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No. 82225-5

SUPREME COURT
OF THE STATE OF WASHINGTON

CITY OF PORT ANGELES, Respondent,

v.

OUR WATER-OUR CHOICE, and PROTECT OUR WATERS,
Petitioners,

v.

WASHINGTON DENTAL SERVICE FOUNDATION, LLC,
Respondent.

OUR WATER OUR CHOICE AND PROTECT OUR WATERS'
ANSWER TO AMICI CURIAE BRIEF OF ASSOCIATION OF
WASHINGTON CITIES AND CITY OF FORKS

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I. INTRODUCTION

Amici Association of Washington Cities and City of Forks (“City Amici”) focus their Amici Brief on the comprehensive state and federal regulations that govern the operation of a water utility by a city and concur with the opinion (“Opinion”) by the Court of Appeals Div. II, (“appellant court”) that the Initiatives are administrative based on an argument that the Initiatives pursue a plan adopted by superior powers.¹ But the truth of the matter is that the fundamental and overriding purpose of the Initiatives is not about the operation of a water utility but rather is about prohibiting or limiting the distribution of drugs using local public water supplies.²

The comprehensive state and federal regulations referenced by City Amici and by the Opinion apply only to regulation of water purveyors whereas the Initiatives are much more general and apply to any person who would put any drug in any local public water supply.³

¹ City Amici Brief at 1, 6-16.

² The Initiative Ordinances are provided in the Petition for Review (9-25-08) (“Petition”) at A-16 to A-19.

³ The OWOC Initiative explicitly makes it “unlawful for any person . . . to put any . . . substance . . . in public water supplies . . . with . . . intent . . . of acting [as] a preventive or treating medication or drug.” Petition at A-19, Section 2. The POW Initiative explicitly requires that a “person . . . shall not add any substance to a public drinking water supply . . . which is intended to act as a medication . . . unless” there is FDA approval. *Id.* at A-17, Sections 3(A) and 4. Together, the Initiatives either prohibit or limit any person putting any drug in any public water supply. To simplify terminology, the Petitioners (“Committees”) will refer to Initiative regulated substances as “drugs” but the Initiatives generally regulate substances added “for the purpose of treating physical or mental disease or affecting the structure or functions of the body of any person,” (*Id.* at A-19, Section 2) or “with the intent to treat or affect the physical or mental functions of the body of any person” (*Id.* at A-17, Section 3(A)). Such substances include poisons and

II. THE LOCAL INITIATIVES CREATE A NEW PERMANENT AND GENERAL LOCAL POLICY AND DO NOT “PURSUE A PLAN” BY A “SUPERIOR POWER” AND THEREFORE ARE LEGISLATIVE AND WITHIN THE INITIATIVE POWER

A. The OWOC Initiative’s Intent “Is To Prohibit Medication Of People Through Public Drinking Water Supplies While Allowing Necessary Treatment Of Water To Make It Safe To Drink”

The expressed intent of the OWOC Initiative is “to prohibit medication of people through public drinking water supplies while allowing necessary treatment of water to make it safe to drink.”⁴ As a matter of law, this expressed intent should be found to be an expression of the fundamental and overriding purpose of the OWOC Initiative.⁵ This Court’s pre-election review of this local Initiative should be limited to determining the fundamental and overriding purpose de novo as a matter of law and then determining if this purpose is “legislative” and within the corporate City’s “power to enact.”⁶

other toxic materials that would not likely be added by a water purveyor but could be added by another person subject to the power of the Initiatives. The Initiatives do not impact water purveyors exercising administrative functions unless they dispense drugs.

⁴ This intent is expressly stated on the face of the OWOC initiative petition. Petition at A-18. The intent of the POW Initiative is explicitly provided in Section 1 of that Initiative and, fundamentally, it is to limit putting drugs in local public water supplies. Petition at A-17.

⁵ The full text of the OWOC Initiative Ordinance is provided in the Petition at A-19 and is consistent with this expressed intent. It is also consistent with the fundamental purpose of both Initiatives urged by the Committees before the appellate court. Petition at A-6, Note 4. The appellate court is correct that the trial court should have determined this purpose. *Id.* However, because this purpose is a question of law, an appellate court and this Court should make a de novo determination based on the language of the Initiatives.

⁶ This Court should explain that in pre-election review of other than procedural matters, lower courts are to determine, as a matter of law, the “fundamental and overriding purpose” of both statewide and local initiatives and limit their review to considering the application of the “legislative” and “power to enact” tests to this purpose. See Issue 3 in the Petition at 2. See also Supplemental Brief of Petitioners at 15-17.

The City Amici and the Opinion of the appellate court focus on comprehensive statewide regulations that just regulate water purveyors.⁷ The Initiatives are local regulations that regulate all persons that are within the jurisdiction of the City and so have a fundamentally different scope than the comprehensive statewide regulations.

B. Local Initiatives That Prohibit Or Limit Any Person Putting Any Drug In Any Local Public Water Supply Are “Legislative”

The standard used to determine if an action is legislative or administrative is provided in Appellants’ Opening Brief.⁸ There are two expressions of the standard. Under the first expression, an ordinance is administrative if “temporary” and of “special character” and is legislative if “permanent” and of “general character.”⁹ The Opinion and the City Amici Brief fail to apply this expression of the standard, but the Initiative Ordinances clearly meet both elements of this test being both permanent and of general application to all persons within City jurisdiction, all drugs,¹⁰ and all local public water supplies.

⁷ The comprehensive statewide regulations referenced are in Chapter 246-290 WAC. City Amici Brief at 9-10; Opinion at 11, Note 9 (Petition at A-11). These regulations only regulate water purveyors. WAC 246-290-001(3) (“Purveyors shall be responsible for complying with the regulatory requirements of this chapter.”) (Appendix C-1 hereto.)

⁸ Appellants’ Opening Brief at 24. A similar test is provided in Mission Springs v. City of Spokane, 134 Wn.2d 947, 969, 954 P.2d 250 (1998) (“An act which applies generally to the community is a legislative one.”)

⁹ Id.

¹⁰ Supra, this brief at 1, Note 3.

Under this first expression of the standard, the Initiative Ordinances are legislative.¹¹

Under the second expression of the standard, an ordinance is legislative if it “prescribes a new policy or plan,” and administrative “if it merely pursues a plan already adopted by the [city council], or some power superior to it.”¹² The new local standards established by the Initiative Ordinances are a “new policy or plan” because, for the first time, the Initiatives implement new local regulations applicable generally to all persons within the jurisdiction of the City and not just to water purveyors as is the case for the so-called comprehensive statewide regulations.¹³

Also the new local standards generally regulate all “drugs”¹⁴ put in local public water supplies by any person as opposed to the comprehensive statewide standards that generally regulate all ANSI/NSF approved “additives” that water purveyors put in potable water.¹⁵ There is a fundamental difference between

¹¹City Amici Brief at 6-7 cites to Heider v. Seattle, 100 Wn.2d 874, 877, 675 P.2d 597 (1984) for the proposition that naming a street pursuant to a comprehensive street naming ordinance although “permanent” was still found to be administrative. But naming a street is of “special character” and not of “general character” and so does not satisfy both elements of the first expression of the standard. Similarly, the City Amici Brief at 7 cites to Leonard v. Bothell, 87 Wn.2d 847, 850, 557 P.2d 1306 (1976) for the proposition that a site-specific rezone is not legislative. Site-specific project permits, including rezones, are not legislative because they are of special character. Durocher v. King County, 80 Wn.2d 139, 153, 492 P.2d 547 (1972).

¹² Appellants’ Opening Brief at 24. The Opinion at 8 (Petition at A-8) modifies “pursue” to become “pursue/affect.” The Initiatives do not “affect” the statewide regulations.

¹³ Supra, this brief at 3, Note 7.

¹⁴ Supra, this brief at 1, Note 3.

¹⁵ The statewide regulations require that any treatment chemical that water purveyors add “to water intended for potable use must comply with ANSI/NSF Standard 60.” WAC

“drugs” and “additives.”¹⁶ A new local ordinance regulating dispensing of “drugs” by any person should not be found to be pursuing a plan established by the comprehensive statewide regulations that regulate use of ANSI/NSF Standard 60 approved “additives” just for water purveyors. The City Amici focus on the impact of the Initiatives on operators of the municipal water system.^{17, 18} But the municipal water system operators always must comply with all general laws

246-290-220(3) (Appendix C-2 hereto). There are currently 35,389 products approved by NSF/ANSI Standard 60 as Drinking Water Treatment Chemicals with 114 different chemical names. (Appendix A-48 to A-49) <http://www.nsf.org/Certified/PwsChemicals/> None of NSF/ANSI Standard 60 “additives” are added to potable water to prevent or reduce any disease unrelated to contaminated water except for fluoride. *Id.* According to NSF, fluoride is added to water for the public health benefit of “preventing and reducing tooth decay.” Appendix A-16. Fluoride is the only current NSF approved “additive” that will be subject to the more strict local general drug regulations and this is because fluoride qualifies as a “drug” regulated by the Initiatives. *Supra*, this brief at 1, Note 3.

¹⁶ Simply put, drugs generally treat people or animals and ANSI/NSF Standard 60 approved “additives” generally treat water to make it safe and potable.

¹⁷ City Amici Brief at 1-16. The City Amici Brief at 13 argues that the POW Initiative has “testing regimens for all additives to drinking water that are inconsistent with the Board of Health Regulations.” This is not true. Substances added to treat water to make water safe or potable are generally unaffected by the Initiatives and no new testing regimens are required for such ANSI/NSF Standard 60 approved “additives.” *Infra*, this brief at 6, Note 22. Only “drugs” (*supra*, this brief at 1, Note 3) have new testing regimens to ensure that contaminants do not exceed the EPA health based standard set by the MCLG. Petition at A-17, Section 3(B). The POW Initiative only regulates that class of substances that qualify as “drugs” under the Initiative and this includes fluoridation chemicals. However, the City Amici Brief at 13 is correct that the POW Initiative requires FDA approval for such “drugs” and the FDA has not approved fluoridation chemicals as “safe and effective” for ingestion as drugs. Therefore, the City Amici Brief at 13 is correct that the FDA requirement results in a prohibition of fluoride at this time. This is stated in the Petition at A-17, Section 5(B). With fluoride prohibited, the POW Initiative will not affect the use of any other ANSI/NSF Standard 60 approved “additives” but will continue to regulate all “drugs” as specified by the Initiative that are put into public water supplies by any person who is under the jurisdiction of the City.

¹⁸ The City Amici Brief at 13, Note 6 argues that the FDA in FDA MOU 225-79-2001 (Appendix A-50 to A-53), ceded its authority over tap water additives to the EPA. Para. I (H) of the MOU (Appendix A-50) notes the authority the FDA ceded is FDA authority “to protect the public from adulteration of food” with regard to regulating tap water. The FDA did not cede its authority over drugs even if dispensed in tap water. The FDA states that “Fluoride, when used in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals, is a drug that is subject to FDA regulation.” Appendix A-34.

including any local general laws that prohibit dispensing of “drugs”¹⁹ through public water supplies. Local laws protecting local water supply purity from all “drugs” do not pursue a plan of a superior power.

The appellate court failed to recognize that the new local regulations generally regulate a different class of persons and generally regulate a different class of substances both when compared to the statewide regulations.²⁰ The appellate court erred in finding that the new local Initiatives “pursue/affect a plan already in place” and are therefore administrative and invalid.²¹ The statewide standards will continue to be in effect unmodified and will continue to apply to local water purveyors who are regulated by those standards. The local Initiatives generally do not regulate use of ANSI/NSF Standard 60 approved “additives” used to treat water to make it safe and potable.²²

This Court should find that the Initiatives are intrinsically legislative because any decision to, or not to, medicate people en masse is a decision that requires the use of legislative discretion to balance benefits and harms for the

¹⁹ Supra, this brief at 1, Note 3.

²⁰ Supra, this brief at 3, Note 7.

²¹ Petition at A-8. The appellate court inappropriately added the word “affect” to the standard test. A local general law regulating every person in the community regarding “drugs” is still legislative even if it “affects” some water purveyors who must also comply with statewide administrative regulations regarding NSF approved “additives.”

²² The OWOC Initiative states, “This ordinance does not apply to substances which are added to treat water to make water safe or potable such as use of agents for disinfection, or corrosion control.” Petition at A-19. The POW Initiative states, “The provisions of this ordinance do not apply to substances which are added to treat water to make water safe or potable.” Petition at A-17. Both ordinances limit substances being added to water that will increase fluoride content more than 0.1 ppm. Petition at A-17 and A-19. Fluoride substances are only added to water with intent to treat and prevent tooth decay. Appendix A-16.

whole community.²³ We request that this Court take judicial notice that medical drugs and other substances to treat people can benefit people but they can also harm people by their side effects.

C. Putting Drugs Or Substances That Treat People Into Public Water Supplies Can Harm People

Putting drugs or substances that treat people into public water supplies can harm people. For example, cities add fluoridation chemicals to their water supplies with the intent to prevent disease.²⁴ Putting fluoride, and more particularly hexafluorosilicic acid, in community drinking water is very controversial.²⁵ Attached to this Brief as Appendix B hereto, is a 1999 article from the Journal of Land Use and Environmental Law that discusses the legal history of fluoridation.²⁶ The article quotes Justice Rand in his opinion in finding that a statute that allowed municipal corporations to treat public water supplies to

²³ See Supplemental Brief of Petitioners Our Water-Our Choice and Protect Our Waters at 14, Note 44 citing to Hughes v. City of Lincoln, 232 Cal.App.2d 741, 746-47, 43 Cal.Rptr. 306 (Cal.App.Dist.3 1965). The City Amici Brief at 15, Note 7, argues that the Hughes Court used a “completely different standard” for determining if an action is legislative but that is not true. Instead the Hughes Court relied on a classical expression (“a declaration of public purpose, and making provision for ways and means of its accomplishment”) of the current standard that a legislative action “prescribes a new policy or plan.” Appellants’ Opening Brief at 24. The Committees have separately shown that the Initiatives do not pursue a plan of a “power superior.” Supra, this Brief at 4-6.

²⁴ We request that this Court take judicial notice that fluoridated water is supplied to mitigate and prevent dental decay, a common disease of mankind in 1954. Kaul v. Chehalis (“Kaul”), 45 Wn.2d 616, 620, 277 P.2d 352 (1954); Respondent’s Clerks Papers at 132 et seq.; Appendix A-16.

²⁵ This can be seen by this Court by reading the anti-fluoridation amici brief and pro-fluoridation answer.

²⁶ John R. Graham et al., *Highlights in North American Litigation During the Twentieth Century on Artificial Fluoridation of Public Water Supplies*, 14:2 J. Land Use & Env’tl. L. 195 (1999). Appendix B hereto.

make the vended water “pure and wholesome” could not be interpreted to allow fluoridation:

But it is not to promote the ordinary use of water as a physical requisite for the body that fluoridation is proposed. That process has a distinct and different purpose; it is not a means to an end of wholesome water for water’s function but to an end of a special health purpose for which water supply is made use of as a means.²⁷

The article reports on three superior court cases where American judges heard evidence pro and con on fluoridation and all three found fluoridation either unsafe or ineffective or both.²⁸

It is controversial as to whether fluoridation is safe and effective.²⁹

While there is no statute that explicitly allows fluoridation, there is a state regulation governing the administrative aspects of fluoridation.³⁰ The regulation provides administrative requirements “where fluoridation is practiced.”³¹ But the choice to practice fluoridation is the fundamental decision and that decision remains legislative.

But fluoridation, however important it might be to the pro-fluoridation and anti-fluoridation forces, is just one of tens of thousands of drugs that are regulated by the proposed initiatives and is the only

²⁷ *Id.* at 213.

²⁸ *Id.* at 239-40 for the summary; *Id.* at 229-40 for the details.

²⁹ John R. Graham et al., *Highlights in North American Litigation During the Twentieth Century on Artificial Fluoridation of Public Water Supplies*, 14:2 J. Land Use & Envtl. L. 195 (1999) (Appendix B hereto); Appendix A-32.

³⁰ WAC 246-290-460. Appendix C-6. The City Amici Brief at 5 and 10 erroneously states that the Department of Health must approve any decision to fluoridate. The Department only approves fluoridation facilities after the decision to fluoridate is made.

³¹ *Id.* Section 2 and 3.

ANSI/NSF Standard 60 approved additive that is put in potable water as the “end of a special health purpose for which water supply is made use of as a means.”³² A decision by the corporate City to prohibit or limit any person putting any drugs in any local public water supply serving the City is permitted by police powers to prevent harms³³ and by statutes giving cities the right to set local water purity standards.³⁴ Such local initiatives are not in conflict with any state or federal law. The lower courts err by not having a clear understanding that the substances to be regulated are “drugs” intended to treat people and are not just “additives” to control water contamination. Respondents and City Amici err when inviting the Court to call these drugs “additives” to avoid general Washington and Federal drug laws.³⁵

III. THE CORPORATE CITY HAS THE “POWER TO ENACT”

A. This Court Should Find That The City Has Authority To Adopt Citywide Water Supply Purity Standards More Restrictive Than The Statewide Standards

The City Amici Brief at 15 argues that the corporate City “does not have authority to adopt water quality standards for substances in drinking water stricter

³² Supra, this brief at 7.

³³ Const. XI, sec. 11 allows corporate cities to use police power reasonably connected to the public peace, health, safety, morals and welfare. *Seattle v. Hill*, 72 Wn.2d 786, 797, 435 P.2d 692 (1967). The initiatives seek to protect the public from harm caused by medicines dispensed through public water supplies without notice, informed consent, controlled doses or consideration of patient histories and sensitivities.

³⁴ RCW 35A.70.070(6) and Chapter 35.88 RCW.

³⁵ 21 U.S.C. sec. 321(g)(1)(B) (Appendix A-1 hereto); RCW 69.41.010(9)(b) (Appendix A-2 hereto); See Supplemental Brief of Respondents at 3 Sec. 2.2.

than those adopted by the Board of Health.” The Opinion attempted to review statewide water supply laws. Additional clarifications are needed. The Opinion states:

The Department of Health has authority under RCW 70.119.050 to adopt rules and regulations relating to public water systems.³⁶

While this is true, the purpose of Chapter 70.119 RCW is to provide for competent operators for public water systems.³⁷ Chapter 70.119 RCW does not address water additives and is not relevant to the Initiatives.

The Opinion also states that RCW 70.119A.080 directs the Department of Health to ensure compliance with the Safe Drinking Water Act.³⁸ This is correct. The Opinion states that pursuant to RCW 43.20.050(2)(a) the State Board of Health is charged with regulating the purity of public water systems.³⁹ This is correct. RCW 70.142.010 directs the State Board of Health to set state standards for chemical contaminants in drinking water.

Chapter 246-290 WAC, the statewide comprehensive regulation was adopted pursuant to the authority granted to the State Board by chapter 43.20 RCW.⁴⁰ As stated previously, Chapter 246-290 WAC only regulates water

³⁶ Opinion at 8 (Petition at A-8).

³⁷ RCW 70.119.010. RCW 70.119.050 authorizes the Secretary to adopt regulations only regarding “certification of operators”, “requirements for renewal of certification,” and regulations “classifying water purification plants and distribution systems.”

³⁸ Opinion at 7 (Petition at A-7).

³⁹ *Id.*

⁴⁰ The State Board also considered RCW 43.20B.020 (concerning fees for services) and chapters 70.119 (public water supply systems – certification and regulation of operators), 70.119A (public water systems – penalties and compliance), 70.142 RCW (chemical

purveyors and not other persons in the City.⁴¹ But nowhere in chapters 43.20, 43.20B, 70.119, 70.119A, 70.142, 70.116, 70.05, or 43.70 RCW or elsewhere, does the Legislature suggest that cities may not continue to use the authority granted to cities by RCW 35A.70.070 and chapter 35.88 RCW to set more stringent citywide standards for the purity of local public water supplies. This Court should harmonize all of these statutes.⁴² The statutes, read together, give authority to establish statewide water supply purity regulations to the State Board and Department of Health pursuant to RCW 43.20.050(2)(a) and RCW 70.119A.080 but give citywide authority to establish more restrictive local water supply purity regulations to the corporate city pursuant to RCW 35A.70.070 and chapter 35.88.

