or prophylactic treatment of dental caries disease (tooth decay, cavities), they are drugs pursuant to [former] RCW 18.64.011(12), 69.04.009, and [former] 69.41.010(9) and the commission has jurisdiction over manufacturing, wholesaling, and distribution of these drugs as well as enforcement authority to ensure that there is compliance with state and federal drug laws. Because the commission has not previously recognized its authority in these matters, and the public is not aware of this commission authority, it is advisable that this regulation be adopted to avoid misunderstandings.

(AR27-28.)

Under RCW 34.05.570(1) and (4) a decision on rule-making may be remanded and/or a declaratory order issued under RCW 34.05.574(1) if the

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[15] Unless the fluoride concentration in the water exceeds 4 parts per million. (40 CFR 141.62.)

decision is arbitrary or capricious. (RCW34.05.570(4)(c)(iii).) In judicial review, Citizen's claimed the Commission's decision was arbitrary and/or capricious. (*See e.g.* Brief of Appellant at 3, first paragraph.)

> [A]gency action is deemed arbitrary and capricious if it is willful and unreasoning, and taken without consideration and in disregard of the facts and circumstances.

(*National Elec. Contractors Ass'n, Cascade Chapter v. Riveland*, 138 Wn.2d 9, 29, 978 P.2d 481 (1999).) "[R]eview is de novo, limited to the agency record available to the court. RCW 34.05.558." (*Northwest Sportfishing Industry Ass'n v. Dep't of Ecology*, 172 Wn.App. 72, 90, 288 P.3d 677 (Div. 2 2012).)

> Where there is room for two opinions, and the agency acted honestly and upon due consideration, this court should not find that an action was arbitrary and capricious, even though this court may have reached the opposite conclusion. This court should not undertake to exercise the discretion that the legislature has placed in the agency.

(*Port of Seattle v. Pollution Control Hearings Bd.*, 151 Wn.2d 568, 589, 90 P.3d 659 (2004) (punctuation and citations omitted).)

Citizens claims that in consideration of the facts and circumstances presented in the rule-making Petition, and, in particular, the analysis of the cryptic statement in *Kaul* at 625, that there is not room for "two opinions." The only possible opinion, in due consideration of the facts and circumstances in the record, is that *Kaul* did not decide on the merits the issue of whether the City's fluoridated water and its fluoridating additives were drugs when intended solely for use in the prevention of tooth decay disease.

Because this is the only possible opinion based on due consideration of the facts and circumstances in the record, the Commission acted in an

arbitrary and capricious manner when it based its decision on dicta in *Protect Peninsula's Future* at 216 that states that *Kaul* determined on the merits "that fluorides in drinking water are not drugs under Washington law."

Citizens' rule-making Petition told the Commission that cases quoting *Kaul*, including *Protect the Peninsula's Future*, did not have the original *Kaul* briefing. (AR25.) The original *Kaul* briefing provided to the Commission by the rule-making Petition is necessary to understand the cryptic statement in *Kaul* at 625. So, while the "selling drugs" assignment of error was rejected by the *Kaul* Court, that rejection did not reach the issue of whether the City's fluoridated water is a drug under former RCW 69.04.009 (Appendix A25), the only state statute that defined drugs when *Kaul* was decided. It was willful and unreasoning action to disregard the facts and circumstances described in the rule-making Petition and then to rely on dicta in *Protect Peninsula's Future* at 216 that states "*Kaul*'s decision [is] that fluorides in drinking water are not drugs under Washington law."

Citizens' rule-making Petition argued that the Commission should find that bottled fluoridated waters and their fluoridating additives are drugs when the claim is "this drinking water is intended for use in the prevention of tooth decay disease." (AR26-27) The FDA considering the same facts and circumstances determined that such bottled waters are drugs. (*Id.*) It is not rational for the Commission to conclude that such bottled waters would not be drugs in Washington State based only on dicta in *Protect Peninsula's Future* which only addresses public piped fluoridated waters.

Citizens made it clear to the Commission that it intended to ask this Court to clarify *Kaul*.