RCW 35.88.020 explicitly recognizes the statewide authority of the State Board of Health and the citywide authority of the corporate city regarding purity of public water supplies:

special police . . . may arrest [for actions which violate a corporate city ordinance], against the purity of the water supply, or which violate any rule or regulation lawfully promulgated by the state board of health for the protection of the purity of such water supply.⁴³

contaminants and water quality) as well as chapters 70.116 (water system coordinated planning), 70.05 (local health departments) and 43.70 (State Department of Health) RCW. WAC 246-290-001. Appendix C-1.

⁴¹ *Supra*, this brief at 4-5.

⁴² *State v. Smalls*, 99 Wn.2d 755, 765, 665 P.2d 384 (1983) (“statutes should be harmonized whenever possible”).

⁴³ RCW 35.88.020 (Petition at A-43 to A-44).

This statute clearly expresses that corporate city ordinances are allowed regarding water supply purity and they are to be enforced along with state regulations regarding water supply purity.⁴⁴ This Court should decide Issue 1 in the Petition for Review in favor of the Committees because the corporate city has authority to pass more restrictive ordinances regulating the purity of City water supplies.

1. The Opinion errs when it does not harmonize the Statutes

The Opinion states that RCW 70.142.040 and chapter 35.88 RCW cannot be harmonized because of the explicit grant of power in RCW 70.142.040.⁴⁵ RCW 70.142.010 authorizes the State Board of Health to establish statewide maximum contaminant levels for public water supplies. RCW 70.142.040 authorizes county boards of health in counties with at least 125,000 people to set more stringent county maximum contaminant levels. Nowhere in the language of chapter 70.142 RCW does the statute expressly, or by necessary implication, preempt cities from setting more stringent city maximum contaminant levels.⁴⁶ Nowhere in chapter 70.142 RCW is any state agency authorized to regulate additives to public water supplies that are intended to treat people instead of treating water. At most, one could argue that the language in RCW 70.142.040 by

⁴⁴ *Id.* Such local regulations do not pursue or affect the statewide plan and so are legislative if they apply generally to the local community. *Supra*, this brief at 3, Note 8.

⁴⁵ Opinion at 13, Note 10 (Petition at A-13).

⁴⁶ The Committees in their Reply Brief at 7 cited to *Tacoma v. Luvene*, 118 Wn.2d 826, 833, 827 P.2d 1374 (1992) for the proposition that “Preemption occurs when the legislature states its intention expressly, or by necessary implication, to preempt the field.”

necessary implication preempted county boards of health in counties with less than 125,000 people from setting more stringent county maximum contaminant levels.

Because chapter 70.142 RCW is silent regarding whether cities can set city maximum contaminant levels, this Court should conclude that a city can even use local police power⁴⁷ pursuant to Const. art. XI, sec. 11 to set more restrictive citywide maximum contaminant levels. But the fact that the Legislature in chapters 43.20, 70.142 RCW, and elsewhere, explicitly gives the state board and department of health authority to set statewide water supply purity standards and gives certain county health departments the right to set more stringent county standards does not preempt or conflict and is not inconsistent with the Legislature's grant of power to cities in RCW 35A.70.070 and chapter 35.88 RCW to set even more restrictive city standards. If, as in the instant case, the local standards do not implement, pursue, or depend on the statewide standards adopted by the "superior power" then the local standards are a new policy or plan.

The Opinion errs when it refuses to harmonize the statutes and refuses to find that the corporate City is authorized by the Legislature to set citywide water purity standards that are more restrictive than statewide

⁴⁷ Health District v. Brockett, 120 Wn.2d 140, 148, 839 P.2d 324 (1992) ("This is a direct delegation of the police power as ample within its limits as that possessed by the legislature itself. It requires no legislative sanction for its exercise so long as the subject-matter is local, and the regulation reasonable and consistent with the general laws . . . ").

standards.⁴⁸ Because the corporate City has its own authority granted by the Legislature as well as police power authority granted by the Constitution to protect the health of local citizens, and because dispensing drugs without prescriptions and informed consent is harmful, the corporate City has the necessary “power to enact.”

B. Maximum Contaminant Levels Are Only Tangentially Related To The Issues Before This Court⁴⁹

The Safe Drinking Water Act is intended to set standards for when and how contaminants should be cleaned-up in public water supplies. It is not intended to regulate additions of any substance to public water supplies unrelated to cleaning up contaminants.⁵⁰ The Safe Drinking Water Act and State implementation of this Act in chapters 43.20 and 70.142 RCW and in other

⁴⁸ City standards may not be less restrictive than statewide standards or they would not meet those statewide standards.

⁴⁹ Maximum contaminant levels set by the state and relied upon by Division II in its Opinion are only tangentially related to the issues before this Court. The concept of maximum contaminant levels was created by the federal Safe Drinking Water Act. The federal administrator of the Safe Drinking Water Act is the United States Environmental Protection Agency (“EPA”). 42 U.S.C. 300f(7). The EPA was mandated to set federal maximum contaminant levels for drinking water supplies. 42 U.S.C. 300f(1)(C)(i). In the process of setting such a maximum contaminant level (“MCL”), the EPA first sets a maximum contaminant level goal (“MCLG”). 42 U.S.C. 300g-1(a)(3). This goal is based solely on health safety as determined by the EPA. 42 U.S.C. 300g-1(b)(4)(A). Then the EPA sets a MCL as close to the MCLG as feasible. 42 U.S.C. 300g-1(b)(4). Feasibility is determined taking into account the cost of cleaning up higher levels of contamination. 42 U.S.C. 300g-1(b)(4)(D).

⁵⁰ National Research Council, *Fluoride in Drinking Water* (2006) (Appendix A-1 to A-2 hereto); Supplemental Brief of Petitioners at 6, including Note 24; 42 U.S.C. sec. 300g-1(b)(11). The City Amici Brief at 10 errs when it states “additives to drinking water” are governed by MCLs set in WAC 246-290-310.

statutes and in WAC 173-200-020,⁵¹ WAC 246-290-72012,⁵² and other regulations focus on identifying contaminants in public water supplies and setting MCLG health safety limits and treatment technique feasible MCLs for identified contaminants. The treatment techniques include additives, but just for the purpose of reducing existing contaminants.⁵³

Therefore, the Safe Drinking Water Act (“SDWA”) and State implementation in Chapter 70.142 RCW and WAC 246-290-72012 are only tangentially related to the Initiatives because the SDWA only regulates “additives” to clean up contaminants and the Initiatives only regulate “drugs” to treat people. Similarly, the statewide comprehensive regulations⁵⁴ generally regulate water purveyors using ANSI/NSF Standard 60 approved “additives” to treat water and the Initiatives generally regulate everyone within the jurisdiction of City who puts substances in public water supplies to affect people’s bodies unrelated to making water safe and potable.⁵⁵

C. The Opinion Errs When It Relies On The City Legislative Body’s Statutory Authority To “Operate Water Utilities” To Give The City Authority To Medicate People Through Its Municipal Water Supply

In Section E of the Opinion, the appellate court finds that the Initiatives fail to meet the “power to enact” test because they interfere with the statutory

⁵¹ Petition at A-48.

⁵² Petition at A-49 to A-62.

⁵³ See Supplemental Brief of Petitioners at 6, including Note 24.

⁵⁴ Supra, this brief at 3, Note 7.

⁵⁵ Supra, this brief at 6, Note 19.

authority of the City’s legislative body to “operate water utilities.”⁵⁶ 2008 AGO No. 5 concludes that a grant of power to operate water utilities “does not delegate public health police powers” and “does not provide authority regarding decisions to fluoridate water.” Because the City legislative body’s statutory authority to “operate water utilities” does not provide authority regarding decisions to fluoridate and otherwise medicate people through its municipal water supply, this Court should find that the Opinion errs when it finds that the Initiatives interfere with such an authority to “operate” granted to the City’s legislative body.

The Opinion finds the “operation of a municipal water system” is “beyond the initiative power.”⁵⁷ And while this is correct, this Court should find that City’s authority regarding decisions to fluoridate and otherwise medicate through municipal water supplies does not derive from the City legislative body’s authority to “operate water utilities.” Instead, this Court should find that authority regarding decisions to fluoridate and otherwise medicate through municipal water supplies derives from police power granted by Const. art. XI, sec. 11 and from RCW 35A.70.070(6) and Chapter 35.88 RCW and these powers belong to the corporate city and not just to the legislative body.

D. The Appellate Court Should Have Applied Laws Regulating Manufacturing, Marketing, Formulating, Prescribing, Dispensing, Possessing, and Administering Drugs – The Initiatives Are Within The Corporate City’s Power To Enact

⁵⁶ Petition at A-10 to A-13. The City Amici Brief at 1-16 strongly relies on City authority to operate utilities.

⁵⁷ Petition at A-11.

Under Washington and Federal law it is unlawful to manufacture, market, formulate, prescribe, dispense, possess or administer a legend (prescription) drug without a license and without compliance with relevant drug laws.⁵⁸

Washington drug laws, even with police powers, require a qualified and licensed practitioner to prescribe and dispense legend drugs.⁵⁹ A licensed practitioner has a “duty to secure an informed consent by a patient or his representatives.”⁶⁰ Water purveyors are generally neither licensed practitioners nor do they obtain patient consent.⁶¹ Members of the public who would put drugs in public water supplies also do not get informed consent. The Initiative Ordinances prohibit or limit any person, including water purveyors such as the City, from putting any drug in any public water supply serving the City.

IV. ARTIFICIALLY-FLUORIDATED WATER IS AN ILLEGAL, UNAPPROVED, LEGEND (PRESCRIPTION) DRUG WHEN USED TO PREVENT, MITIGATE OR TREAT DENTAL DISEASE

⁵⁸ Chapter 69.41 RCW; U.S.C. 21, Chapter 9 (“Federal Food, Drug, and Cosmetic Act”). The Initiatives recognize that it is impractical to comply with Washington drug laws when manufacturing and dispensing “water and drug” compounds through public water systems.

⁵⁹ “Legend drugs” means any drugs which are required by state law or regulation of the state board of pharmacy to be dispensed on prescription only or are restricted to use by practitioners only. RCW 69.41.010(12).

⁶⁰ RCW 7.70.050(1).

⁶¹ Appendix A-41 to A-47 are true and correct copies of petitions with 105 signatures of people who declare under penalty of perjury that they drink City fluoridated water but have not consented to be medicated through the municipal water supply. It is not practical to secure informed consent from everyone who might drink a “water and drug” compound such as fluoridated water dispensed through a public water system.

The Washington State Board of Pharmacy (“BOP”) issued an interpretive opinion that fluoride, when used to prevent, mitigate or treat disease is a legend drug and it explains the sound reasoning that supports its opinion:

Fluoride is a legend drug regulated under chapter 69.41 RCW. RCW 69.41.010 defines a “legend drug” as drugs “which are required by state law or regulation of the state board of pharmacy to be dispensed on prescription only or are restricted to use by practitioners only.” In WAC 246-883-020(2), the Board specified that “legend drugs are drugs which have been designated as legend drugs under federal law and are listed as such in the 2002 edition of the *Drug Topics Red Book*.”^{62,63}

The Initiatives using the corporate City’s police power authority to prohibit or limit putting drugs including fluoride into any public water supply serving the City do not violate any general law. However, the putting of fluoride or other legend drugs into municipal public water supplies with intent to prevent and/or treat disease does violate Washington and Federal general drug laws unless the drug and water compound is manufactured and dispensed in accord with the following general laws.

“Legend drugs shall not be sold, delivered, dispensed or administered except in accordance with this chapter.” RCW 69.41.020 (preamble).

⁶² State of Washington Department of Health Board of Pharmacy June 4, 2009 letter to Bill Osmunson DDS (Appendix A-4 to A-8 hereto) at A-4; RCW 69.41.010(12) (Appendix A-2 hereto) defines legend drugs; WAC 246-883-020(2) (Appendix A-9 hereto) states legend drugs are listed in 2002 *Drug Topics Red Book* (relevant *Red Book* pages including page 342 that lists “Fluoride” are attached to the above-referenced Board letter (Appendix A-5 to A-7 hereto). We request that this Court take judicial notice that fluoride when used to prevent dental disease is a legend drug in this state.

⁶³ The above-referenced Board letter (Appendix A-4 hereto) continues, “While RCW 69.41.010 restricts the dispensing of prescription drugs to practitioners, the legislature has authorized water districts to fluoridate their water supplies in RCW 57.08.012.” This Court should note, the City is not a water district (Appellants’ Clerk’s Papers (“ACP”) at 30, Para. 3.15) and may not fluoridate under RCW 57.08.012.

“It shall be unlawful for any person to sell, deliver, or possess any legend drug except upon the order or prescription of a physician [or other authorized provider].” RCW 69.41.030(1).

“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.” RCW 69.41.040(1).

“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 either by the brand or generic name and strength per unit dose, name of patient and date. . . .” RCW 69.41.050(1).

A legend (prescription) drug is misbranded in conflict with RCW 69.04.470 if there is not prominent labeling with directions; in conflict with RCW 69.04.490 if active and certain inactive ingredients are not listed; in conflict with RCW 69.04.500 if there are not adequate warnings of possible dangerous use; in conflict with RCW 69.04.520 if it can be dangerous to health; and in conflict with RCW 69.04.540 if a legend drug is dispensed at retail without a written prescription.

The two Initiatives propose either that the addition of drugs to any public water system serving the City be prohibited or prohibited unless they are dispensed as approved by the FDA and meet certain other requirements.

Currently the City dispenses “fluoridated water” which this Court should find to be a legend drug.⁶⁴

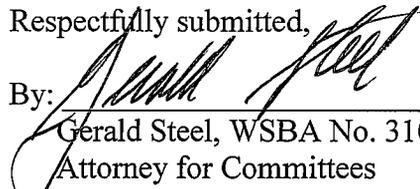
⁶⁴ We request that this Court take judicial notice that fluoridated water is supplied to mitigate and prevent dental decay. Kaul at 620 (1954); Respondent’s Clerks Papers at 132 et seq. We request that this Court also take judicial notice that sodium fluoride,

V. **THE APPELLATE COURT OPINION, IF NOT REVERSED, COULD PREVENT FUTURE LOCAL INITIATIVES AND REFERENDUMS ON FLUORIDATION IN THIS STATE AND IN THIS NATION**

The appellate court Opinion rests on two erroneous conclusions. The first is that the Initiatives administrative because they pursue/affect the comprehensive regulations in chapter 246-290 WAC. But the Initiatives operate on a different class of substances (“drugs” instead of NSF “additives”) and on a different class of persons (all persons within the jurisdiction of the City instead of just water purveyors). The second is that a grant of power to “operate” water utilities “delegates public health police powers.” This Court should reverse these errors and find that the Initiatives meet the “legislative” and “power to enact” tests and this Court should order that the Initiatives be placed on the ballot.

Dated this 12th day of February, 2010.

Respectfully submitted,

By: 

Gerald Steel, WSBA No. 31084
Attorney for Committees

sodium fluorosilicate, and fluorosilicic acid (this latter substance, also called hydrofluorosilicic acid, is used by the City of Port Angeles) are the commonly used active ingredients in water fluoridation. (Appendix A-16 hereto). This Court can confirm that fluoridated water with these active ingredients is not an “approved” drug product by going to www.fda.gov and searching for Drugs@FDA, and then in that FDA approved drug database searching for these active ingredients. This Court can confirm in the Electronic Orange Book that water with fluoride added using any of these active ingredients is not approved for ingestion for the prevention or mitigation of dental decay by going to <http://www.accessdata.fda.gov/scripts/cder/ob/docs/queryai.cfm> We request that this Court take judicial notice that water fluoridated by addition of any of these active ingredients is not a FDA Drug Division or Washington state “approved” over-the-counter or legend drug for ingestion for the prevention or mitigation of dental decay.

CERTIFICATE OF SERVICE

I certify that on the 12th day of February, 2010, I caused a true and correct copy of this certificate and the Our Water Our Choice and Protect Our Waters' Answer to Amici Curiae Brief of Association of Washington Cities and City of Forks to be served on the following by first class mail with proper postage:

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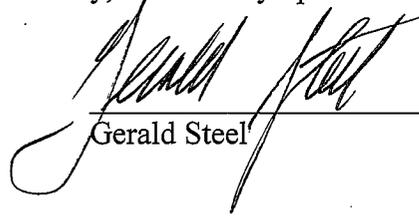
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SUPREME COURT
STATE OF WASHINGTON
10 FEB 12 PM 4:51
BY RONALD R. CARPENTER

Counsel for City of Forks:

William Rodney Fleck
City of Forks
500 E. Division St.
Forks WA 98331

Dated this 12th day of February, 2010 at Olympia Washington.



Gerald Steel

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C	Excerpts from Chapter 246-290 WAC.

21 U.S.C. § 321 : US Code - Section 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.

RCW 69.41.010: Definitions.

**RCW 69.41.010
Definitions.**

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

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

- (a) A practitioner; or
- (b) The patient or research subject at the direction of the practitioner.

(2) "Community-based care settings" include: Community residential programs for the developmentally disabled, certified by the department of social and health services under chapter 71A.12 RCW; adult family homes licensed under chapter 70.128 RCW; and boarding homes licensed under chapter 18.20 RCW. Community-based care settings do not include acute care or skilled nursing facilities.

(3) "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.

(4) "Department" means the department of health.

(5) "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.

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

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

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

(9) "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.

(10) "Electronic communication of prescription information" means the communication of prescription information by computer, or the transmission of an exact visual image of a prescription by facsimile, or other electronic means for original prescription information or prescription refill information for a legend drug between an authorized practitioner and a pharmacy or the transfer of prescription information for a legend drug from one pharmacy to another pharmacy.

(11) "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.

(12) "Legend drugs" means any drugs which are required by state law or regulation of the state board of pharmacy to be dispensed on prescription only or are restricted to use by practitioners only.

(13) "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.

(14) "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 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.

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

(16) "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, 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

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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.

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

[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; 1998 c 178 § 16; 1994 sp.s. c 9 § 736; prior: 1989 1st ex.s. c 9 § 428; 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.]

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STATE OF WASHINGTON
DEPARTMENT OF HEALTH

June 4, 2009

Bill Osmunson DDS, MPH
Aesthetic Dentistry of Bellevue
1418 112th Avenue NE, Suite 200
Bellevue, Washington 98004

Dear Dr. Osmunson:

This letter is in response to your request at the May 7, 2009 meeting of the Washington Board of Pharmacy for a response to your question about designating fluoride as a poison under chapter 69.38 RCW. RCW 69.38.020 states that "[a]ll substances regulated under chapters 15.58, 17.21, 69.04, and 69.50, and chapter 69.45 RCW are exempt from the provisions [of chapter 69.38 RCW]. Fluoride is a legend drug regulated under chapter 69.41 RCW. RCW 69.41.010 defines a "legend drug" as drugs "which are required by state law or regulation of the state board of pharmacy to be dispensed on prescription only or are restricted to use by practitioners only." In WAC 246-883-020 (2), the Board specified that "legend drugs are drugs which have been designated as legend drugs under federal law and are listed as such in the 2002 edition of the *Drug Topics Red Book*." Enclosed are copies of pages 169, 342, and 690 of the 2002 edition of the *Drug Topics Red Book*. Page 169 is the key to the products requiring prescription (legend drugs) and page 342 contains the fluoride products. Page 690 contains the listing of over-the-counter fluoride products, primarily toothpaste containing fluoride.

While RCW 69.41.010 restricts the dispensing of prescription drugs to practitioners, the legislature has authorized water districts to fluoridate their water supplies in RCW 57.08.012. This authority was recognized by the Washington Supreme Court in *Portland Light & Water Company v. Tacoma-Pierce County Board of Health, et al.*, 151 Wn.2d 428 (2004). By adopting a specific statute on the fluoridation of water supplies, the legislature has superseded the more general statutes in the legend drug act requiring a practitioner to dispense fluoride. *Twistall v. Bergeson*, 141 Wn.2d 201, 211 (2000).

For the above-stated reasons, the Board of Pharmacy will not be considering your request to designate fluoride as a poison under chapter 69.38 RCW.

Sincerely,

Susan Teil Boyer, MS, RPh, FASMP
Executive Director
Washington State Board of Pharmacy
PO Box 47852
Olympia WA 98504-7852

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ORANGE BOOK CODES

The Orange Book Codes supply the FDA's therapeutic equivalence rating for applicable multi-source categories. Codes beginning with "A" signify that the product is deemed therapeutically equivalent to the reference product for the category. Codes beginning with "B" indicate that bioequivalence has not been confirmed. In certain instances, a number is added to the end of the AB codes to make it a three-character code (i.e., AB1, AB2, AB3, etc.). Three-character codes are assigned only in situations where more than one reference listed drug of the same strength has been designated under the same heading. "EE" is assigned by Red Book to products that have been evaluated by the FDA but for which an equivalence rating is not available.

Products appearing in the Orange Book have historically been limited to those manufacturers holding the original approved New Drug Application (NDA) or Abbreviated New Drug Application (ANDA). However, in recognition of the fact that generic products are available from a widespread number of sources, Red Book publications and database services extend Orange Book ratings to distributors and generic labelers other than the holder of the NDA or ANDA. All ratings applied to such labelers have been directly supplied to Red Book through written certification attesting to the accuracy of the codes supplied.

- AA.....No bioequivalence problems in conventional dosage forms
- AB.....Meets bioequivalence requirements
- AB1.....Meets bioequivalence requirements to AB1 rated reference drug
- AB2.....Meets bioequivalence requirements to AB2 rated reference drug
- AN.....Solution or powder for aerosolization
- AO.....Injectable oil solution
- AP.....Injectable aqueous solution
- AT.....Topical product
- BC.....Controlled-release tablet, capsule, or injectable
- BD.....Documented bioequivalence problem
- BE.....Enteric-coated oral dosage form
- BN.....Product in aerosol-nebulizer delivery system
- BP.....Potential bioequivalence problem
- BR.....Suppository or enema for systemic use
- BS.....Testing standards are insufficient for determination
- BT.....Topical product with bioequivalence issues
- BX.....Insufficient data to confirm therapeutic equivalence
- BC.....Requires further FDA investigation and review
- EE.....This entry has been evaluated by the FDA, but a rating is not available for its labeled product

OTHER DESCRIPTIVE ABBREVIATIONS

The following abbreviations are used to provide additional descriptive information about products:

- A.F.....Alcohol-free
- AMP.....Ampute
- D.F.....Dye-free
- EXT STR.....Extended strength
- E.F.....Fragrance-free
- FR.....French
- INSTIT USE.....Institutional use
- MAY STR.....Multiple strength
- P.O.....Proprietary
- P.C.....Plastic container
- P.F.....Preservative-free
- R.N.P.....Reversed number
- S.D.....Single dose
- S.D.V.....Single dose vial
- S.F.....Sugar free
- SRM.....Syringe
- TAX INCL.....Includes excise tax
- U.S.P.....United States Pharmacopeia

STANDARD DOSAGE FORM DESCRIPTIONS

The following three-character abbreviations are used to indicate the form in which a product is available:

- ACC Accessory
- AER Aerosol liquid
- APP Medication-filled stick
- ARO Aerosol powder
- BAN Bandage
- BAR Bar
- BEA Beads
- C12 Capsule, extended release, 12-hr.
- C24 Capsule, extended release, 24-hr.
- CAK Cake
- CAP Capsule
- CEB Capsule, extended release
- CHI Chip
- CRE Cream
- CRY Crystal
- CTS Tablet, chewable
- CTC Cartridge
- DEV Device
- DRE Dressing
- DSK Disk
- EEC Capsule, delayed release
- ECT Tablet, enteric-coated
- ELI Elixir
- EMM Emulsion
- FDS Food, solid
- FIL Film
- FLA Flake
- FOA Foam
- GAS Gas
- GEP Powder, effervescent
- GEL Gel/jelly
- GER Granule, extended release
- GFS Gel-forming solution
- GRA Granules
- GUM Gum
- INS Insert, extended release
- IMP Implant
- INI Injection
- KIT Kit
- LEA Leaf
- LIQ Liquid
- LOT Lotion
- LOZ Lozenge/trachea
- LUM Lump
- NMA Enema
- ODT Tablet, disintegrating
- OIL Oil
- QIN Ointment
- PAD Pad
- PAK Patient pack
- PAS Paste
- PDR Powder for suspension
- PDS Powder for solution
- PEL Pellet
- PII Powder for suspension, 1-month
- PI3 Powder for suspension, 3-month
- PI4 Powder for suspension, 4-month
- PIH Powder for inhalation
- PICT Packet
- POD Pod
- POW Powder
- PRO Prophylactic
- PUD Padding
- SER Suspension
- SOL Capsule, liquid-filled
- SHA Shampoo
- SOA Soap
- SPE Suppository, extended release
- SOL Solution
- SPG Sponge
- SPS Spray
- STI Stick
- SUF Suppository
- SUS Suspension
- SWA Swab
- SYR Syrup
- T12 Tablet, extended release, 12-hr.
- T24 Tablet, extended release, 24-hr.
- TAB Tablet
- TAM Tampon
- TAP Tape
- TCP Tablet, coated particles
- TDM Patch, extended release
- TEF Tablet, effervescent
- TER Tablets, extended
- TES Test
- TIN Tincture
- WAF Water
- WAX Wax

ABBRE

- Generic
- Single in full
- Multi-the al follow
- ACE.....
- ACEBN
- ACET...
- AL ACE
- AL CL...
- AL CHL
- AL CHL
- ALGIN
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- AL HVE
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A-6

PROD/MFR	NDC	AVP	DP	ORC	PROD/MFR	NDC	AVP	DP	ORC	PROD/MFR	NDC	AVP	DP	ORC
(Gallipot)					FLUOCINONIDE (Major)					(U.S.P. REAGENT)				
POW, 100 (MICRONIZED, U.S.P.)	51562-0058-01	32.50			CRE, TP, 0.05%, 30 gm...	00904-0770-01	10.15		AB	500 mg (WATER SOLUBLE)	F5801030	97.85		
1 gm	51562-0058-06	236.34			FLUOGEN (Phys Total Care)					500 gm	F5805020	52.15		
					ASACIN					(Novartis Ophth) See ANGIOCEIN				
(Ivax Pharm)					Influenza virus vaccine (subvirion)					(Deemed) See OCU-FLUR 10				
CRE, TP, 0.05%, 60 ml	00102-5050-60	26.18			SOL, IM (M.O.V., STERIL-VIAL, 99-60)					FLUORESCIN/PROPARGAINE				
(Major) See FLUOCINONIDE					45 mcg/0.5 ml					(Akorn) See FLUORACAIN				
(Major)					5 ml	54868-4124-00	30.96			(Bausch) See FLUORACAIN				
CRE, TP, 0.05%, 15 gm	00904-0770-36	7.30			FLUOR-A-DAY (Pharmasolence Labn)					FLUORESCITE (Alcon Ophthalmic)				
60 gm	00904-0770-02	16.50			sodium fluoride					fluorescein sodium				
SOL, TP, 0.05%, 60 ml	00904-0759-03	25.45			CTB, PO (S.F. RASPBERRY)					SOL, IV (AMP)				
(Mediate) See LIDEX					0.25 mg, 120s ea	51817-0611-16	7.02			10%, 5 ml	00065-0092-06	10.00		
(Mediate) See LIDEX-E					0.5 mg, 120s ea	51817-0622-16	7.02			(SRU, 10 ML)	00005-0063-00	37.20		
(Mediate)					LIO, PO (DROPS)					10%, 6 ml	00000-0093-00	37.20		
					~ 80 ml ea	51817-0686-51	5.81			(AMP)	00000-0093-02	22.02		
					LOZ, PO (S.F. MINT)					FLUORETS (Akorn)				
					1 mg, 100s ea	51017-0072-16	7.25			fluorocaine sodium				
					(Advantix)					TES, OP (STRIP)				
					FLUORACAIN					1 mg, 100s ea	77478-0480-01	13.50		
					CTB, PO (S.F. RASPBERRY)					FLUORI-METHANE (Gebaue)				
					0.25 mg, 30s ea	56130-0104-20	1.23			dichloro/trichloromono				
					FLUOR-J-STRIP (Bausch&Lomb Pharm)					SPR, TP (FINE)				
					fluorescein sodium					15%-8%, 103 ml	00386-0083-04	23.70		
					TES, OP (STRIP)					(Alcon) See FLUORACAIN				
					2 mg, 300s ea	24200-0288-00	77.00			FLUORIN				
					(Alcon) See FLUORACAIN					SPR, TP (FINE)				
					FLUOR-J-STRIP A.T. (Bausch&Lomb Pharm)					15%-8%, 103 ml	54560-3567-00	23.89		
					fluorescein sodium					(Phys Total Care)				
					TES, OP (STRIP)					SPR, TP (FINE)				
					1 mg, 300s ea	24200-0391-00	79.30			15% (AMP)				
					FLUOR-OP (Novartis Ophth)					SPR, TP (FINE)				
					sodium fluoride					15%-8%, 103 ml	54560-4158-00	25.70		
					fluorometolone					(Phys Total Care)				
					SUS, OP, 0.1%, 5 ml	58768-0355-05	15.03		AB	FLUORIDE (Vintage)				
					10 ml	58768-0358-10	22.86		AB	sodium fluoride				
					15 ml	58768-0358-15	20.16		AB	L.I.O. PO (DROPS)				
					FLUORABON (Perry Med)					0.5% (AMP)				
					sodium fluoride					0.2%, 120 ml	00041-0351-07	7.49		
					and thiazide w/it w/it d					(A.E. MINT)				
					SOL, PO (DROPS, BASIC)					FLUORINSE (Oral B Lab)				
					(Perry Med) 10 ml, 60 ml	11763-0519-20	4.18			sodium fluoride				
					CTB, PO (DROPS)					SOL, PO (A.E. GINNAMON)				
					1 mg, 100s ea	11763-0525-01	1.99			0.2%, 120 ml	00041-0350-07	7.49		
					(ORANGE)					FLUORINSE (Oral B Lab)				
					LIO, PO (DROPS)					sodium fluoride				
					1 ml, 100s ea	11763-0522-01	1.99			SOL, PO (A.E. GINNAMON)				
					60 ml	11763-0824-20	3.76			0.2%, 120 ml	00041-0351-07	7.49		
					0.25 mg/0.6 ml					(A.E. MINT)				
					FLUORACAIN (Akorn)					FLUORINSE (Oral B Lab)				
					fluorescein/propargaine					sodium fluoride				
					SOL, OP (GLASS BOTTLE)					SOL, PO (A.E. GINNAMON)				
					0.25%-0.4%, 5 ml	77478-0314-10	9.15			0.2%, 120 ml	00041-0351-07	7.49		
					FLUORESCIN (Alcon)					(A.E. MINT)				
					fluorescein sodium					FLUORINSE (Oral B Lab)				
					SOL, OP (GLASS BOTTLE)					sodium fluoride				
					0.25% (AMP)					SOL, PO (A.E. GINNAMON)				
					10 ml	00041-0350-07	7.49			0.2%, 120 ml	00041-0351-07	7.49		
					30 ml	00041-0350-07	7.49			(A.E. MINT)				
					60 ml	00041-0350-07	7.49			FLUORINSE (Oral B Lab)				
					120 ml	00041-0350-07	7.49			sodium fluoride				
					BEL, TP, 0.05%, 15 gm	51672-1270-01	20.87			30%, 120 gm	51326-0025-04	15.00		
					30 gm	51672-1270-02	28.52			50%, 120 gm	51326-0027-04	25.00		
					50 gm	51672-1270-03	48.52			70%, 120 gm	51326-0029-04	35.00		
					70 gm	51672-1270-04	68.52			FLUOROLY PADS (Topix)				
					90 gm	51672-1270-05	88.52			glycolic acid				
					110 gm	51672-1270-06	108.52			Prod. TO OFFICE USE ONLY				
					130 gm	51672-1270-07	128.52			30% (AMP)				
					150 gm	51672-1270-08	148.52			50%, 30s ea	51326-0006-30	30.00		
					170 gm	51672-1270-09	168.52			70%, 30s ea	51326-0008-30	50.00		
					190 gm	51672-1270-10	188.52			70%, 30s ea	51326-0010-30	70.00		
					210 gm	51672-1270-11	208.52			FLUOROMETH/SULFACET SOD				
					230 gm	51672-1270-12	228.52			(Alcon) See F.M.L. S. LIQUIFILM				
					250 gm	51672-1270-13	248.52			FLUOROMETHOLOME				
					270 gm	51672-1270-14	268.52			SUS, OP, 0.1%, 5 ml				
					290 gm	51672-1270-15	288.52			(Alcon) See F.M.L. S. LIQUIFILM				
					310 gm	51672-1270-16	308.52			(Alcon) See F.M.L. LIQUIFILM				
					330 gm	51672-1270-17	328.52			(Alcon) See F.M.L. S. O.C.E.				
					350 gm	51672-1270-18	348.52			SUS, OP, 0.1%, 5 ml	54559-4371-00	13.04		EE
					370 gm	51672-1270-19	368.52			(Alcon) See F.M.L. S. O.C.E.				
					390 gm	51672-1270-20	388.52			10 ml	54559-4372-00	28.18		EE
					410 gm	51672-1270-21	408.52			(Bausch&Lomb Pharm)	54559-4373-00	35.20		EE
					430 gm	51672-1270-22	428.52			SUS, OP, 0.1%, 5 ml	24200-0288-05	15.00		AB
					450 gm	51672-1270-23	448.52			15 ml	24200-0288-10	35.18		AB
					470 gm	51672-1270-24	468.52			10 ml	24200-0288-10	26.18		AT
					490 gm	51672-1270-25	488.52			(Cartmark Inc.)				
					510 gm	51672-1270-26	508.52			SUS, OP, 0.1%, 5 ml	00339-5000-50	15.03		AB
					530 gm	51672-1270-27	528.52			10 ml	00339-5000-51	23.62		AB
					550 gm	51672-1270-28	548.52			10 ml	00339-5000-52	31.00		AB
					570 gm	51672-1270-29	568.52			SUS, OP, 0.1%, 5 ml	51314-0328-05	15.80		AB
					590 gm	51672-1270-30	588.52			(Falcon Ophthalmics)				
					610 gm	51672-1270-31	608.52			10 ml	R1314-0328-10	26.20		AB
					630 gm	51672-1270-32	628.52			15 ml	51314-0328-15	35.20		AB
					650 gm	51672-1270-33	648.52							
					670 gm	51672-1270-34	668.52							
					690 gm	51672-1270-35	688.52							
					710 gm	51672-1270-36	708.52							
					730 gm	51672-1270-37	728.52							
					750 gm	51672-1270-38	748.52							
					770 gm	51672-1270-39	768.52							
					790 gm	51672-1270-40	788.52							
					810 gm	51672-1270-41	808.52							
					830 gm	51672-1270-								

PROD/MFR	HTL, UPC, NDC	AWP	SRP
FLEET PREP KIT 3 (Fluor, S.B.) KIT, NA (W/SMALL VOLUME ENEMA) ea 01320-2120-1d 4.47			
FLEET SOF-LAX (Fluor, C.D.) TAB, PO (865 CARLET) 100 mg, 60s ea 01320-7516-00 5.60			
FLEET SOF-LAX OVERNIGHT (Fluor, C.B.) TAB, PO (DEL CAPLET) 30 mg-100 mg 01320-7553-00 4.00 60s ea 01320-7560-00 8.00			
FLETCHER'S CASTORIA (Men/Infants) LID, PO, 6.9% 75 ml 0742-0032-10 3.59			
FLEXALL 454 (Chatham) GEL, TP, 7% 80 gm 41157-1601-10 3.24 120 gm 41167-1601-30 4.26 240 gm 41167-1601-50 7.58			
FLEXALL 454 MAXIMUM STRENGTH (Chatham) GEL, TP, 4% 80 gm 41167-1902-10 3.24 90 gm 41167-1902-20 4.86 180 gm 41167-1902-40 7.58			
FLEXALL ULTRA PLUS (Chatham) GEL, TP (SHEELESS) 3.1% 165-10% 60 gm 41157-1603-10 4.05 120 gm 41167-1603-30 6.88			
FLEX-SEM FECAL COLLECTOR (Bepvafac) DEV, NA (W/TAZ CLIPS) 10s ea 00003-8500-78 70.97 92.91			
FLEX-TRAK ANCHORING (Convulser) ACC, NA (LARGE) 50s ea 00003-0374-49 30.28 34.84			
FLEXIBLE FABRIC STRIPS (Chalc Drug Marketing) BAND, TP (ASURITE) 20s ea 63308-0030-30 0.90			
FLEXIFIX TRANSPARENT ADHESIVE FILM (Smith & Nephew) TAP, TP (2"X1"YD ROLL) ea 00223-4181-30 14.04 10.78 ea 00223-4161-40 25.86 34.84			
FLEXIFLO III PUMP W/SPRINK (Nasala) KIT, NA ea 00085-9017-05 0.94			
FLEXIFLO QUANTUM COLDMARK PUMP (Ross Nutr) KIT, NA (W/PIERCING PIN & 5 USH BAG) ea 70074-8249-00 15.54 W/PIERCING PIN 70074-5245-00 10.64 W/TOP-FILL & FLUSH BAGS 70074-6456-10 21.38 W/TOP-FILL BAG 70074-5454-00 16.40			
FLEXIFLO QUANTUM ENTERAL PUMP (Ross Nutr) DEV, NA ea 70074-5059-70 1380.00 KIT, NA (40HA) 70074-5080-30 7.95			
FLEXIFLO QUANTUM PUMP (Ross Nutr) KIT, NA (W/PIERCING PIN & FLUSH BAG) ea 70074-5080-50 13.74 W/PIERCING PIN 70074-5000-10 0.84			
FLEXIFLO-III COLDMARK PUMP (Ross Nutr) KIT, NA (W/PIERCING PIN) ea 70074-5248-00 0.66			
FLEXIFLO-III ENTERAL NUTRITION PUMP (Ross Nutr) DEV, NA (REFURBISHED) 70074-0455-10 330.00 KIT, NA ea 70074-0007-70 6.26 W/PIERCING PIN 70074-0007-80 7.28			
FLEXITAINER 500 CONTAINER (Ross Nutr) KIT, NA (ENTERAL NUTRITION) ea 70074-0005-00 6.23			
FLEXITAINER NUTRITION CONTAINER (Ross Nutr) ACC, NA ea 70074-0006-50 9.20			
FLEXOPLAST (Waters Medical) BAND, TP (ELASTIC ADHESIVE) 12s ea 611003 102.99 (3" REVERSE ADHESIVE) 611009 102.99 (4" ELASTIC ADHESIVE) 611004 123.31			