> Mr. Steel was very upfront . . . that Citizens bring this petition . . . as the first step in asking the Supreme Court to . . . clarify . . . *Kaul*.

(Trial Court RP2 at 40-41; CP111; CP182)

E. ARGUMENT

This Court should accept review because this Petition involves an issue of substantial public interest that must be determined by the Supreme Court. The only way that Courts like the *Protect Peninsula's Future* Court will realize that *Kaul* did not decide "that fluorides in drinking water are not drugs under Washington law" is if the Supreme Court clarifies cryptic statement of *Kaul* at 625 when this Court scrutinizes the record to determine if the Commission decision was rational. (*See Rios v. Washington Dept. of Labor and Industries* ("*Rios*"), 145 Wn.2d 483, 501-02, 39 P.3d 961, (2002).)

It was a focus of the rule-making Petition to attach Appellant Kaul's brief to the Petition and identify the "selling drugs" assignment of error that the *Kaul* Court failed to identify but summarily rejected. Appellant Kaul claimed error because the trial court found the City "is not engaging in selling drugs as defined in [former] RCW 18.64.010." (AR57.) The rule-making Petition states the "selling drugs" assignment of error was rejected because it was not argued. (AR24.)

The only state definition of drugs in the 1950's when *Kaul* was decided was in former RCW 69.04.009 adopted in 1945. (AR32 from the rule-making Petition.) Appellant Kaul's assignment of error relied on a "drugs" definition allegedly from former RCW 18.64.010. (*Supra*) The Administrative Record shows that "drugs" was first defined in former Ch. 18.64 RCW in 1963. (AR139-141, and particularly AR141.) In the 1950's

there was no definition of drugs in former Ch. 18.64 RCW. (*Id.*; Appendix A1 to A6.) The "selling drugs" assignment of error was not argued because Appellant Kaul realized the term "drugs" was not defined in former Ch. 18.64 RCW. (*Id.*)

When a water purveyor provides health care by distributing a drug to its customers, Washington citizens have a right to informed consent. (RCW 7.70.050.) By leaving the *Kaul* Court decision vague, the Commission and Appellate Courts such as *Protect Peninsula's Future* can falsely believe that it is decided law in Washington state that fluorides added to drinking water solely for the prevention of tooth decay disease are not drugs. (*See* AR148; *see also Protect Peninsula's Future* at 216). Whether or not such fluorides and fluoridated waters are drugs is for the Commission or Courts to decide in the future. But it does a disservice to the citizens of this state who receive public drinking water with fluoride added solely to prevent tooth decay disease for this Court to fail to clarify that *Kaul* has not decided whether such fluorides and fluoridated waters are drugs. This Court, of course, has a right to find that such fluorides and fluoridated waters are drugs based on the administrative record in this case.

This case involves issues of substantial public interest that should be determined by the Supreme Court because, today, about half of the people who live in Washington State are being supplied with drinking water fluoridated to prevent tooth decay disease piped directly into their homes. This fluoridated drinking water is manufactured by adding bulk fluoride products to source drinking water. There are only fifty-two public water purveyors in this state who manufacture fluoridated water. (AR 149-53)

Three quarters of these water purveyors operate municipal water systems and together these municipal systems directly supply 1.9 million people. (*Id.*) The remainder of these fifty-two public water purveyors (only eight of which are water districts) directly supply 0.3 million people. (*Id.*)

In addition, there are 136 other water purveyors in Washington State who only serve water obtained from the said fifty-two fluoridated water manufacturers and who may also serve some unfluoridated water. (*Id.*) These 136 other water purveyors together serve 1.3 million people. (*Id.*) This means that approximately 3.5 million people in this state receive piped public fluoridated water supplied with intent to prevent tooth decay disease.

The Office of Financial Management estimates that on April 1, 2011 for the 2010 census there were approximately 6.8 million people in our state. If fluoridated water is a drug, then about half the people in the state are being drugged by local agencies without people's consent and without the knowledge of the agencies or the people served. It is an issue of major public interest for the population and water purveyors to be able to have the question decided by Commission and the Courts as to whether their public fluoridated water and fluoridating additives are drugs when the intent is to prevent tooth decay disease.