PROD/MFR	HTL, UPC, NDC	AWP	SRP
EXTEND SKIN BARRIER NON-STERILE (Hollister) DEV, NA (8"X10") 3s ea 3001 57.59 65.01 (4"X4") 8s ea 3000 25.24 28.76			
FLEXZAN (Bortek) DIRE, TP (4"X3" SHEETS) 5s ea 62704-0080-32 35.25 (8"X11" SHEETS) 62704-0082-64 70.50 6s ea 62704-0084-64 70.50 10s ea 62704-0086-68 24.00 (4"X4" SHEETS) 62704-0085-18 32.00			
FLEXZAN EXTRA (Bortek) DIRE, TP (4"X3") 5s ea 62704-0081-32 40.60 (8"X11") 62704-0081-64 77.00			
FLINTSTONES (Bayer Cons) CTB, PO, 60s ea 16500-0701-00 4.46 100s ea 16500-0701-40 6.52			
FLINTSTONES COMPLETE (Bayer Cons) CTB, PO, 60s ea 10500-0000-00 6.54 120s ea 16500-0971-30 10.88			
FLINTSTONES PLUS CALCIUM (Bayer Cons) CTB, PO, 60s ea 16500-0770-00 3.67			
FLINTSTONES PLUS EXTRA 2 (Bayer Cons) CTB, PO, 60s ea 10500-0001-00 5.67 100s ea 16500-0801-30 9.23			
FLINTSTONES W/IRON (Bayer Cons) CTB, PO, 60s ea 16500-0700-00 5.67 100s ea 16500-0700-60 7.59			
FLIP-FLO INCONTINENCE VALVE (Dard Medical) ACC, NA (12 OZ BONUS PACK) ea 150419 23.56 20.57 19 OZ W/LATEX STRAP 150319 6.42 8.02 32 OZ BONUS PACK 150402 23.65 25.57			
FLIPPER HOLDER/BACK (Barnett Corp) ACC, NA (HOLD 12 FLIPPERS) ea 0001 32.05			
FLIPPER W/FOUR CELLS (Barnett Corp) DEV, NA (EMPTY, NO LENSES) ea 004F 6.50			
FLIPPER W/TWO PAIRS OF LENSES (Barnett Corp) DEV, NA (1/4"-2.25" D(OPTERS)) ea 0C1270 18.06 (1/4"-2.25" D(OPTERS)) 0C9270 17.85 ANY COMBINATION 001270S 28.65			
FLU-GARD PUMP W/SPRINK (Heslin) KIT, NA ea 00065-9000-99 6.54			
FLORICAL (Morgan) CAP, PO, 364 mg-0.3 mg 00304-0102-02 6.90 500s ea 00304-0102-06 46.25 TAB, PO, 364 mg-0.3 mg 00304-0100-02 6.12 500s ea 00304-0100-06 42.89			
FLORIDA FOAM IMPROVED (Hill Bern) LID, TP, 240 ml 20105-0080-00 5.31			
FLOW DETECTOR (Abbott Hosp) KIT, NA (B4) ea 00074-1007-28 163.65			
FLU & COLIC MEDICINE (Parke) POR, PO (LEMON, PACKET) 650 mg-1 mg-60 mg 69940-0110-01 3.36			
FLU COLD & COUGH NIGHTTIME (Cardinal Health) PKT, PO (MAX STR, LEMON) 6s ea 37245-0334-51 3.52 (Mint) 00004-3401-00 3.95 PKT, PO (MAX STR, A.F, LEMON) 6s ea 00004-3401-00 3.95			
FLU MULTI-SYMPTOM MAXIMUM STRENGTH (Schering) TAB, PO (GELCAP, NON-DROWSY) 500 mg-15 mg-30 mg 19450-0276-01 4.00 20s ea 19450-0276-01 4.00			
FLU SOLUTION (Dallies) PEL, SL, 6s ea 00174-0001-11 4.17 8.05			

PROD/MFR	HTL, UPC, NDC	AWP	SRP
FLU SOLUTION PLUS (Dallies) TAB, SL, 45s ea 00174-0506-41 4.17 8.05			
FLU, COLD & COUGH MEDICINE (Cardinal Health) POR, PO (PACKET, LEMON) 6s ea 87209-0330-21 3.14			
FLU-BELIEF (Parke) TAB, PO, 325 mg-2 mg-30 mg 00027-9324-62 2.94 5.29 36s ea 00027-9324-62 2.94 5.29			
FLU/COLD/COUGH MEDICINE (Barnett Runswin) POS, PO (MAX STR, PACKET, LEMON) 6s ea 24904-0800-01 3.59 4.39 (PACKET, LEMON) 6s ea 24904-0800-01 3.19 3.95			
FLUORIDE YANFAR CONTROL TOOTHPASTE (Parke) POS, PO (PACKET, LEMON) 5s ea 50040-0530-01 2.30			
FLUORIDE YANFAR CONTROL TOOTHPASTE (Parke) GEL, TP (FRESHMINT) 0.15% 131 gm 58040-0270-20 1.74 PAS, TP (ORIGINAL) 50040-0230-20 1.74 192 gm 50040-0230-20 1.74			
FLUORIDE TOOTHPASTE (Parke) PAS, TP (MINT) 50040-0007-20 1.59 (REGULAR) 50040-0016-20 1.59			
FLUORIGARD (Hemphill Orl) GOL, PO, 0.02%, 473 ml 00126-0220-10 3.65			
FO-FIL (Barnett Corp) LID, PO, 30 ml 41954-0281-00 4.50 8.90			
FOAM INVALID RING REPLACEMENT COVER (Hormel) ACC, NA (FOR 1R210, 12, 14) ea 107210/12/14 2.75 (FOR 1R211, 13, 15) ea 107211/13/15 4.00			
FOAM INVALID RING W/COVER (Hormel) DEV, NA (14 1/4"X12 3/4" PLAD) ea 107000 6.16 (14 1/4"X12 3/4" POLYDOT) 107070 6.60 ea 107000 6.60 (16 1/4"X13 PLAD) 107070 6.25 (16 1/4"X13 POLYDOT) 107060 3.10 (16 1/4"X15 1/4" POLYDOT) 107040 7.40			
FOAM PAD (Hormel) ACC, NA (10" LARGE, BLACK) ea 463L 1.00 (10" LARGE, WHITE) 431L 1.30 ea 431L 1.30 (12" REGULAR, BLACK) 433L 1.80 (12" REGULAR, WHITE) 431L 1.30 (12" SPEC SMALL, BLACK) 433L 1.80 (12" SPEC SMALL, WHITE) 433L 1.80 ea 431L 1.30 (12" VERY LARGE, BLACK) 434V 2.26 ea 432V 1.36 (12" X-LARGE, BLACK) 4340 2.26 (12" X-LARGE, WHITE) 4320 1.40 (12" X-SMALL, BLACK) 433E 1.80 (12" X-SMALL, WHITE) 431E 1.30 ea 731L 1.30 (1/8" REGULAR, WHITE) 7310 1.30 (1/8" SPEC SMALL, WHITE) 7318 1.30 ea 732V 1.36 (1/8" X-LARGE, WHITE) 7320 1.40 ea 731E 1.30			

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WAC 246-883-020

Agency filings affecting this section

Identification of legend drugs for purposes of chapter 69.41 RCW.

(1) In accordance with chapter 69.41 RCW, the board of pharmacy finds that those drugs which have been determined by the Food and Drug Administration, under the Federal Food, Drug and Cosmetic Act, to require a prescription under federal law should also be classified as legend drugs under state law because of their toxicity or potential for harmful effect, the methods of their use and the collateral safeguards necessary to their use, indicate that they are only safe for use under the supervision of a practitioner.

(2) For the purposes of chapter 69.41 RCW, legend drugs are drugs which have been designated as legend drugs under federal law and are listed as such in the 2002 edition of the *Drug Topics Red Book*. Copies of the list of legend drugs as contained in the *Drug Topics Red Book* are available for public inspection at the headquarters office of the State Board of Pharmacy, 1300 Quince Street S.E., P.O. BOX 47863, Olympia, Washington 98504-7863. To obtain copies of this list, interested persons must submit a written request and payment of seventy-six dollars for each copy to the board.

(3) There may be changes in the marketing status of drugs after the publication of the above reference. Upon application of a manufacturer or distributor, the board may grant authority for the over the counter distribution of certain drugs which had been designated as legend drugs in this reference. These determinations will be made after public hearing and will be published as an amendment to this chapter.

[Statutory Authority: RCW 69.41.075 and 18.64.005(7), 02-14-049, § 246-883-020, filed 6/27/02, effective 7/28/02. Statutory Authority: RCW 69.41.075, 18.64.005, 00-06-078, § 246-883-020, filed 3/1/00, effective 4/1/00. Statutory Authority: RCW 69.41.075, 96-21-041, § 246-883-020, filed 10/11/96, effective 11/11/96. Statutory Authority: RCW 18.64.005, 92-09-070 (Order 264B), § 246-883-020, filed 4/14/92, effective 5/15/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW, 91-18-057 (Order 191B), recodified as § 246-883-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005 and 69.44.075 [69.41.075], 85-18-091 (Order 196), § 360-32-050, filed 9/4/85. Statutory Authority: RCW 18.64.005 and 69.41.075, 83-20-053 (Order 176), § 360-32-050, filed 9/29/83. Statutory Authority: RCW 69.41.075, 81-10-025 (Order 160), § 360-32-050, filed 4/28/81. Statutory Authority: 1979 1st ex. s. c 139, 79-09-136 (Order 149, Resolution No. 9/79), § 360-32-050, filed 9/5/79.]

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From: CDER DRUG INFO [mailto:DRUGINFO@fda.hhs.gov]
Sent: Wednesday, July 22, 2009 7:20 AM
To: Bill
Subject: RE: The legend drug fluoride

Dear Dr. Osmunson:

Thank you for writing the Division of Drug Information, in the FDA's Center for Drug Evaluation and Research.

A search of the Drugs@FDA database (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>) of approved drug products and the Electronic Orange Book (<http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>) does not indicate that sodium fluoride, silicofluoride, or hydrofluorosilicic acid has been approved under a New Drug Application (NDA) or Abbreviated New Drug Application (ANDA) for ingestion for the prevention or mitigation of dental decay.

The FDA is aware of sodium fluoride-containing products in various dosage forms that are currently marketed. At the present time, the FDA is deferring any regulatory action on sodium fluoride products that were marketed prior to 1962 as long as the currently marketed product is identical to the pre-1962 product. Any prescription sodium fluoride-containing product coming into the marketplace after 1962 that is not identical to the pre-1962 labeling and that has drug claims, is subject to the FDA drug review process prior to marketing.

Best regards,
Drug Information SH
Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration

For up-to-date drug information, follow the FDA's Division of Drug Information on Twitter: http://twitter.com/fda_drug_info
<http://twitter.com/fda_drug_info>

This communication is consistent with 21CFR10.85(k) and constitutes an informal communication that represents our best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of the FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: Bill [mailto:bill@teachingsmiles.com]
Sent: Saturday, July 18, 2009 2:52 PM
To: CDER DRUG INFO
Subject: The legend drug fluoride

Dear FDA,

I am writing an Amicus for the Washington State Supreme Court. In an effort to give them the best information without them having to do the research and digging on the web site, I am requesting a letter or email from the FDA stating that the FDA has not approved the ingestion of sodium fluoride or silicofluorides for the prevention of dental decay.

Specifically to my question, "Is sodium fluoride, silicofluoride or hydrofluorosilicic acid an approved drug for ingestion for the prevention or mitigation of dental decay?"

Bill Osmunson DDS, MPH
25977 Canyon Creek Suite G
Wilsonville, OR 97070
425.466.0100
bill@teachingsmiles.com

A-10

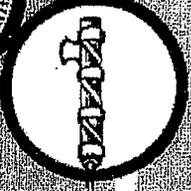
NDA withdrawn for fluoride and vitamin combinations

The FDA has addressed a "regulatory letter" to approximately 35 companies marketing combination drugs consisting of fluoride and vitamins. The letter states that these drugs are related to a product (Enziflur lozenges) for which FDA has withdrawn approval of a new drug application. The NDA for Enziflur was withdrawn because there is no substantial evidence of drug effectiveness as presented, recommended, or suggested in its labeling.

The FDA has therefore advised manufacturers of combination fluoride and vitamin preparations that their continued marketing is in violation of the new drug provisions of the *Federal Food, Drug, and Cosmetic Act*; they have, therefore, requested that marketing of these products be discontinued.

DRUG THERAPY/JUNE 1975

July 2008



Washington State Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

Dept. of Health, PO Box 47863, Olympia, WA 98504-7863
<https://fortress.wa.gov/doh/hpqa1/hps4/pharmacy/default.htm>

No. 969 National Standardized Examination for Pharmacy Technician Certification

The Washington State Board of Pharmacy adopted rule changes at its public hearing on May 29, 2008. The amended rules result in new requirements for certification as a pharmacy technician. Effective January 1, 2009, all technician applicants must pass a national standardized examination. In addition, all applicants are still required to complete a Board-approved technician training program. Individuals who have obtained a pharmacy technician credential before January 1, 2009, will not be required to meet the new standards.

In the next few months, the Board will be developing the criteria for a Board-approved examination. The plan for applying the rule includes adopting examination standards and identifying which examination(s) are Board-approved. The rule changes also require updates to the basic standards for Board-approved training programs. It is expected that these activities will be further defined at the July 17, 2008, business meeting.

For updates, please visit the Board's Web page at <https://fortress.wa.gov/doh/hpqa1/hps4/Pharmacy/default.htm>. (WAC 246-901-030 & 060)

No. 970 New Preceptor Certifications

If you have renewed your pharmacist license recently, you may have noticed some changes. With the implementation of the new licensing system, your preceptor certification no longer appears on your pharmacist license. A separate license is now issued to pharmacists with active preceptor certifications.

During the implementation of the new system, we discovered that the issue and expiration date of several active preceptor certifications were not correctly transferred from the old system. We are working on correcting this matter and plan to issue replacement preceptor certifications. Please note: Board staff can access past preceptor license history for verification when a pharmacy intern submits hours while under your supervision.

A certificate of participation is mailed to all original and renewed preceptor licensees. Participation in this program will earn the licensee 0.3 continuing education credits. Preceptor certification expires on the licensee's birthday and is issued for no more than five years from the activation date.

When applying for a new or renewing a pharmacist preceptor certification, please use the new application form found on the Board's Web site.

No. 971 Frequently Asked Questions

Q. How should prescriptions from Canada be handled?

Prescriptions from a Canadian province that shares a common border with Washington can be dispensed here. Currently, British Columbia is the only province that qualifies.

Prescriptions from Canada for Food and Drug Administration-approved legend drugs can be filled if written by one of the following practitioners licensed in Canada:

- ◆ physician licensed to practice medicine and surgery;
- ◆ physician licensed to practice osteopathic medicine and surgery;
- ◆ dentist licensed to practice dentistry;
- ◆ podiatric physician and surgeon licensed to practice podiatric medicine and surgery;
- ◆ veterinarian licensed to practice veterinary medicine. (RCW 69.41.030)

In addition, all state and applicable federal requirements for prescriptions must also be met.

Prescriptions for Schedule II through V medications cannot be filled in Washington if written in Canada.

Q. Where can I find information on practitioners' prescriptive authority?

You can find information on the Board of Pharmacy's Web site under the site directory titled "Prescribing Authority." The chart lists the professions that have prescribing authority and notes any restrictions or limitations. The relevant state laws and rules are also noted.

The list includes professions that can administer medications under a prescriber's order. The section on "General Limitations" contains information on prescribing, such as not prescribing controlled substances for yourself*, and which out-of-state practitioners you can accept prescriptions from, etc. Lastly, there is a section that lists professions whose scope does not allow prescribing, administering, or dispensing of medications.



A Community Pharmacy Technician's Role in Medication Reduction Strategies



This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and Food and Drug Administration (FDA) in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the recommendations for prevention of reported errors that you can put into practice today, subscribe to *ISMP Medication Safety Alert! Community/Ambulatory Edition* by visiting www.ismp.org. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800-23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 200 Lakeside Dr, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismptinfo@ismp.org.

Pharmacy technicians play a major role in community pharmacy practice. The pharmacist relies on the technician to provide an extra layer of safety. It is important for technicians to follow system-based processes and inform the pharmacist when these processes do not work or are unmanageable.

Prescription Drop Off

The date of birth should be written on every hard copy prescription so the pharmacist has a second identifier readily available during verification. Allergy information should be questioned and updated at every patient encounter. Medical condition information, such as pregnancy, communicated to the technician at drop off should be updated in the computerized profile system to help the verification pharmacist determine counseling opportunities. Knowing a person's medical conditions also helps the pharmacist determine if prescriptions are written incorrectly or for the wrong drug.

Data Entry

Medication safety is enhanced when technicians know the particular language of pharmacy when entering a prescription.

New drugs are at a particular risk because it is more likely that the technician is not aware of the new drug and a more familiar drug is selected. Pharmacists and technicians should work together to determine the best method of distributing information regarding availability of new drugs on the market.

It is important that the technician understands the safety features of the computer system and does not create work-arounds to improve efficiency at the risk of decreasing accuracy and safety. Drug alerts can be numerous, and the technician may be inclined to override the alert and not "bother" the pharmacist. A better way to resolve too many alerts would be to establish protocol between the technician and the pharmacist to determine which level and type of alert needs pharmacist intervention.

Production

Mix-ups occur primarily due to incorrectly reading the label. The problem is aggravated by what is referred to as *confirmation bias*. Often a technician chooses a medication container based on a mental picture of the item, whether it be a characteristic of the drug label, the shape and size or color of the container, or the location of the item on a shelf. Consequently the wrong product is picked. Physically separating drugs

with look-alike labels and packaging helps to reduce this contributing factor.

Point of Sale

Correctly filled prescriptions sold to a patient for whom it was not intended is an error that can be avoided by consistent use of a second identifier at the point of sale. Ask the person picking up the prescription to verify the address or in the case of similar names, the date of birth, and compare the answer to the information on the prescription receipt.

Internal errors should be discussed among all staff for training purposes. In addition, it is important to read about and discuss errors and methods of prevention occurring and being employed at other pharmacies within a chain and in other pharmacies, nationwide. ISMP Medication Safety Alert! Community/Ambulatory Edition offers this information to both pharmacists and technicians.

FDA's Effort to Remove Unapproved Drugs From the Market

Pharmacists are often not aware of the unapproved status of some drugs and have continued to unknowingly dispense unapproved drugs because the labeling does not disclose that they lack FDA approval. FDA estimates that there are several thousand unapproved drugs illegally marketed in the United States. FDA is stepping up its efforts to remove unapproved drugs from the market.

Background

There are three categories of unapproved drugs that are on the market. The first category consists of those that have been approved for safety, or that are identical, related, or similar to those drugs, and either have been found not to be effective, or for which FDA has not yet determined that they are effective. Between 1938 (passage of the Federal Food, Drug, and Cosmetic Act) and 1962, manufacturers were only required to demonstrate that drugs were safe; the requirement that they also demonstrate that drugs were effective was added in 1962. Drugs that fall in this category have been part of the DESI (Drug Efficacy Study Implementation) review, which was implemented to determine whether drugs approved between 1938 and 1962, or drugs that are identical, related, or similar to such drugs, met the new effectiveness requirements. While the DESI review is mostly completed, some parts of it are still continuing. The second category of unapproved drugs consists of those drugs that were on the market prior to 1938 (passage of the Federal Food, Drug, and Cosmetic Act). The third category, new unapproved drugs, comprises unapproved drugs that were first marketed (or changed) after 1962. Some also may have already been the subject of a formal agency finding that they are new drugs.

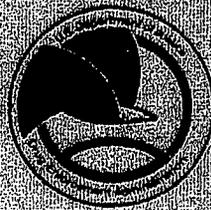
FDA's Concerns About Unapproved Drugs

FDA has serious concerns that drugs marketed without FDA approval may not meet modern standards for safety, effectiveness, manufacturing quality, labeling, and post-market surveillance. For example, FDA-approved drugs must demonstrate that their manufacturing processes can reliably produce drug products of expected identity, strength, quality, and purity. In addition, FDA's review of the applicant's labeling ensures that health care professionals and patients have the information necessary to understand a drug product's risks and its safety and efficacy.

Sponsors that market approved products are subject to more extensive reporting requirements for adverse drug events than sponsors of unapproved drugs. Reporting of adverse events by health care professionals and patients is voluntary, and under-reporting is well documented. FDA, therefore, cannot assume that an unapproved drug is safe or effective simply because it has been marketed for some period of time without reports of serious safety or effectiveness concerns.

Compliance News

(All News is a paid subscription service. All information is provided as a service to our subscribers.)



Enforcement Priorities

Manufacturers of unapproved drugs are usually fully aware that their drugs are marketed illegally, yet they continue to circumvent the law and put consumers' health at risk.

Most recently, in June 2006, FDA issued a guidance entitled "Marketed Unapproved Drugs—Compliance Policy Guide" (CPG) outlining its enforcement policies aimed at bringing all such drugs into the approval process. (The CPG is available at www.fda.gov/cder/guidance/691/final.pdf) The agency provided industry with specific notice that anyone who markets an unapproved drug is subject to enforcement action. This CPG outlines the agency's risk-based enforcement policies aimed at bringing all such drugs into the approval process without imposing undue burdens on consumers or unnecessarily disrupting the market. For all unapproved drugs, the CPG gives highest enforcement priority to the following:

- ◆ Drugs with potential safety concerns
- ◆ Drugs that lack evidence of effectiveness
- ◆ Fraudulent drugs
- ◆ Drugs with formulation changes made as a pretext to avoid enforcement
- ◆ Unapproved drugs that directly compete with an approved drug

Table 1 lists examples of drugs or classes of drugs that, consistent with the CPG, FDA has identified as a higher priority because of safety or other concerns. For six of them, FDA has specifically announced its intention to take enforcement action against companies marketing unapproved versions of those drug products. FDA has withdrawn the approval of the seventh product.

Table 1: Examples of FDA Actions Regarding Unapproved Drugs

Extended release combination drug products containing guaifenesin (competed with approved products)
Trimethobenzamide hydrochloride suppositories (lacked evidence of effectiveness)
Ergotamine-containing drug products (labeling did not include critical warnings regarding the potential for serious, possibly fatal interactions with other drugs)
Quinine sulfate drug products (665 reports of adverse events, including 93 deaths, and the labeling lacked necessary warnings and safe dosing information)
Carbinoxamine drug products (associated with 21 infant deaths)
Colchicine injectables (50 reports of adverse events, including 23 deaths)

Importance to Pharmacists

FDA is taking steps to ensure that all marketed US drugs have met approval requirements. FDA recognizes that some unapproved drugs may provide benefits; however, since these products have not undergone FDA review for safety and efficacy, the agency recommends that pharmacists, prescribers, and patients carefully consider the medical condition being treated, the patient's previous response to a drug, and the availability of approved alternatives for treatment. FDA will proceed on a case-by-case basis and make every effort to avoid adversely affecting public health, imposing undue burdens on health care professionals and patients, and unnecessarily disrupting the drug supply. More information regarding the FDA's Unapproved Drug Initiative can be found on its Web site: www.fda.gov/cder/drug/unapproved_drugs/.

NABP Educates Public on Buying from Internet Pharmacies with New Section on its Web site

On May 16, 2008, the National Association of Boards of Pharmacy® (NABP®) launched the Internet Pharmacies section of its Web site, educating patients on the potential dangers of buying medicine online and empowering them to make informed choices. As of mid-June, the site listed 250 Internet drug outlets that appear to be out of compliance with state and federal laws or NABP patient safety and pharmacy practice standards, thereby putting those who purchase from these sites in danger of purchasing drugs that could cause patients serious harm or even death.

NABP developed these standards for its new Internet Drug Outlet Identification program with input from its member boards of pharmacy, interested stakeholders, and regulatory agencies, including the FDA and the US Drug Enforcement Administration. Internet drug outlets operating in conflict with these criteria are listed on the NABP Web site as "not recommended." NABP has identified another 300 suspiciously operating Internet drug outlets and is in the process of verifying its findings before posting these sites to the "not recommended" list. Of the hundreds of sites reviewed under this program so far, only nine have been found to be potentially legitimate, pending verification of licensure and other criteria. At this time, NABP recommends that patients buying medicine online use only Internet pharmacies accredited through the VIPPS® (Verified Internet Pharmacy Practice Sites™) program. NABP has verified that these pharmacies are appropriately licensed and have successfully completed the well-recognized and rigorous VIPPS criteria evaluation and on-site inspection. These pharmacies, representing more than 12,000 pharmacies, are listed on the NABP Web site as "recommended."

These lists, along with program criteria and related patient information, are accessible in the Internet Pharmacies section of the NABP Web site.

The new program is an outgrowth of a 2007 NABP resolution, "Internet Pharmacy Public Safety Awareness," in which the Association pledges to continue collaborating with federal agencies and other interested stakeholders to educate the public and health care professionals of the dangers of acquiring drugs illegally through the Internet and from foreign sources. As part of this initiative, NABP will provide information to assist state and federal regulators in their efforts to shut down rogue Internet drug outlets.

RxPatrol Video Helps Pharmacists Address and Prevent Pharmacy Theft

Pharmacy theft is a serious crime that is on the rise, costing pharmacies billions annually in stolen medication according to the Federal Bureau of Investigation (FBI). RxPatrol® has teamed up with Crime Stoppers and other law enforcement officials to disseminate information regarding pharmacy crime. One resource that pharmacists can use to educate themselves and their coworkers is a training video that provides tips for pharmacists to address the rising issue of pharmacy robberies. The video includes interviews with law enforcement officials from the FBI and police department about what can be done to prevent such activity. The video can be found on the RxPatrol Web site at www.rxpatrol.com/videos.asp and by clicking on "Pharmacy Safety - Robbery."

RxPatrol is a collaborative effort between industry and law enforcement designed to collect, collate, analyze and disseminate pharmacy theft information. RxPatrol helps protect the pharmacy environment and ensure legitimate patients' access to life-sustaining medicines.

Continued from page 1

You may also link to other professions' Web sites by selecting "Profession Links (A-Z)" for the site directory.

*On February 28, 2008, the Medical Quality Assurance Commission (MQAC) adopted a policy regarding Self-Treatment or Treatment of Immediate Family Members. Visit the MQAC Web site for more information at <https://fortress.wa.gov/doh/hpqa1/hps5/Medical/default.htm>.

Q. When do ancillary personnel utilization plans need to be updated?

New or amended utilization plans must be submitted to the Board office for approval. The plans should be tailored specifically to the needs and practice situation of your individual pharmacy. *Sample Ancillary Personnel Utilization Plans* are available on our Web site through the "Forms/Applications" page under the "Forms" section. The pharmacy technician plan also includes a section on the requirements for approval of specialized functions. Visit <https://fortress.wa.gov/doh/hpqa1/HPS4/Pharmacy/forms.htm>.

No. 972 Treating Partners of Patients with Sexually Transmitted Diseases

Recently, the Board provided input to the MQAC on a special prescribing protocol for partners of patients with sexually transmitted chlamydia and gonorrhea. Adequate treatment of these sexually transmitted diseases has long been a difficult public health issue. A study by Dr Mathew Golden of Public Health Seattle and King County (PHSKC) demonstrated success with the use of the special prescribing protocol in treating partners. In the protocol, antibiotic treatment is provided by public health staff and pharmacies to partners through use of prepackaged "partner packs." The MQAC urges practitioners to use all reasonable efforts to ensure that appropriate information and advice is made available to the absent partner or partners. Absent partners are advised to seek a medical evaluation for sexually transmitted disease.

Contact your local Public Health clinic for more specific information on the special prescribing protocol. To view MQAC's policy, please visit its Web site at <https://fortress.wa.gov/doh/hpqa1/hps5/Medical/default.htm>.

No. 973 Are Your ADDDs Approved?

ADDDs are not extra-hyper druggists, but automated drug distribution devices. These devices may also be known as automated cabinets or automated dispensing systems. Used as drug storage devices in many health care settings, ADDDs provide access, security, and accountability in the use of medications. The use of all ADDDs must be approved by the Board and is restricted to those facilities listed in the rule. The rule also describes the responsibilities of the pharmacy and the facility. To request approval, pharmacies must send policies and procedures to the Board office for review. For more information, visit the Board's Web site at <https://fortress.wa.gov/doh/hpqa1/hps4/Pharmacy/default.htm> for the application form and applicable rules.

No. 974 Welcome New Board Member

Governor Chris Gregoire has appointed Albert Linggi to the Board of Pharmacy. Mr Linggi's four-year term began on March 10, 2008.

Mr Linggi is a graduate of the University of Washington. He has an executive masters in business administration from Fuqua

School of Business at Duke University. Mr Linggi has over 30 years of experience in the pharmaceutical industry. His positions include appointments as administrative director of pharmacy for St. Joseph, regional director for Franciscan Health Systems, and vice president for McKesson Corporate Business Development. We look forward to Al bringing his expertise and willingness to serve the people of Washington through his Board appointment.

No. 975 Fifty-year Certificates

We would like to acknowledge and congratulate the following pharmacists for 50 years of licensure in Washington State. The honorees were recognized at the Northwest Pharmacy Conference in June of this year. Harold E. Bennett, Seattle, WA; John A. Benson, Bellingham, WA; Elwin H. Blair, Bellevue, WA; Walter G. Davison, Port Angeles, WA; Ann C. Donnelly, Tucson, AZ; Ronald D. Gilbert, Portland, OR; Robert J. Grady, Whitefish, MT; Ralph N. Herbison, Spokane, WA; Donald L. Kelly, Wenatchee, WA; Michael D. Lyon, Prosser, WA; John S. McCluskey, Naches, WA; Laverne F. Moore, Pendleton, OR; Daniel J. Nault, Lynnwood, WA; Charles E. Nunn, Buckley, WA; Joan C. Skalabrin, Port Orchard, WA; Donald A. Stoebner, Anacortes, WA; James C. Wright, Gig Harbor, WA; Marvin L. Wheeler, Harrison, ID.

No. 976 Upcoming Board of Pharmacy Meetings

The Board of Pharmacy is encouraging all pharmacists to mark their calendars with the following meeting dates.

July 17, 2008	Turnwater
September 4, 2008	Yakima
October 30, 2008	Kent
December 11, 2008	Kent

Board meetings are open to the public and pharmacists and auxiliary staff are encouraged to attend. Pharmacists are able to earn up to three contact hours (0.3 CEUs) of continuing education credit each license renewal period for attending a Board meeting. While the meetings have a formal structure, there are often public comment periods for the agenda items. If you are interested in receiving the meeting agenda, please contact WSBOP@listserv.wa.gov. This is a great opportunity to help the profession progress.

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The Washington State Board of Pharmacy News is published by the Washington State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

Steven M. Saxe - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor
& Executive Editor

Larissa Doucette - Communications Manager

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NSF Fact Sheet on Fluoridation Chemicals

Introduction

This fact sheet provides information on the fluoride containing water treatment additives that NSF has tested and certified to NSF/ANSI Standard 60: Drinking Water Chemicals - Health Effects. According to the latest Association of State Drinking Water Administrators Survey on State Adoption of NSF/ANSI Standards 60 and 61, 45 states require that chemicals used in treating potable water must meet Standard 60 requirements. If you have questions on your state's requirements, or how the NSF/ANSI Standard 60 certified products are used in your state, you should contact your state's Drinking Water Administrator.

Water fluoridation is the practice of adjusting the fluoride content of drinking water. Fluoride is added to water for the public health benefit of preventing and reducing tooth decay and improving the health of the community. The U.S. Centers for Disease Control and Prevention is a reliable source of information on this important public health intervention. For more information please visit www.cdc.gov/fluoridation/.

NSF certifies three basic products in the fluoridation category:

1. Fluorosilicic Acid (aka Fluosilicic Acid or Hydrofluosilicic Acid).
2. Sodium Fluorosilicate (aka Sodium Silicofluoride).
3. Sodium Fluoride.

NSF Standard 60

Products used for drinking water treatment are evaluated to the criteria specified in NSF/ANSI Standard 60. This standard was developed by an NSF-led consortium, including the American Water Works Association (AWWA), the American Water Works Association Research Foundation (AWWARF), the Association of State Drinking Water Administrators (ASDWA), and the Conference of State Health and Environmental Managers (COSHEM). This group developed NSF/ANSI Standard 60, at the request of the US EPA Office of Water, in 1988. The NSF Joint Committee on Drinking Water Additives continues to review and maintain the standard annually. This committee consists of representatives from the original stakeholder groups as well as other regulatory, water utility and product manufacturer representatives.

Standard 60 was developed to establish minimum requirements for the control of potential adverse human health effects from products added directly to water during its treatment, storage and distribution. The standard requires a full formulation disclosure of each chemical ingredient in a product. It also requires a toxicology review to determine that the product is safe at its maximum use level and to evaluate potential contaminants in the product. The standard requires testing of the treatment chemical products, typically by dosing these in water at 10 times the maximum use level, so that trace levels of contaminants can be detected. A toxicology evaluation of test results is required to determine if any contaminant concentrations have the potential to cause adverse human health effects. The standard sets criteria for the establishment of single product allowable concentrations (SPAC) of each respective contaminant. For contaminants regulated by the U.S. EPA, this SPAC has a default level not to exceed ten-percent of the regulatory level to provide protection for the consumer in the unlikely event of multiple sources of the contaminant, unless a lower or higher number of sources can be specifically identified.

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NSF Certification

NSF also developed a testing and certification program for these products, so that individual U.S. states and waterworks facilities would have a mechanism to determine which products were appropriate for use. The certification program requires annual unannounced inspections of production and distribution facilities to ensure that the products are properly formulated, packaged, and transported with safe guards against potential contamination. NSF also requires annual testing and toxicological evaluation of each NSF Certified product. NSF Certified products have the NSF Mark, the maximum use level, lot number or date code and production location on the product packaging or documentation shipped with the product.

The use of this standard and the associated certification program have yielded benefits in ensuring that drinking water additives meet the health objectives that provide the basis for public health protection. NSF maintains listings of companies that manufacture and distribute treatment products at www.nsf.org. These listings are updated daily and list the products at their allowable maximum use levels. In recognition of the important safeguards that NSF Standard 60 provides to public drinking water supplies, 45 U.S. States and 10 Canadian Provinces and Territories require drinking water treatment chemicals to comply with the requirements of the standard.

Treatment products that are used for fluoridation are addressed in Section 7 of NSF/ANSI Standard 60. The products are allowed to be used up to concentrations that result in a maximum use level of 1.2 mg/L fluoride ion in water. The NSF standard requires that the treatment products added to drinking water, as well as any impurities in the products, are supported by toxicological evaluation. The following text explains the rationale for the allowable levels established in the standard for 1) fluoride, 2) silicate, and 3) other potential contaminants that may be associated with fluoridation chemicals.

Fluoride

NSF/ANSI Standard 60 requires, when available, that the US EPA regulated maximum contaminant level (MCL) be used to determine the acceptable level for a contaminant. The EPA MCL for fluoride ion in water is 4 mg/L. The NSF Standard 60 single product allowable concentration (SPAC) for fluoride ion in drinking water from NSF Certified treatment products is 1.2 mg/L, or less than one-third of the EPA's MCL. Based on this the allowable maximum use level (MUL) for the NSF Certified fluoridation products are:

1. Fluorosilicic Acid: 6 mg/L.
2. Sodium Fluorosilicate: 2 mg/L.
3. Sodium Fluoride: 2.3 mg/L.

Silicate

There is no EPA MCL for silicate in drinking water. When an MCL does not exist for a contaminant, NSF/ANSI Standard 60 provides criteria to conduct a toxicological risk assessment of the contaminant and the development of a SPAC. NSF has established a SPAC for silicate at 16 mg/L. A fluorosilicate product, applied at its maximum use level, results in silicate drinking water levels that are substantially below the 16 mg/L SPAC established by NSF. For example, a sodium fluorosilicate product dosed at a concentration into drinking water that would provide the maximum concentration of fluoride allowed (1.2mg/L) would only contribute 0.8 mg/L of silicate – or 5 percent of the SPAC allowed by NSF 60.

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Potential Contaminants

The NSF toxicology review for a chemical product considers all chemical ingredients in the product as well as the manufacturing process, processing aids, and other factors that have an impact on the contaminants present in the finished drinking water. This formulation review identifies all the contaminants that need to be analyzed in testing the product. For example, fluosilicic acid is produced by adding sulfuric acid to phosphate ore. This is typically done during the production of phosphate additives for agricultural fertilizers. The manufacturing process is documented by an NSF inspector at an initial audit of the manufacturing site and during each annual unannounced inspection of the facility. The manufacturing process, ingredients, and potential contaminants are reviewed annually by NSF toxicologists, and the product is tested for any potential contaminants. A minimum test battery for all fluoridation products includes metals of toxicological concern and radionuclides.

Many drinking water treatment additives, including fluoridation products, are transported in bulk via tanker trucks to terminals where they are transferred to rail cars, shipped to distant locations or transferred into tanker trucks, and then delivered to the water treatment plants. These tanker trucks, transfer terminals and rail cars are potential sources of contamination. Therefore, NSF also inspects, samples, tests, and certifies products at rail transfer and storage depots. It is always important to verify that the location of the product distributor (the company that delivers the product to the water utility) matches that in the official NSF Listing for the product (available at www.nsf.org).

NSF has compiled data on the level of contaminants found in all fluoridation products that have applied for, or have been listed by, NSF. The statistical results in Table 1 (attached) include the test results for these products, as well as the annual monitoring tests from the period 2000 to 2006. This includes 245 separate samples analyzed during this time period. The concentrations reported represent contaminant levels that would be expected when the product is dosed into water at the Maximum Use Level (MUL). Lower product doses would produce proportionately lower contaminant concentrations (e.g. a 0.6 mg/L fluoride dose would produce one half the contaminant concentrations listed in Table 1.)

Table 1 documents that there is no contamination of drinking water from the fluoridation products NSF has tested and certified. NSF issued previous summaries of contaminant levels in fluoridation products for earlier reporting periods in 1999 and 2003. While some contaminant levels in those earlier periods were slightly higher than the current data for certain contaminants, there has not been a single fluoride product tested since the initiation of the program in 1988 with a contaminant concentration in excess of its corresponding SPAC. The documented reduction of impurities for this most current time period is due, at least in part, to the effectiveness of NSF/ANSI Standard 60 and the NSF certification program for drinking water treatment additives, and demonstrates the effectiveness of the program. The reduction in impurities is further attested to by an article in the Journal of the American Water Works Association entitled, "Trace Contaminants in Water Treatment Chemicals."¹

Arsenic

The results in Table 1 indicate that the most common contaminant detected in these products is arsenic, but it is detected in only 43% of the product samples. This means that levels of arsenic

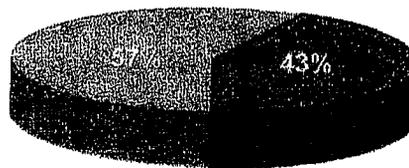
¹ Brown, R., et al., "Trace Contaminants in Water Treatment Chemicals: Sources and Fate." Journal of the American Water Works Association 2004; 96:12:111.

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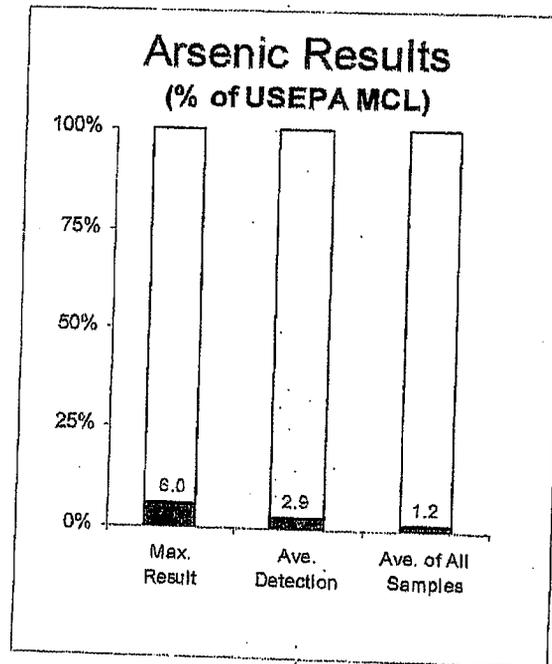
in 57% of the samples were non-detectable, even though products are tested at 10 times their maximum use level. All detections were at levels below the Single Product Allowable Concentration, if the product is added to drinking water at (or below) its maximum use level. The SPAC, as defined in NSF/ANSI Standard 60, is one tenth of the US EPA's MCL. The current MCL for arsenic is 10 ppb, the highest detection of arsenic from a fluoridation chemical was 0.6 ppb (shown on Table 1), and the average concentration was 0.12 ppb. Even the highest concentration of 0.6 ppb was only detected because the standard requires testing the chemical at 10 times its maximum use level to detect these trace levels of contaminants. Had the dose of fluoridation additives been tested in water at the maximum use level, instead of at 10 times their maximum use levels, the arsenic concentration measured would have been below the 1 ppb reporting limit for arsenic for 100 percent of the samples measured.