If fluoridated water and fluoridating additives are drugs, people deserve to have drug warnings of adverse effects for their health, safety, and welfare. The powers and duties of the Commission include:

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

(RCW 18.64.005(7); AR34.) If fluoridated waters and fluoridating additives are drugs, the vagueness of *Kaul* at 625 is preventing the Commission from performing it duties. This impacts public health, safety, and welfare of half of the people living in this state.

Medical safety can only be achieved when substances that are drugs are regulated as drugs.

> It is the intent of the legislature to promote medical safety as a top priority for all citizens of our state.

(RCW 69.41.010 Findings - Intent - 2000 c. 8 s. 1.; AR141) The vagueness of *Kaul* at 625 should no longer be allowed to prevent the Legislature's intent from being accomplished.

F. CONCLUSION

First and foremost, Citizens requests when this Court scrutinizes the Administrative Record, that it clarify the cryptic statement in *Kaul* at 625:

> Appellant's remaining assignments of error . . . that the city is not engaged in selling drugs . . . as defined by statute [is] not well taken.

This Court should clarify that this statement alone may not be interpreted to state that fluoridated waters and their fluoridating additives are not drugs when intended to prevent tooth decay disease.

Second, Citizens requests that this Court scrutinize the administrative record as required by *Rios* at 501-02 and find that there is not room for two opinions regarding whether the *Kaul* Court decided under former RCW 69.04.009 that fluoridating substances used in piped and bottled drinking waters cannot be drugs. There is only room for one opinion and that is that these issues were not decided in *Kaul*.

If this Court decides that the Commission willfully made its decision in an unreasoning manner in disregard and with inadequate consideration of the facts and circumstances in the Administrative Record, then Citizens requests that this Court remand the matter back to the Commission for bottled water and/or public piped water for further proceedings consistent with this Court's Opinion.

Dated this 26th day of April, 2018.

Respectfully submitted,

GERALD STEEL PE

By: _____
Gerald B. Steel, WSBA #31084
Attorney for Citizens

CERTIFICATE OF SERVICE

I certify that on the date noted below, I caused a true and correct copy of this Certificate and the Petition for Review to be served on the following by first class mail:

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and to be personally filed with:

The Court of Appeals, Div. II
c/o Supreme Court Clerk
Supreme Court State of Washington
P.O. Box 40929
Olympia WA 98504-0929

Dated this 26th day of April, 2018, at Olympia, Washington.

_____
Gerald Steel

APPENDIX INDEX

Appendix 1	Copy of the March 27, 2018 unpublished Opinion in *King County Citizens Against Fluoridation v. Washington State Pharmacy Quality Assurance Commission*, 50022-1-II.
Appendix A	A copy of the Attachments to the Brief of Appellant in Case No. 50022-1-II

APPENDIX 1

Copy of the March 27, 2018 unpublished Opinion in *King County Citizens Against Fluoridation v. Washington State Pharmacy Quality Assurance Commission*, 50022-1-II.

Filed
Washington State
Court of Appeals
Division Two

March 27, 2018

IN THE COURT OF APPEALS OF THE STATE OF WASHINGTON

DIVISION II

KING COUNTY CITIZENS AGAINST FLUORIDATION, a nonprofit corporation, Appellants, v. WASHINGTON STATE PHARMACY QUALITY ASSURANCE COMMISSION, an administrative agency, Respondent.	No. 50022-1-II UNPUBLISHED OPINION

SUTTON, J. — King County Citizens Against Fluoridation (Citizens) appeals the Washington State Pharmacy Quality Assurance Commission's (Commission) decision denying Citizens' petition for rulemaking regarding the Commission's jurisdiction over fluoridating additives and fluoridated water. Citizens argues that the Commission's decision was arbitrary and capricious because the Commission misinterpreted prior case law and misapplied the plain language of the statutory definitions of the term "drug." The Commission argues that its decision was not arbitrary or capricious because it relied on statements made in prior case law declaring that the fluorides in water are not drugs. Because the Commission reasonably relied on prior case law, its decision was not arbitrary or capricious even if Citizens presents alternative interpretations of that case law.