Figure A

57% of Fluoride products do not contain measurable amounts of Arsenic.



43% of Fluoride products contain measurable Arsenic, but the highest level recorded was only 6% of the USEPA MCL.

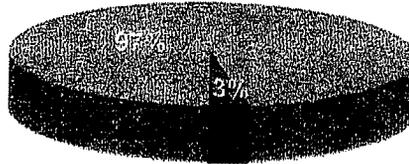


Copper

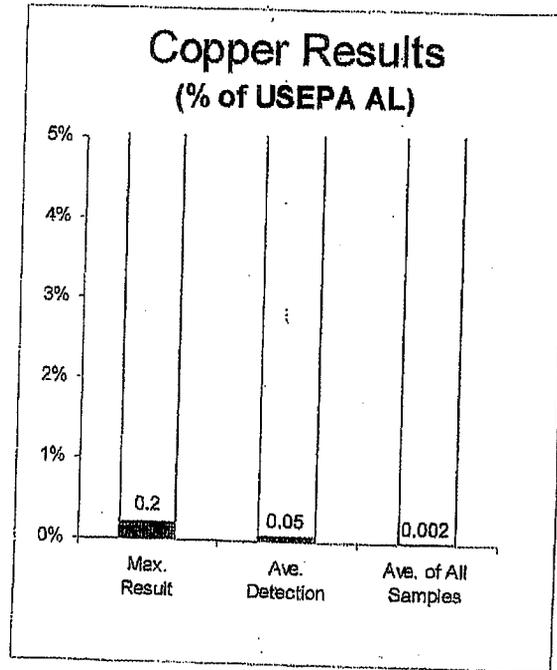
The second most common contaminant found, and on a much less frequent basis, is copper, and 97% of all samples tested had no detectable levels of copper. The average concentration of copper has been 0.02 ppb with 2.6 ppb being the highest concentration detected. This is well below the 130 ppb SPAC requirement of NSF 60.

Figure B

97% of Fluoride products do not contain measurable amounts of Copper.



3% of Fluoride products contain measurable Copper, but the highest level recorded was only 0.2% of the USEPA Action Level.



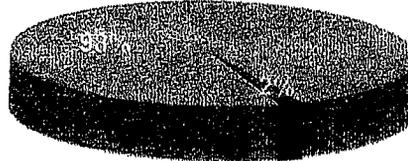
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Lead

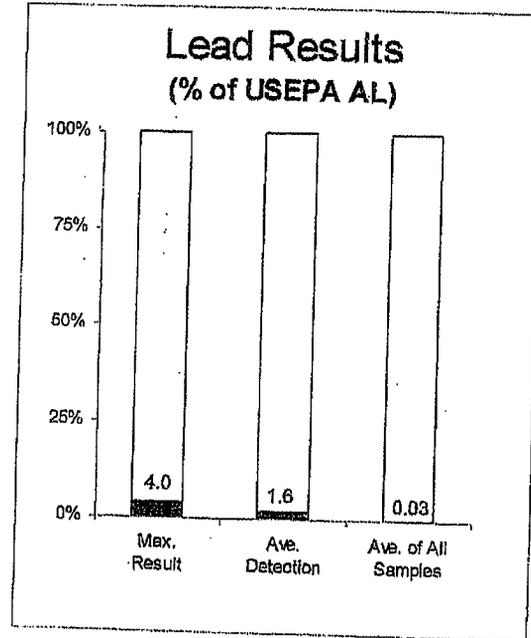
The third most common contaminant found is lead. It occurs on a much less frequent basis, and 98% of all samples tested had no detectable levels of lead. The average concentration of lead has been 0.005 ppb with 0.6 ppb being the highest concentration detected. This is well below the 1.5 ppb SPAC requirement of NSF 60.

Figure C

98% of Fluoride products do not contain measurable amounts of Lead.



2% of Fluoride products contain measurable Lead, but the highest level recorded was only 4% of the USEPA Action Level of 15ppb.



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Radionuclides

Fluoridation products are also tested for radionuclides. All samples tested have not had any detectable levels of alpha or beta radiation.

Summary

In summary, the majority of fluoridation products as a class, based on NSF test results, do not add measurable amounts of arsenic, lead, other heavy metals, or radionuclide contamination to drinking water.

Additional information on fluoridation of drinking water can be found on the following web sites:

American Water Works Association (AWWA) Fluoridation Chemical Standards

<http://www.awwa.org/Bookstore/producttopicsresults.cfm?MetaDataID=121&navItemNumber=5093>

American Water Works Association (AWWA) position

<http://www.awwa.org/Advocacy/pressroom/fluoride.cfm>

American Dental Association (ADA) <http://www.ada.org/public/topics/fluoride/index.asp>

U.S. Centers for Disease Control and Prevention (CDC) <http://www.cdc.gov/fluoridation>

Table 1

	Percentage of Samples with Detectable Levels	Mean Contaminant Concentration in all samples (ppb)	Mean Contaminant Concentration in detectable samples (ppb)	Maximum Contaminant Concentration in detectable samples (ppb)	NSF/ANSI Standard 60 Single Product Allowable Concentration	US EPA Maximum Contaminant or Action Level
Antimony	0%	ND	ND	ND	0.6	6
Arsenic	43%	0.12	0.29	0.6	1	10
Barium	<1%	0.001	0.3	0.3	200	2000
Beryllium	0%	ND	ND	ND	0.4	4
Cadmium	1%	0.001	0.08	0.12	0.5	5
Chromium	<1%	0.001	0.15	0.2	10	100
Copper	3%	0.02	0.68	2.6	130	1300
Lead	2%	0.005	0.24	0.6	1.5	15
Mercury	<1%	0.0002	0.04	0.04	0.2	2
Radionuclides - alpha pCi/L	0%	ND	ND	ND	1.5	15
Radionuclides - beta mrem/yr	0%	ND	ND	ND	0.4	4
Selenium	<1%	0.016	1.95	3.2	5	50
Thallium	<1%	0.0003	0.04	0.06	0.2	2

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Abbreviations used in this Fact Sheet

ANSI – American National Standards Institute

AWWA – American Water Works Association

AWWARF – American Water Works Association Research Foundation

ASDWA – Association of State Drinking Water Administrators

COSHEM – Conference of State Health and Environmental Managers

EPA – U.S. Environmental Protection Agency

MCL – maximum contaminant level

mrem/yr – millirems per year – measurement of radiation exposure dose

MUL – Maximum use level

NSF – NSF International (formerly the National Sanitation Foundation)

ppb – parts per billion

PCi/L – pico curies per liter – concentration of radioactivity

SPAC – Single Product Allowable Concentration

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9, 141 and 142

[WH-FRL-6934-9]

RIN 2040-AB75

National Primary Drinking Water Regulations; Arsenic and
Clarifications to Compliance and New Source Contaminants Monitoring

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Today EPA is establishing a health-based, non-enforceable Maximum Contaminant Level Goal (MCLG) for arsenic of zero and an enforceable Maximum Contaminant Level (MCL) for arsenic of 0.01 mg/L (10 µg/L). This regulation will apply to non-transient non-community water systems, which are not presently subject to standards on arsenic in drinking water, and to community water systems.

In addition, EPA is publishing clarifications for monitoring and demonstration of compliance for new systems or sources of drinking water. The Agency is also clarifying compliance for State-determined monitoring after exceedances for inorganic, volatile organic, and synthetic organic contaminants. Finally, EPA is recognizing the State-specified time period and sampling frequency for new public water systems and systems using a new source of water to demonstrate compliance with drinking water regulations. The requirement for new systems and new source monitoring will be effective for inorganic, volatile organic, and synthetic organic contaminants.

DATES: This rule is effective March 23, 2001, except for the amendments to Secs. 141.23(i)(1), 141.23(i)(2), 141.24(f)(15), 141.24(h)(11), 141.24(h)(20), 142.16(e), 142.16(j), and 142.16(k) which are effective January 22, 2004.

The compliance date for requirements related to the clarification for monitoring and compliance under Secs. 141.23(i)(1), 141.23(i)(2), 141.24(f)(15), 141.24(f)(22), 141.24(h)(11), 141.24(h)(20), 142.16(e), 142.16(j), and 142.16(k) is January 22, 2004. The compliance date for requirements related to the revised arsenic standard under Secs. 141.23(i)(4), 141.23(k)(3), 141.23(k)(3)(ii), 141.51(b), 141.62(b), 141.62(b)(16), 141.62(c), 141.62(d), and 142.62(b) is January 23, 2006. For purposes of judicial review, this rule is promulgated as of January 22, 2001.

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**FLUORIDE IN DRINKING WATER:
A Scientific Review of EPA's Standards**

Committee on Fluoride in Drinking Water
Board on Environmental Studies and Toxicology
Division on Earth and Life Studies

NATIONAL RESEARCH COUNCIL
OF THE NATIONAL ACADEMIES

THE NATIONAL ACADEMIES PRESS
Washington, D.C.
www.nap.edu

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Summary

Under the Safe Drinking Water Act, the U.S. Environmental Protection Agency (EPA) is required to establish exposure standards for contaminants in public drinking-water systems that might cause any adverse effects on human health. These standards include the maximum contaminant level goal (MCLG), the maximum contaminant level (MCL), and the secondary maximum contaminant level (SMCL). The MCLG is a health goal set at a concentration at which no adverse health effects are expected to occur and the margins of safety are judged "adequate." The MCL is the enforceable standard that is set as close to the MCLG as possible, taking into consideration other factors, such as treatment technology and costs. For some contaminants, EPA also establishes an SMCL, which is a guideline for managing drinking water for aesthetic, cosmetic, or technical effects.

Fluoride is one of the drinking water contaminants regulated by EPA. In 1986, EPA established an MCLG and MCL for fluoride at a concentration of 4 milligrams per liter (mg/L) and an SMCL of 2 mg/L. These guidelines are restrictions on the total amount of fluoride allowed in drinking water. Because fluoride is well known for its use in the prevention of dental caries, it is important to make the distinction here that EPA's drinking-water guidelines are not recommendations about adding fluoride to drinking water to protect the public from dental caries. Guidelines for that purpose (0.7 to 1.2 mg/L) were established by the U.S. Public Health Service more than 40 years ago. Instead, EPA's guidelines are maximum allowable concentrations in drinking water intended to prevent toxic or other adverse effects that could result from exposure to fluoride.

In the early 1990s at the request of EPA, the National Research Council (NRC) independently reviewed the health effects of ingested fluoride and the scientific basis for EPA's MCL. It concluded that the MCL was an appropriate interim standard but that further research was needed to fill data gaps on total exposure to fluoride and its toxicity. Because new research on fluoride is now available and because the Safe Drinking Water Act requires periodic reassessment of regulations for drinking-water contaminants, EPA requested that the NRC again evaluate the adequacy of its MCLG and SMCL for fluoride to protect public health.

COMMITTEE'S TASK

In response to EPA's request, the NRC convened the Committee on Fluoride in Drinking Water, which prepared this report. The committee was charged to review toxicologic,

epidemiologic, and clinical data on fluoride—particularly data published since the NRC's previous (1993) report—and exposure data on orally ingested fluoride from drinking water and other sources. On the basis of its review, the committee was asked to evaluate independently the scientific basis of EPA's MCLG of 4 mg/L and SMCL of 2 mg/L in drinking water and the adequacy of those guidelines to protect children and others from adverse health effects. The committee was asked to consider the relative contribution of various fluoride sources (e.g., drinking water, food, dental-hygiene products) to total exposure. The committee was also asked to identify data gaps and to make recommendations for future research relevant to setting the MCLG and SMCL for fluoride. Addressing questions of artificial fluoridation, economics, risk-benefit assessment, and water-treatment technology was not part of the committee's charge.

THE COMMITTEE'S EVALUATION

To accomplish its task, the committee reviewed a large body of research on fluoride, focusing primarily on studies generated since the early 1990s, including information on exposure; pharmacokinetics; adverse effects on various organ systems; and genotoxic and carcinogenic potential. The collective evidence from *in vitro* assays, animal research, human studies, and mechanistic information was used to assess whether multiple lines of evidence indicate human health risks. The committee only considered adverse effects that might result from exposure to fluoride; it did not evaluate health risk from lack of exposure to fluoride or fluoride's efficacy in preventing dental caries.

After reviewing the collective evidence, including studies conducted since the early 1990s, the committee concluded unanimously that the present MCLG of 4 mg/L for fluoride should be lowered. Exposure at the MCLG clearly puts children at risk of developing severe enamel fluorosis, a condition that is associated with enamel loss and pitting. In addition, the majority of the committee concluded that the MCLG is not likely to be protective against bone fractures. The basis for these conclusions is expanded upon below.

Exposure to Fluoride

The major sources of exposure to fluoride are drinking water, food, dental products, and pesticides. The biggest contributor to exposure for most people in the United States is drinking water. Estimates from 1992 indicate that approximately 1.4 million people in the United States had drinking water with natural fluoride concentrations of 2.0 to 3.9 mg/L, and just over 200,000 people had concentrations equal to or exceeding 4 mg/L (the presented MCL). In 2000, it was estimated that approximately 162 million people had artificially fluoridated water (0.7 to 1.2 mg/L).

Food sources contain various concentrations of fluoride and are the second largest contributor to exposure. Beverages contribute most to estimated fluoride intake, even when excluding contributions from local tap water. The greatest source of nondietary fluoride is dental products, primarily toothpastes. The public is also exposed to fluoride from background air and from certain pesticide residues. Other sources include certain pharmaceuticals and consumer products.

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Highly exposed subpopulations include individuals who have high concentrations of fluoride in drinking water, who drink unusually large volumes of water, or who are exposed to other important sources of fluoride. Some subpopulations consume much greater quantities of water than the 2 L per day that EPA assumes for adults, including outdoor workers, athletes, and people with certain medical conditions, such as diabetes insipidus. On a per-body-weight basis, infants and young children have approximately three to four times greater exposure than do adults. Dental-care products are also a special consideration for children, because many tend to use more toothpaste than is advised, their swallowing control is not as well developed as that of adults, and many children under the care of a dentist undergo fluoride treatments.

Overall, the committee found that the contribution to total fluoride exposure from fluoride in drinking water in the average person, depending on age, is 57% to 90% at 2 mg/L and 72% to 94% at 4 mg/L. For high-water-intake individuals, the drinking-water contribution is 86% to 96% at 2 mg/L and 92% to 98% at 4 mg/L. Among individuals with an average water-intake rate, infants and children have the greatest total exposure to fluoride, ranging from 0.079 to 0.258 mg/kg/day at 4 mg/L and 0.046 to 0.144 mg/kg/day at 2 mg/L in drinking water. For high-water-intake individuals exposed to fluoride at 4 mg/L, total exposure ranges from 0.294 mg/kg/day for adults to 0.634 mg/kg/day for children. The corresponding intake range at 2 mg/L is 0.154 to 0.334 mg/kg/day for adults and children, respectively.

Dental Effects

Enamel fluorosis is a dose-related mottling of enamel that can range from mild discoloration of the tooth surface to severe staining and pitting. The condition is permanent after it develops in children during tooth formation, a period ranging from birth until about the age of 8. Whether to consider enamel fluorosis, particularly the moderate to severe forms, to be an adverse health effect or a cosmetic effect has been the subject of debate for decades. In previous assessments, all forms of enamel fluorosis, including the severest form, have been judged to be aesthetically displeasing but not adverse to health. This view has been based largely on the absence of direct evidence that severe enamel fluorosis results in tooth loss; loss of tooth function; or psychological, behavioral, or social problems.

Severe enamel fluorosis is characterized by dark yellow to brown staining and discrete and confluent pitting, which constitutes enamel loss. The committee finds the rationale for considering severe enamel fluorosis only a cosmetic effect to be much weaker for discrete and confluent pitting than for staining. One of the functions of tooth enamel is to protect the dentin and, ultimately, the pulp from decay and infection. Severe enamel fluorosis compromises that health-protective function by causing structural damage to the tooth. The damage to teeth caused by severe enamel fluorosis is a toxic effect that is consistent with prevailing risk assessment definitions of adverse health effects. This view is supported by the clinical practice of filling enamel pits in patients with severe enamel fluorosis and restoring the affected teeth. Moreover, the plausible hypothesis concerning elevated frequency of caries in persons with severe enamel fluorosis has been accepted by some authorities, and the available evidence is mixed but generally supportive.

Severe enamel fluorosis occurs at an appreciable frequency, approximately 10% on average, among children in U.S. communities with water fluoride concentrations at or near the current MCLG of 4 mg/L. Thus, the MCLG is not adequately protective against this condition.

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Two of the 12 members of the committee did not agree that severe enamel fluorosis should now be considered an adverse health effect. They agreed that it is an adverse dental effect but found that no new evidence has emerged to suggest a link between severe enamel fluorosis, as experienced in the United States, and a person's ability to function. They judged that demonstration of enamel defects alone from fluorosis is not sufficient to change the prevailing opinion that severe enamel fluorosis is an adverse cosmetic effect. Despite their disagreement on characterization of the condition, these two members concurred with the committee's conclusion that the MCLG should prevent the occurrence of this unwanted condition.

Enamel fluorosis is also of concern from an aesthetic standpoint because it discolors or results in staining of teeth. No data indicate that staining alone affects tooth function or susceptibility to caries, but a few studies have shown that tooth mottling affects aesthetic perception of facial attractiveness. It is difficult to draw conclusions from these studies, largely because perception of the condition and facial attractiveness are subjective and culturally influenced. The committee finds that it is reasonable to assume that some individuals will find *moderate* enamel fluorosis on front teeth to be detrimental to their appearance and that it could affect their overall sense of well-being. However, the available data are not adequate to categorize moderate enamel fluorosis as an adverse health effect on the basis of structural or psychological effects.

Since 1993, there have been no new studies of enamel fluorosis in U.S. communities with fluoride at 2 mg/L in drinking water. Earlier studies indicated that the prevalence of moderate enamel fluorosis at that concentration could be as high as 15%. Because enamel fluorosis has different distribution patterns among teeth, depending on when exposure occurred during tooth development and on enamel thickness, and because current indexes for categorizing enamel fluorosis do not differentiate between mottling of anterior and posterior teeth, the committee was not able to determine what percentage of moderate cases might be of cosmetic concern.

Musculoskeletal Effects

Concerns about fluoride's effects on the musculoskeletal system historically have been and continue to be focused on skeletal fluorosis and bone fracture. Fluoride is readily incorporated into the crystalline structure of bone and will accumulate over time. Since the previous 1993 NRC review of fluoride, two pharmacokinetic models were developed to predict bone concentrations from chronic exposure to fluoride. Predictions based on these models were used in the committee's assessments below.

Skeletal Fluorosis

Skeletal fluorosis is a bone and joint condition associated with prolonged exposure to high concentrations of fluoride. Fluoride increases bone density and appears to exacerbate the growth of osteophytes present in the bone and joints, resulting in joint stiffness and pain. The condition is categorized into one of four stages: a preclinical stage and three clinical stages that increase in severity. The most severe stage (clinical stage III) historically has been referred to as the "crippling" stage. At stage II, mobility is not significantly affected, but it is characterized by

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sporadic pain, stiffness of joints, and osteosclerosis of the pelvis and spine. Whether EPA's MCLG of 4 mg/L protects against these precursors to more serious mobility problems is unclear.

Few clinical cases of skeletal fluorosis in healthy U.S. populations have been reported in recent decades, and the committee did not find any recent studies to evaluate the prevalence of the condition in populations exposed to fluoride at the MCLG. Thus, to answer the question of whether EPA's MCLG protects the general public from stage II and stage III skeletal fluorosis, the committee compared pharmacokinetic model predictions of bone fluoride concentrations and historical data on iliac-crest bone fluoride concentrations associated with the different stages of skeletal fluorosis. The models estimated that bone fluoride concentrations resulting from lifetime exposure to fluoride in drinking water at 2 mg/L (4,000 to 5,000 mg/kg ash) or 4 mg/L (10,000 to 12,000 mg/kg ash) fall within or exceed the ranges historically associated with stage II and stage III skeletal fluorosis (4,300 to 9,200 mg/kg ash and 4,200 to 12,700 mg/kg ash, respectively). However, this comparison alone is insufficient for determining whether stage II or III skeletal fluorosis is a risk for populations exposed to fluoride at 4 mg/L, because bone fluoride concentrations and the levels at which skeletal fluorosis occurs vary widely. On the basis of the existing epidemiologic literature, stage III skeletal fluorosis appears to be a rare condition in the United States; furthermore, the committee could not determine whether stage II skeletal fluorosis is occurring in U.S. residents who drink water with fluoride at 4 mg/L. Thus, more research is needed to clarify the relationship between fluoride ingestion, fluoride concentrations in bone, and stage of skeletal fluorosis before any conclusions can be drawn.

Bone Fractures

Several epidemiologic studies of fluoride and bone fractures have been published since the 1993 NRC review. The committee focused its review on observational studies of populations exposed to drinking water containing fluoride at 2 to 4 mg/L or greater and on clinical trials of fluoride (20-34 mg/day) as a treatment for osteoporosis. Several strong observational studies indicated an increased risk of bone fracture in populations exposed to fluoride at 4 mg/L, and the results of other studies were qualitatively consistent with that finding. The one study using serum fluoride concentrations found no appreciable relationship to fractures. Because serum fluoride concentrations may not be a good measure of bone fluoride concentrations or long-term exposure, the ability to show an association might have been diminished in that study. A meta-analysis of randomized clinical trials reported an elevated risk of new nonvertebral fractures and a slightly decreased risk of vertebral fractures after 4 years of fluoride treatment. An increased risk of bone fracture was found among a subset of the trials that the committee found most informative for assessing long-term exposure. Although the duration and concentrations of exposure to fluoride differed between the observational studies and the clinical trials, bone fluoride content was similar (6,200 to more than 11,000 mg/kg ash in observational studies and 5,400 to 12,000 mg/kg ash in clinical trials).

Fracture risk and bone strength have been studied in animal models. The weight of evidence indicates that, although fluoride might increase bone volume, there is less strength per unit volume. Studies of rats indicate that bone strength begins to decline when fluoride in bone ash reaches 6,000 to 7,000 mg/kg. However, more research is needed to address uncertainties associated with extrapolating data on bone strength and fractures from animals to humans. Important species differences in fluoride uptake, bone remodeling, and growth must be

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considered. Biochemical and physiological data indicate a biologically plausible mechanism by which fluoride could weaken bone. In this case, the physiological effect of fluoride on bone quality and risk of fracture observed in animal studies is consistent with the human evidence.

Overall, there was consensus among the committee that there is scientific evidence that under certain conditions fluoride can weaken bone and increase the risk of fractures. The majority of the committee concluded that lifetime exposure to fluoride at drinking-water concentrations of 4 mg/L or higher is likely to increase fracture rates in the population, compared with exposure to 1 mg/L, particularly in some demographic subgroups that are prone to accumulate fluoride into their bones (e.g., people with renal disease). However, three of the 12 members judged that the evidence only supports a conclusion that the MCLG *might not* be protective against bone fracture. Those members judged that more evidence is needed to conclude that bone fractures occur at an appreciable frequency in human populations exposed to fluoride at 4 mg/L and that the MCLG is not *likely* to be protective.

There were few studies to assess fracture risk in populations exposed to fluoride at 2 mg/L in drinking water. The best available study, from Finland, suggested an increased rate of hip fracture in populations exposed to fluoride at concentrations above 1.5 mg/L. However, this study alone is not sufficient to judge fracture risk for people exposed to fluoride at 2 mg/L. Thus, no conclusions could be drawn about fracture risk or safety at 2 mg/L.

Reproductive and Developmental Effects

A large number of reproductive and developmental studies in animals have been conducted and published since the 1993 NRC report, and the overall quality of that database has improved significantly. Those studies indicated that adverse reproductive and developmental outcomes occur only at very high concentrations that are unlikely to be encountered by U.S. populations. A few human studies suggested that high concentrations of fluoride exposure might be associated with alterations in reproductive hormones, effects on fertility, and developmental outcomes, but design limitations make those studies insufficient for risk evaluation.

Neurotoxicity and Neurobehavioral Effects

Animal studies designed to test motor coordination, performance of species-typical behaviors, and some forms of learning and memory have reported deficits in performance related to fluoride exposure. A few epidemiologic studies of Chinese populations have reported IQ deficits in children exposed to fluoride at 2.5 to 4 mg/L in drinking water. Although the studies lacked sufficient detail for the committee to fully assess their quality and relevance to U.S. populations, the consistency of the results appears significant enough to warrant additional research on the effects of fluoride on intelligence.

A few animal studies have reported alterations in the behavior of rodents after treatment with fluoride, but the committee did not find the changes to be substantial in magnitude. More compelling were studies on molecular, cellular, and anatomical changes in the nervous system found after fluoride exposure, suggesting that functional changes could occur. These changes might be subtle or seen only under certain physiological or environmental conditions. More research is needed to clarify the effect of fluoride on brain chemistry and function.

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EPA Union: "We hold that Fluoridation is an Unreasonable Risk"

The following is a letter from Dr. J. William Hirzy, Senior Vice President of the EPA's Headquarters Union (NTEU Chapter 280) in Washington D.C. The letter is addressed to Ted Crawford, of the Bennington Citizens Against Fluoridated Water. To read Dr. Hirzy's recent testimony to the US Senate, where he announced the Union's request for a "national moratorium on fluoridation" (June 29, 2000) visit: www.fluoridealert.org/testimony.htm

March 26, 2001

Dear Ted,

I understand that you have a meeting coming up at which you want to report on our union's position with respect to water fluoridation. Here is the latest word from us.

Our union comprises and represents the toxicologists, chemists, biologists, engineers and other professional employees at the Headquarters location of the U.S. Environmental Protection Agency in Washington, D.C. The Agency's position on fluoride may not correspond to the one that we professionals have taken. We have done our own homework on this matter and have reached our own conclusions.

As you know, our union first voted in 1997 on legislation relating to fluoridation, when we endorsed a Citizens For Safe Drinking Water initiative in California to prohibit the addition of fluoride to that State's water supplies. Our opposition to fluoridation has grown stronger in the three years since that first action because of the accumulation of research reports that ever more clearly show: 1) that fluoridation of drinking water does not reduce dental caries rates; and 2) the hazards associated with ingestion of fluoride, especially fluoride derived from hydrofluosilicic acid or its sodium salt (a.k.a. silicofluorides, SiF).

There are two specific and compelling concerns related to the use of SiF. First, use of SiF in fluoridation systems in the United States has been identified as a factor related to increased risk of elevated blood-lead levels in children (1,2). Second, SiF contributes significant amounts of arsenic to the water supplies to which it is added. The importance of this is that the U.S. Environmental Protection Agency (EPA) has established a (non-enforceable) Maximum Contaminant Level Goal for arsenic of zero, meaning that as a health protection measure, drinking water ought not to contain any arsenic whatsoever. Recently, EPA reported (3) that the National Academy of Sciences recommended that EPA should lower its enforceable Maximum Contaminant Level (MCL) for arsenic from 50 parts per billion (ppb) to possibly as low as 3 ppb as a cancer preventative measure; EPA then proposed an MCL of 5 ppb, finally setting it at 10 ppb for political reasons. Recent action by Administrator Whitman has suspended that proposal.

SiF may add ca. 0.5 ppb arsenic to water. Arsenic is known to cause cancer in humans.

The alternative to SiF as a fluoridating agent, sodium fluoride, has been shown to cause changes in the brain structure of test animals at the level used in fluoridation, i.e. at 1 part per million fluoride ion (4). Two other studies (5,6) demonstrate the neurotoxicity of sodium fluoride, including the induction of permanent hyperactivity in test animals exposed to fluoride before birth.

While promoters of fluoridation continue to cite decades-old studies purporting to show huge benefits of fluoridation, e.g. (7), they pointedly ignore the more recent and better conducted work that indicates little or no benefit derives from ingestion of fluoride, e.g. (8,9). Even the Centers for Disease Control, long an avid fluoridation promoting agency of the federal government, now admits that any benefits from fluoride are primarily topical.

While the factors I cite above are important ones, our opposition to fluoridation is based on other aspects of the practice as well, and these are summarized in our position paper of May 1, 1999. This paper can be accessed on the union website at www.nfeu280.org.

In summary, we hold that fluoridation is an unreasonable risk. That is, the toxicity of fluoride is so great and the purported benefits associated with it are so small - if there are any at all - that requiring every man, woman and child in America to ingest it borders on criminal behavior on the part of governments.

Please feel free to use this message as you see fit to help your government officials better understand this important public health issue.

J. William Hirzy, Ph.D.
Senior Vice-President
NTEU Chapter 280

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 21 2000

The Honorable Ken Calvert
Chairman
Subcommittee on Energy and Environment
Committee on Science
House of Representatives
Washington, D.C. 20515-6301

Dear Mr. Chairman:

Thank you for the letter of May 8, 2000, to Dr. Jane E. Henney, Commissioner of Food and Drugs, regarding the use of fluoride in drinking water and drug products. We apologize for the delay in responding to you.

We have restated each of your questions, followed by our response.

- 1. If health claims are made for fluoride-containing products (e.g. that they reduce dental caries incidence or reduce pathology from osteoporosis), do such claims mandate that the fluoride-containing product be considered a drug, and thus subject the product to applicable regulatory controls?**

Fluoride, when used in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animal, is a drug that is subject to Food and Drug Administration (FDA) regulation. FDA published a final rule on October 6, 1995, for anticaries drug products for over-the-counter (OTC) human use (copy enclosed). This rule establishes the conditions under which OTC anticaries drug products are generally recognized as safe and effective and not misbranded. The rule has provisions for active ingredients, packaging conditions, labeling, and testing procedures that are required by manufacturers in order to market anticaries products. A new drug application (NDA) may be filed for a product containing fluoride that does not meet the provisions stated in the final rule. As you know, the Environmental Protection Agency regulates fluoride in the water supply.

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2. Are there any New Drug Applications (NDA) on file, that have been approved, or that have been rejected, that involve a fluoride-containing product (including fluoride-containing vitamin products) intended for ingestion with the stated aim of reducing dental caries? If any such NDA's have been rejected, on what grounds were they rejected? If any such NDA have been approved, please provide the data on safety and efficacy that FDA found persuasive.

No NDAs have been approved or rejected for fluoride drugs meant for ingestion. Several NDAs have been approved for fluoride topical products such as dentifrices and gels. Fluoride products in the form of liquid and tablets meant for ingestion were in use prior to enactment of the Kefauver-Harris Amendments (Drug Amendments of 1962) to the Food, Drug, and Cosmetic Act in which efficacy became a requirement, in addition to safety, for drugs marketed in the United States (U.S.). Drugs in use prior to 1962 are being reviewed under a process known as the drug efficacy study implementation (DESI). The DESI review of fluoride-containing products has not been completed.

3. Does FDA consider dental fluorosis a sign of over exposure to fluoride?

Dental fluorosis is indicative of greater than optimal ingestion of fluoride. In 1988, the U.S. Surgeon General reported that dental fluorosis, while not a desirable condition, should be considered a cosmetic effect rather than an adverse health effect. Surgeon General M. Joycelyn Elders reaffirmed this position in 1994.

4. Does FDA have any action-level or other regulatory restriction or policy statement on fluoride exposure aimed at minimizing chronic toxicity in adults or children?

The monograph for OTC anticaries drug products sets acceptable concentrations for fluoride dentifrices, gels and rinses (all for topical use only). This monograph also describes the acceptable dosing regimens and labeling including warnings and directions for use. FDA's principal safety concern regarding fluoride in OTC drugs is the incidence of fluorosis in

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Page 3 - The Honorable Ken Calvert

children. Children under two years of age do not have control of their swallowing reflex and do not have the skills to expectorate toothpaste properly. Young children are most susceptible to mild fluorosis as a result of improper use and swallowing of a fluoride toothpaste. These concerns are addressed in the monograph by mandating maximum concentrations, labeling that specifies directions for use and age restrictions, and package size limits.

Thanks again for contacting us concerning this matter. If you have further questions, please let us know.

Sincerely,



Melinda K. Plaisier
Associate Commissioner
for Legislation

Enclosure

"Final Rule/Federal Register - October 6, 1995
Over-the-Counter Anticaries Drug Products"

Web site administrator's note:

To perform query to access this document

Enter: http://www.access.gpo.gov/su_docs/aces/aces140.html

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Enter: On: 10/06/95

Enter: Search terms: anticaries

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Drugs

New Drug Application (NDA)

Introduction

For decades, the regulation and control of new drugs in the United States has been based on the New Drug Application (NDA). Since 1938, every new drug has been the subject of an approved NDA before U.S. commercialization. The NDA application is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S. The data gathered during the animal studies and human clinical trials of an Investigational New Drug (IND) become part of the NDA.

The goals of the NDA are to provide enough information to permit FDA reviewer to reach the following key decisions:

- Whether the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks.
- Whether the drug's proposed labeling (package insert) is appropriate, and what it should contain.
- Whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity.

The documentation required in an NDA is supposed to tell the drug's whole story, including what happened during the clinical tests, what the ingredients of the drug are, the results of the animal studies, how the drug behaves in the body, and how it is manufactured, processed and packaged. The following resources provide summaries on NDA content, format, and classification, plus the NDA review process:

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Resources for NDA Submissions

The following resources have been gathered to provide you with the legal requirements of a new drug application, assistance from CDER to help you meet those requirements, and internal NDA review principles, policies and procedures.

Guidance Documents for NDAs

Guidance documents represent the Agency's current thinking on a particular subject. These documents are prepared for FDA review staff and applicants/sponsors to provide guidelines to the processing, content, and evaluation/approval of applications and also to the design, production, manufacturing, and testing of regulated products. They also establish policies intended to achieve consistency in the Agency's regulatory approach and establish inspection and enforcement procedures. Because guidances are not regulations or laws, they are not enforceable, either through administrative actions or through the courts. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. For information on a specific guidance document, please contact the originating office.

For the complete list of CDER guidances, please see the [Guidance Index](#). For information on a specific guidance document, please contact the originating office.

Guidance documents to help prepare NDAs include:

- [Bioavailability and Bioequivalence Studies for Orally Administered Drug Products - General Considerations](#) (Issued 10/2000, Posted 10/27/2000). This guidance should be useful for applicants planning to conduct bioavailability (BA) and bioequivalence (BE) studies during the IND period for an NDA, BE studies intended for submission in an ANDA, and BE studies conducted in the postapproval period for certain changes in both NDAs and ANDAs.

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- Changes to an Approved NDA or ANDA [HTML] or [PDF] (Issued 11/1999, Posted 11/19/1999)
 - Changes to an Approved NDA or ANDA: Questions and Answers [HTML] or [PDF] (Issued 1/2001, Posted 1/22/2001)
- Container Closure Systems for Packaging Human Drugs and Biologics. (Issued 5/1999, Posted 7/6/1999)
- Format and Content of the Chemistry, Manufacturing and Controls Section of an Application. (Withdrawn as per FR notice, 6/1/2006)
- Format and Content of the Microbiology Section of an Application.
- Format and Content of the Clinical and Statistical Sections of an Application. (Issued 7/1988, Posted 5/21/1997)
- Format and Content of the Summary for New Drug and Antibiotic Applications. (Issued 2/1987, Posted 3/2/1998)
- Formatting, Assembling and Submitting New Drug and Antibiotic Applications. (Issued 2/1987, Posted 3/2/1998)
- Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Substances.
- Submitting Documentation for the Stability of Human Drugs and Biologics. (Issued 2/1987, Posted 3/2/1998)
- Submitting Samples and Analytical Data for Methods Validation.
- Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Products.
- NDAs: Impurities in Drug Substances (Issued 2/2000, Posted 2/24/2000).
- Format and Content of the Human Pharmacokinetics and Bioavailability Section of an Application. (Issued 2/1987, Posted 3/2/1998)
- Format and Content of the Nonclinical Pharmacology/Toxicology Section of an Application. (Posted 3/2/1998)
- Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products. Describes the quantity of evidence, and the documentation

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of the quality of evidence necessary to support a claim of drug effectiveness.

- Drug Master Files. A Drug Master File (DMF) is a submission to the FDA that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs.
- Required Specifications for FDA's IND, NDA, and ANDA Drug Master File Binders
- Qualifying for Pediatric Exclusivity. Certain applications may be able to obtain an additional six months of patent exclusivity.
- PET Drug Applications - Content and Format for NDAs and ANDAs [HTML] or [PDF] (Issued 3/7/2000, Posted 3/7/2000)
- Refusal to File. (Issued 7/12/1993, Posted 11/26/99) Clarifies CDER's decisions to refuse to file an incomplete application.

Laws, Regulations, Policies and Procedures

The mission of FDA is to enforce laws enacted by the U.S. Congress and regulations established by the Agency to protect the consumer's health, safety, and pocketbook. The Federal Food, Drug, and Cosmetic Act is the basic food and drug law of the U.S. With numerous amendments, it is the most extensive law of its kind in the world. The law is intended to assure consumers that foods are pure and wholesome, safe to eat, and produced under sanitary conditions; that drugs and devices are safe and effective for their intended uses; that cosmetics are safe and made from appropriate ingredients; and that all labeling and packaging is truthful, informative, and not deceptive.