We decline to consider any additional arguments that Citizens makes because Citizens' additional arguments address the merits of whether fluoridating additives or fluoridated water are

drugs and these arguments exceed the scope of our review of the Commission's decision. Accordingly, we affirm the Commission's decision denying Citizens' petition for rulemaking.

FACTS

Citizens filed a petition for adoption of a new rule with the Commission. The purpose of the proposed new rule was to clarify the extent of the Commission's jurisdiction over fluoride and fluoridation products added to bottled and municipal drinking water. Specifically, the petition asked that the Commission adopt a rule stating that "fluoridation chemical additives" and "fluoridated drinking waters" were considered "drugs" as defined under former RCW 18.64.011(12) (2015), RCW 69.04.009, and former RCW 69.41.010(9) (2013). Administrative Record (AR) at 21. The proposed new rule stated,

> (1) Fluoridation chemical additives (whether or not certified under NSF/ANSI Standard 60) and fluoridated drinking waters (bottled and/or from public water systems, that are fluoridated with such additives) are drugs pursuant to RCW 18.64.011(12), 69.04.009, and 69.41.010(9) when the intended use is to aid in the prevention, mitigation, and/or prophylactic treatment of dental caries disease (tooth decay, cavities).
>
> (2) Fluoridation chemical additives include:
> (a) Fluorosilicic Acid (aka Fluosilicic Acid or Hydrofluosilicic Acid).
> (b) Sodium Fluorosilicate (aka Sodium Silicofluoride).
> (c) Sodium Fluoride.
> (d) Calcium Fluoride.
>
> (3) It is presumed that the intended use of such additives and such fluoridated drinking waters is to aid in the prevention, mitigation, and/or prophylactic treatment of dental caries disease (tooth decay, cavities).
>
> (d) (sic) The pharmacy quality assurance commission has jurisdiction to ensure that distribution, wholesaling, and manufacturing of fluoridation chemical additive drugs and fluoridated water drugs in this state provide for the protection and promotion of the public health, safety, and welfare.

AR at 21-22.

The Commission denied Citizens' petition for rulemaking. In its decision, the Commission stated,

> 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), 69.04.008, 69.04.009, and 69.41.010(9).

AR at 148.

Citizens filed a petition for review in superior court. The superior court denied Citizens' petition and affirmed the Commission's decision denying Citizens' petition for rulemaking. Citizens appeals.

ANALYSIS

For the purposes of Citizens' appeal, it is important to define the scope of the agency action before us. The only agency action before us for review is the Commission's denial of Citizens' petition for rulemaking. As explained below, the only ground on which we may reverse the Commission's decision to forgo rulemaking is if the agency's action is arbitrary or capricious.[1] However, as Citizens repeatedly points out, the remedy it actually seeks is a holding from us that fluoridating additives and fluoridated drinking water are drugs under the relevant statutory definitions. Citizens erroneously treats its appeal as though we are reviewing the merits of the

[1] Citizens also argues that the Commission's decision was "contrary to law." Br. of Appellant at 16. However, there is no "contrary to law" standard for reviewing an agency's decision denying a petition for rulemaking. Rather, the closest standard of review is when an agency acts outside of its statutory authority. RCW 34.05.570(4)(b)(ii). Here, it is undisputed that the Commission's decision denying Citizens' petition for rulemaking was within the statutory authority of the Commission. Accordingly, the only ground for reversing the Commission's decision to deny the petition for rulemaking is that the decision is arbitrary or capricious.

Commission's finding that fluoridating additives and fluoridated water are not drugs. However, the Commission has not made any such findings—the Commission simply denied Citizens' petition for rulemaking.

Therefore, we limit our review to whether the Commission's decision to deny the petition for rulemaking was arbitrary or capricious. And we hold that the Commission's decision was not arbitrary or capricious. Accordingly, we affirm the Commission's decision.

I. STANDARD OF REVIEW FOR AGENCY RULEMAKING

An agency's decision to deny a rulemaking petition is subject to judicial review under RCW 34.05.570(4) of the Administrative Procedures Act (APA), chapter 34.05 RCW. *Squaxin Is. Tribe v. Dep't. of Ecology*, 177 Wn. App. 734, 740, 312 P.3d 766 (2013). RCW 34.05.570(4) provides that this court will reverse a decision denying a petition for rulemaking only if we determine that the decision is: (1) unconstitutional, (2) outside the statutory authority of the agency or the authority conferred by a provision of law, (3) arbitrary or capricious, or (4) taken by persons who were not properly constituted as agency officials lawfully entitled to take such action.

"Arbitrary or capricious agency action is willful and unreasoning action taken without regard to the attending facts or circumstances." *Squaxin Is. Tribe*, 177 Wn. App. at 742. An agency has wide discretion in deciding to forgo rulemaking. *Squaxin Is. Tribe*, 177 Wn. App. at 742. We review the agency record to determine only whether the agency reached its decision "'through a process of reason, *not whether the result was itself reasonable in the judgment of the court.*'" *Squaxin Is. Tribe*, 177 Wn. App. at 742 (internal quotation marks omitted) (quoting *Rios v. Dep't of Labor & Indus.*, 145 Wn.2d 483, 501, 39 P.3d 961 (2002). An agency action is not

arbitrary or capricious simply because of contradictory evidence or the possibility of deriving conflicting conclusions from the evidence. *Squaxin Is. Tribe*, 177 Wn. App. at 742.

II. ARBITRARY OR CAPRICIOUS AGENCY ACTION

Citizens asserts that "[b]y 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." Br. of Appellant at 16-17. Citizens makes no other argument to support the contention that the Commission's decision was arbitrary or capricious. The Commission argues that its decision was not arbitrary or capricious because it considered and relied on existing precedent from the courts to support its decision not to engage in rulemaking. Because the Commission relied on a reasonable interpretation of prior case law in reaching its decision not to engage in rulemaking, the Commission's decision was not arbitrary or capricious. Accordingly, we affirm the Commission's decision to deny Citizens' petition for rulemaking.

The Commission cited *Protect the Peninsula's Future* as the basis for its decision to deny Citizen's petition for rulemaking. In *Protect the Peninsula's Future*, we recognized that an earlier case from our Supreme Court decided "that fluorides in drinking water are not drugs under Washington Law." 175 Wn. App. at 216. Because this statement in *Protect the Peninsula's Future* supports the Commission's decision to deny Citizen's petition for rulemaking, the Commission's decision is not arbitrary or capricious.

Citizens has presented extensive argument as to how *Protect the Peninsula's Future* and the Supreme Court case it relies on, *Kaul v. City of Chehalis*, 45 Wn.2d 616, 277 P.2d 352 (1954), could be read to leave open the issue of whether fluoridating additives and fluoridated water are drugs under the specific statutory definitions Citizens cites. However, the existence of a contrary interpretation of the case law does not render the Commission's decision arbitrary or capricious so long as the Commission reached its decision through some process of reason. As explained above, the Commission engaged in a process of reason by reviewing the applicable case law and by relying on the plain language of the case law to support its decision. Accordingly, the existence of Citizens' contrary interpretation of the case law does not render the Commission's decision arbitrary or capricious.

Here, the Commission based its decision on existing case law that expressly stated fluorides in water are not drugs. The existing case law was a reasoned basis for the Commission's decision regardless of whether Citizens can present an alternative interpretation of the case law. Because the Commission had a reasoned basis for its decision to deny Citizens' petition for rulemaking, the Commission's decision was not arbitrary or capricious. Accordingly, we affirm the Commission's decision denying Citizens' petition for rulemaking.

III. CITIZENS' REMAINING ARGUMENTS

Citizens dedicates the majority of its briefing to two arguments that will not be addressed by this court.[2] First, Citizens reviews the prior case law stating that fluorides in water are not drugs in an attempt to demonstrate that there is no precedent conclusively determining that fluoridating additives and fluoridated water are not drugs. Second, Citizens argues that under the plain language of the statutory definitions of the term "drugs" it cites, that we should hold that fluoridating additives and fluoridated water are drugs in certain circumstances. Neither of these arguments are within the scope of our review of the Commission's action and we decline to address them.

A. PRIOR CASE LAW

Citizens extensively argues that the prior case law addressing whether fluorides in water are drugs has been misinterpreted and improperly relied upon. As a result, Citizens asks us to "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.'" Br. of Appellant at 50.

However, because our review is limited to whether the Commission's decision to deny Citizens' petition for rulemaking was arbitrary or capricious, the question before us is not to conclusively determine the meaning of prior case law. *See* RCW 34.05.570(4); *Squaxin Is. Tribe*,

[2] Citizens also argues that the superior court erred by striking certain paragraphs of its petition for judicial review, specifically subsection K, section V related to the prerequisites for judicial review. However, we review the agency action sitting in the same position as the superior court. *Squaxin Is. Tribe*, 177 Wn. App. at 740. Accordingly, we are not reviewing the superior court's decision and we decline to address Citizens' argument that the superior court abused its discretion by striking the paragraphs from Citizens' petition.

177 Wn. App. at 740. Rather, as explained above, our review is whether the Commission engaged in a reasoned process when it relied on this prior case law to reach its decision on Citizens' petition for rulemaking. Because it is unnecessary for us to review the entire precedential body of case law addressing fluorides in water to determine whether the Commission's decision was arbitrary or capricious, we decline to address Citizens' arguments regarding prior case law.

B. STATUTORY LANGUAGE

Citizens also asks us to interpret and apply the plain language of the statutory definitions of "drug" and "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." Br. of Appellant at 50. But this request also exceeds the scope of this court's limited review.

Here, the Commission only declined to engage in rulemaking on the issue. Even if we were to determine that the Commission's decision to deny Citizens' petition for rulemaking was arbitrary or capricious, which it was not, the appropriate remedy would be to reverse the Commission's decision and remand to the Commission to make an appropriate rulemaking decision.

To comply with Citizens' request would require us to engage in the rulemaking process on behalf of the Commission, which exceeds not only the scope of our review, but also the scope of our authority. Accordingly, we do not consider the merits of whether fluoridating additives or fluoridated water are drugs under the statutory definition because that question is not properly presented to us for review.

We affirm the Commission's decision denying Citizens' petition for rulemaking.

A majority of the panel having determined that this opinion will not be printed in the Washington Appellate Reports, but will be filed for public record in accordance with RCW 2.06.040, it is so ordered.

Sutton, J.
SUTTON, J.

We concur:

Bridgen, C.J.
BRIDGEN, C.J.

Johanson, J.
JOHANSON, J.

APPENDIX A
No. 50022-1-II
ATTACHMENTS

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.

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

VOLUME 2

STATE PRINTING PLANT OLYMPIA, WASH. 1951

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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-

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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

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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-

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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' perscriptions 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

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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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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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VOLUME 2

STATE PRINTING PLANT OLYMPIA, WASH. 1951

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Chapter 18.71

PHYSICIANS AND SURGEONS

Sections

Abortion: Chapter 9.02.

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

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

Crimes relating to pregnancy and childbirth: Chapter 9.48.

Death due to ministration by intoxicated physician: RCW 9.48.130.

Examining committee in basic sciences: Chapter 43.74.

Lien of doctors: Chapter 60.44.

License of doctors as examining physician for contestants in boxing and wrestling matches: RCW 67.08-.100.

Medical disciplinary board act: Chapter 18.72.

Rebating by practitioners of healing professions prohibited: Chapter 19.68.

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).

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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 medicine 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.

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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, opthalmology, orthopedic surgery, otolaryngology, pediatrics, physical medicine and rehabilitation, preventive medicine and public

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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 attached 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

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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-

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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.

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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 18.72.080.

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.]

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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

efinitions.

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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June 30, 1973.

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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

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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.

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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

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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.

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Filed in Office of Secretary of State April 26, 1973.

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of
WASHINGTON

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VOLUME 5

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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)

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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.]

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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.]

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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.]

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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

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(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

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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.]

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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

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);

(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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