Code of Federal Regulations (CFR)

Code Of Federal Regulations (CFR) The final regulations published in the Federal Register (daily published record of proposed rules, final rules, meeting notices, etc.) are collected in the CFR. The CFR is divided into 50 titles which represent broad areas subject to Federal regulations. The FDA's

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Declaration of Nonconsent

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	Printed Name	Signature	Date	Address (Street, City, Zip)
1	JANET KAILIN	Janet Kailin	12/4/09	2902 S. Regent St., Port Angeles, WA 98362
2	John Hughes	JOHN W. HUGHES	04 Dec 09	2902 S. Regent St. Port Angeles WA 98362
3	CURT CROSTEN	Curt Crosten	12/5/09	207 Alderwood Cir Port Angeles 98362
4	KAY S. Croston	Kay S. Croston	12-5-09	207 Alderwood Circle Port Angeles WA 98362
5	John R. Thompson	John R. Thompson	12/5/09	2914 S. Regent St. Port Angeles, WA 98362
6	Gail L. Miller	Gail L. Miller	12/5/09	181 E. Park Ave. Port Angeles WA 98362
7	Frank L. Thompson	Frank L. Thompson	12-5-09	2914 S. Regent St. Port Angeles, WA 98362
8	Carl L. Bawer	Carl L. Bawer	12-5-09	3121 S. Regent St. Port Angeles, WA 98362
9	Ellen K. Gane	Ellen K. Gane	12-5-09	203 N. 6th St Port Angeles, WA 98362
10	Dee Renee Ericks	Dee Renee Ericks	12-5-09	622 S. Francis St. Port Angeles, WA 98362
11	Nancy O'Garra	Nancy O'Garra	12/05/09	2901 S. Regent St. Port Angeles WA 98362
12	Kermit Crocker	Kermit Crocker	12-5-09	2904 Regent Port Angeles, WA 98362
13	Silene Shenkel	Silene Shenkel	12-05-09	2906 Regent Port Angeles, WA 98362
14	ARLENE LAMOREUX	Arlene Lamoreux	12-05-09	602 W. Liberty Port Angeles, WA 98362
15	PAUL LAMOREUX	Paul Lamoreux	12/5/09	602 W. LIBBY PORT ANGELES WA 98362

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Declaration of Nonconsent

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	Printed Name	Signature	Date	Address (Street, City, Zip)
1	Gary Chastner	<i>Gary Chastner</i>	12/12/09	3324 Upland Lane, Port Angeles, WA 98362
2	Herb Gault Adams	<i>Herb Gault Adams</i>	12/12/09	212 E. 11th St. Port Angeles, 98362
3	Serid Estberg	<i>Serid Estberg</i>	12/2/09	1022 Schuyler St. Port Angeles, 98362
4	DIANA L. ESTBERG	<i>Diana L. Estberg</i>	12/2/09	1022 S CHERRY ST., FORT ANGELES, WA 98362
5	SHARON M. OWEN	<i>Sharon M. Owen</i>	12/2/09	624 E 7th St. Port Angeles, WA 98362
6	FRANCIS STIGGALL	<i>Francis Stiggall</i>	12/2/09	1022 S CHERRY ST. PORT ANGELES, WA 98362
7	SHIRLEY PETERS	<i>Shirley Peters</i>	12/2/09	916 E 10th St. PORT ANGELES WA 98362
8	DAVID NASSÉ	<i>David Nassé</i>	12/2/09	192 N. Solmar Dr. Sequim. 98382
9	Rosemary Moorhead	<i>Rosemary Moorhead</i>	12/2/09	4124 Old Mill Rd. Port Angeles, WA 98362
10	Sandra Schultz	<i>Sandra Schultz</i>	12/2/09	15 N. Oakland Ln. Pt. Angeles, 98362
11	BOB CARLSON	<i>Bob Carlson</i>	12-2-09	1686 OLSON ST. SEQUIM 98382
12	Loula Dument	<i>Loula Dument</i>	12-2-09	47733 Hwy 112 Joyce, WA 98343
13	WYNNE PETERS	<i>Wynne Peters</i>	12-3-09	916 E 10th PORT ANGELES, WA 98362
14	Corinne Winnes	<i>Corinne Winnes</i>	12/2/09	2042 Juniper Hill Road Pt. Angeles, WA 98362
15	ROBERT L. PHOTO	<i>Robert L. Photo</i>	12/2/09	309 Will Postengale Rd. 98362

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Declaration of Nonconsent

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Printed Name	Signature	Date	Address (Street, City, Zip)
1 RICHARD T. SMITH	<i>Richard T. Smith</i>	11-30-09	803 Island View Road Port Angeles WA 98362
2 WALTER H. BARBER	<i>Walter H. Barber</i>	4-Dec-09	481 AMERICA BLVD, SEQUIM, WA 98382
3 CLINON CLAMSEN	<i>Clm. A. Cl</i>	4-Dec-09	199 Fulte Lane Sequim, WA 98382
4 DENICK PICKINSON	<i>Denick Pickinson</i>	4-Dec-09	258612 Hwy 101 Sequim WA 98382
5 KRISTY LAWRENCE	<i>Kristy Lawrence</i>	12-4-09	2354 E. 3rd Ave PA WA 98362
6 CAI BLANK	<i>CAI BLANK</i>	12-4-09	152 CHICKEN COPPED - SEQUIM WA 98382
7 KELLY STEED	<i>Kelly Steed</i>	12-4-09	605 THISTLE ST. Port Angeles, WA 98362
8 FRANK LAWRENCE	<i>Frank Lawrence</i>	12-4-09	731 W. 4TH PORT ANGELES WA 98362
9 JOHN R. JARVIS	<i>John R. Jarvis</i>	12-4-09	231 W 4TH PORT ANGELES WA 98362
10 M. Q. KUTZ	<i>M. Q. Kutz</i>	12-4-09	2442 E. Hwy 101 Port Angeles WA 98362
11	<i>John F. Moore</i>	12-4-09	1012 W 7th St Port Angeles WA 98362
12 ROBERT MOORE	<i>Robert Moore</i>	12-4-09	922 S University Port Angeles WA 98362
13 JOHN STETSON	<i>John Stetson</i>	12/4/09	123 W 12TH PORT ANGELES WA 98362
14 RICKI B. MACK	<i>Ricki B. Mack</i>	12/4/09	316 Vashon Ave Port Angeles, WA 98362
15 JOHN ROBERTS	<i>John Roberts</i>	12/4/09	2412 E. Ryan Ave - Port Angeles, WA 98362

Declaration of Nonconsent

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	Printed Name	Signature	Date	Address (Street, City, Zip)
1	SUSAN H. DANIELSON	<i>[Signature]</i>	12/2	121 Uphill Dr Port Angeles 98362
2	Crystal Traylor	<i>[Signature]</i>	12/3	2222 Taylor Cottaf Sequim 98387
3	Shonda Traylor Bubens	<i>[Signature]</i>	12/3	317 E 6th St PA WA 98362
4	Jeffrey Allyn	<i>[Signature]</i>	12/3	Pomer 2489 WA 98362
5	MARJORIE HRETZE	<i>[Signature]</i>	12/3	302 E. Annetter Rd P.A. 98362
6	SHARON ANN	<i>[Signature]</i>	12-3	301 50th dining Spore. near Sequim 98387
7	DALLIA S. PEREZ	<i>[Signature]</i>	12-3	1017 1/2 E 6th St, Pa. WA 98362
8	Rhyn Scarab	<i>[Signature]</i>	12-3	1231 Cambden Apt 3. PA, WA. 98362
9	Noah Smith	<i>[Signature]</i>	12-3	605 W 11th St P.A. WA. 98362
10	MARGARET JAROS	<i>[Signature]</i>	12-3	1455 PARK VIEW LANE PA. WA 98363
11	NOVEN SWANM	<i>[Signature]</i>	12/3	710 SOUTH A ST. P.A., WA 98363
12	Robert J. Flake	<i>[Signature]</i>	12/3	3752 HILL GROVE P.A., WA. 98362
13	Veronica Flake	<i>[Signature]</i>	12/3	3752 Hill Circle PA WA 98362
14	HAZEL E MEIER	<i>[Signature]</i>	12/3	3736 Hill Circle PA WA 98362
15	DANELONG	<i>[Signature]</i>	12/3	3770 Hill CR PAWA 98362

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Declaration of Nonconsent

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	Printed Name	Signature	Date	Address (Street, City, Zip)
1	ANN W MATHEWSON	<i>Ann Mathewson</i>	12/2/09	1923 W 6th St Port Angeles WA 98363-1609
2	PATRICIA FLORES INSLEY	<i>Patricia Flores</i>	12/2/09	1104 E 4th St. Port Angeles, WA 98362
3	Jesse C. Wilson	<i>Jesse C. Wilson</i>	12/2/09	1025 West 17th St. Port Angeles, WA 98363
4	Kambra Reader	<i>Kambra Reader</i>	10/4/09	PO BOX 1696 Port Angeles, WA 98362
5	Stephanie Baldacci	<i>Stephanie Baldacci</i>	10/4/09	1080 Fournment Ave. PA 98363
6	CHAD CRAWLEY	<i>Chad Crawley</i>	12/16/09	Newell Rd Apartments Apt C-1 Port Angeles WA 98363
7	SPENCER T. LEWIS	<i>Spencer T. Lewis</i>	12/16/09	1016 W 7th St PA WA 98363
8	Lynnea R. Tucker	<i>Lynnea R. Tucker</i>	12/16/09	1120 W 7th St PA WA 98363
9	Jeanette Graf	<i>Jeanette Graf</i>	12/16/09	707 1/2 W 5th St PA 98363
10	Erin Shields	<i>Erin Shields</i>	12/16/09	525 W. 4th St. Port Angeles, WA 98362
11	COLLEEN CUNNINGHAM	<i>Colleen Cunningham</i>	12/16/09	537 W. 7th St. Port Angeles, WA 98362
12	MARGARET ALBERT	<i>Margaret Albert</i>	12/16/09	204 W 4th St Port Angeles 98362
13	Danet Rose Marshall	<i>Danet Rose Marshall</i>	12/16/09	196 S. Barr Rd Port Angeles 98362
14	Richard A. Marshall	<i>Richard A. Marshall</i>	12/16/09	162 S. Barr Rd PA WA 98362
15	Alfred Quirk	<i>Alfred Quirk</i>	12/16/09	4872 Deer Pt Rd PA WA 98362

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Declaration of Nonconsent

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	Printed Name	Signature	Date	Address (Street, City, Zip)
1	Bert Grable	Bert Grable	12/2/09	1117 S Peabody St, Port Angeles, WA 98362
2	Jessica R. Grable	Jessica R. Grable	12/2/09	1117 S Peabody St, Port Angeles, WA 98362
3	Terri L. McManis	Terri L. McManis	12/2/09	305 Duff Rd. Jefferson WA 98382
4	Karen Ann Anderson	Karen Ann Anderson	12/2/09	428 S. Oak St. Port Angeles WA 98382
5	Jessie C. Reid	Jessie C. Reid	12/3	503 W 4th St. Port Angeles
6	Jim R. Armstrong	Jim R. Armstrong	12/4	820 1/2 S. C. St. Port Angeles 98362
7	Fernie Osterberg	Fernie Osterberg	12/4	33 N. Hendock Cr., Port Angeles 98362
8	CAROL THOMASSOV	Carol Thomassov	12/5	1107 S Peabody Port Angeles WA 98362
9	Jerry Filbeck	Jerry Filbeck	12/5	528 W Linn St. Port Angeles WA 98362
10	Connie L. Zentz	Connie L. Zentz	12/5	528 W Linn St. Port Angeles WA 98362
11	Lillian Pelkov	Lillian Pelkov	12/5	528 W Linn St. Port Angeles WA 98362
12	SUSAN PASINIK	Susan Pasinik	12/5	528 W Linn St. Port Angeles WA 98362
13	MARY GALYEAN	Mary Galyeon	12/5	528 W Linn St. Port Angeles WA 98362
14	Christopher Standley	Christopher Standley	12/5	528 W Linn St. Port Angeles WA 98362
15	Mary G. M. L.	Mary G. M. L.	12/5	528 W Linn St. Port Angeles WA 98362

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Declaration of Nonconsent

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Printed Name	Signature	Date	Address (Street, City, Zip)
1 Rudolph Meyer	Rudolph Meyer	12/4	1703 Leinbert PA 98362
2 Shelley Dorfman Schostek	Shelley Dorfman Schostek	12/4	6575 S. Mt Angeles PA 98362
3 Estelita Yella	Estelita Yella	12/4	134 Mt Pleasant Court West - PA 98362
4 Baena Young	Baena Young	12/5	133 Walker Valley Rd Port Angeles, WA 98362
5 Carol PAUL REANDEAU	Carol Paul Reandean	12/5	111 FIFTEENTH Port Angeles 98362
6 Colleen Miller	Colleen Miller	12/5	805 C 5th St Apt Port Angeles WA 98362
7 Rutha Rupleyle	Rutha Rupleyle	12/5	6024 S. B St PA 98362
8 Cynthia Spawin	Cynthia Spawin	12/5	918 E 9th PA 98362
9 Shelby ELLIEMAN	Shelby Elliemann	12/5	145 VIEWCREST AVE. PA 98362
10 Delaney Ronish	Delaney Ronish	12/5	1622 West 14th Street Port Angeles, WA 98362
11 Mary Morris	Mary Morris	12/5	2913 S. Rainbow St. Port Angeles, WA 98362
12 Kia Armstrong	Kia Armstrong	12/5	4661 Segusum - DuPontness Way, SD 98382
13 Abby Hare	Abby Hare	12/5	4091 Blue Mt Rd Port Angeles, WA
14 David Applebaum	David Applebaum	12/5	585 Washington Rd, PA, 98362
15 Russell Lawson	Russell Lawson	12/5	" "



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NSF Product and Service Listings

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Warning: NSF is concerned about fraudulent downloading and manipulation of website text. If you have received this listing in hard copy, always confirm this certification/listing information by going directly to <http://www.nsf.org/Certified/PwsChemicals/Listings.asp?> for the latest most accurate information.

NSF/ANSI STANDARD 60 Drinking Water Treatment Chemicals - Health Effects

6N Silicon Inc.
1 Royal Gate Boulevard
Vaughan, ON L4L 8Z7
Canada
905-856-0367
Visit this company's website

Facility : Vaughan, Ontario, Canada

Polyaluminum Chloride[AL]

Trade Designation

PAC

6 N PAC

Poyaluminum Chloride Solution

Product Function

Coagulation & Flocculation

Coagulation & Flocculation

Coagulation & Flocculation

Max Use

250mg/L

250mg/L

250mg/L

[AL] Based on an evaluation of health effects data, the level of aluminum in the finished drinking water shall not exceed 2 mg/L.

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Zschimmer & Schwarz
Mohsdorf GmbH & Co KG

Chemnitztalstrasse 1

09217 Burgstaedt

Germany

49 3724 67-231

[Visit this company's website](#)

</TD<
tr>

Facility : Burgstaedt, Germany

Miscellaneous Water Supply Products

Trade Designation

Cublen A 4015

Product Function

Distillation Antiscalant

Max Use

15mg/L

Reverse Osmosis Antiscalant

Cublen AP 5

Reverse Osmosis Antiscalant

9mg/L

Distillation Antiscalant

Number of matching Manufacturers is 847

Number of matching Products is 35389

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memo-of-understanding-fda-epa-225-79-2001-epa-to-regulate-water-additives
MOU 225-79-2001
[http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/
DomesticMOUs/ucm116216.htm](http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm116216.htm)

Memorandum of Understanding
Between
The Environmental Protection Agency
and
The Food and Drug Administration

I. Purpose:

This Memorandum of Understanding establishes an agreement between the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) with regard to the control of direct and indirect additives to and substances in drinking water.

EPA and FDA agree:

A. That contamination of drinking water from the use and application of direct and indirect additives and other substances poses a potential public health problem;

B. That the scope of the additives problem in terms of the health significance of these contaminants in drinking water is not fully known;

C. That the possibility of overlapping jurisdiction between EPA and FDA with respect to control of drinking water additives has been the subject of Congressional as well as public concern;

D. That the authority to control the use and application of direct and indirect additives to and substances in drinking water should be vested in a single regulatory agency to avoid duplicative and inconsistent regulation;

E. That EPA has been mandated by Congress under the Safe Drinking Water Act (SDWA), as amended, to assure that the public is provided with safe drinking water;

F. That EPA has been mandated by Congress under the Toxic Substances Control Act (TSCA) to protect against unreasonable risks to health and the environment from toxic substances by requiring, inter alia, testing and necessary restrictions on the use, manufacture, processing, distribution, and disposal of chemical substances and mixtures;

G. That EPA has been mandated by Congress under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to assure, inter alia, that when used properly, pesticides will perform their intended function without causing unreasonable adverse effects on the environment; and,

H. That FDA has been mandated by Congress under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended, to protect the public from, inter alia, the adulteration of food by food additives and poisonous and deleterious substances. It is the intent of the parties that:

A. EPA will have responsibility for direct and indirect additives to and other substances in drinking water under the SDWA, TSCA, and FIFRA; and,

B. FDA will have responsibility for water, and substances in water, used in food and for food processing and responsibility for bottled drinking water under the FFDCA.

II. Background:

A. FDA Legal Authority

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"Food" means articles used for food or drink for man or other animals and components of such articles. (FFDCA Section 201(F)). Under Section 402, inter alia, a food may not contain any added poisonous or deleterious substance that may render it injurious to health, or be prepared, packed or handled under unsanitary conditions. Tolerances may be set, under Section 406, limiting the quantity of any substance which is required for the production of food or cannot be avoided in food. FDA has the authority under Section 409 to issue food additive regulations approving, with or without conditions, or denying the use of a "food additive." That term is defined in Section 201(s) to include any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, if such substance is not generally recognized as safe.

In the past, FDA has considered drinking water to be a food under Section 201(F). However, both parties have determined that the passage of the SDWA in 1974 implicitly repealed FDA's authority under the FFDCA over water used for drinking water purposes. Under the express provisions of Section 410 of the FFDCA, FDA retains authority over bottled drinking water. Furthermore, all water used in food remains a food and subject to the provisions of the FFDCA. Water used for food processing is subject to applicable provisions of FFDCA. Moreover, all substances in water used in food are added substances subject to the provisions of the FFDCA, but no substances added to a public drinking water system before the water enters a food processing establishment will be considered a food additive.

B. EPA Legal Authority

The SDWA grants EPA the authority to control contaminants in drinking water which may have any adverse effect on the public health, through the establishment of maximum contaminant levels (MCLs) or treatment techniques, under Section 1412, which are applicable to owners and operators of public water systems. The expressed intent of the Act was to give EPA exclusive control over the safety of public water supplies. Public water systems may also be required by regulation to conduct monitoring for unregulated contaminants under Section 1445 and to issue public notification of such levels under Section 1414(c).

EPA's direct authority to control additives to drinking water apart from the existence of maximum contaminant levels or treatment techniques is limited to its emergency powers under Section 1431. However, Section 1442(b) of the Act authorizes EPA to "collect and make available information pertaining to research, investigations, and demonstrations with respect to providing a dependably safe supply of drinking water together with appropriate recommendations therewith."

TSCA gives EPA authority to regulate chemical substances, mixtures and under some circumstances, articles containing such substances or mixtures. Section 4 permits EPA to require testing of a chemical substance or mixture based on possible unreasonable risk of injury to health or the environment, or on significant or substantial human or environmental exposure while Section 8 enables EPA to require submission of data showing substantial risk of injury to health or the environment, existing health and safety studies, and other data. For new chemical substances, and significant new uses of existing chemical substances, Section 5 requires manufacturers to provide EPA with pre-manufacturing notice. Under Section 6 the manufacture, processing, distribution, use, and disposal of a chemical substance or mixture determined to be harmful may be restricted or banned. Although Section 3(2)(B) of TSCA excludes from the definition of "chemical substance" food and food additives as defined under FFDCA, the implicit repeal by the SDWA of FDA's authority over drinking water enables EPA to regulate direct and indirect additives to drinking water as chemical substances and mixtures under TSCA.

The FIFRA requires EPA to set restrictions on the use of pesticides to assure that when used properly, they will not cause unreasonable adverse effects on the

memo-of-understanding-fda-epa-225-79-2001-epa-to-regulate-water-additives environment. EPA may require, inter alia labeling which specifies how, when, and where a pesticide may be legally used. In addition, EPA has, under Section 409 of the FFDCA, required FIFRA registrants at times to obtain a food additive tolerance before using a pesticide in or around a drinking water source. Such tolerances establish further restrictions on the use of a pesticide which are enforceable against the water supplier as well as the registrant of the pesticide.

III. Terms of Agreement:

A. EPA's responsibilities are as follows:

1. To establish appropriate regulations, and to take appropriate measures, under the SDWA and/or TSCA, and FIFRA, to control direct additives to drinking water (which encompass any substances purposely added to the water), and indirect additives (which encompass any substance which might leach from paints, coatings or other materials as an incidental result of drinking water contact), and other substances.
2. To establish appropriate regulations under the SDWA to limit the concentrations of pesticides in drinking water; the limitations on concentrations and types of pesticides in water are presently set by EPA through tolerances under Section 409 of the FFDCA.
3. To continue to provide technical assistance in the form of informal advisory opinions on drinking water additives under Section 1442(b) of the SDWA.
4. To conduct and require research and monitoring and the submission of data relative to the problem of direct and indirect additives in drinking water in order to accumulate data concerning the health risks posed by the presence of these contaminants in drinking water.

B. FDA's responsibilities are as follows:

1. To take appropriate regulatory action under the authority of the FFDCA to control bottled drinking water and water, and substances in water, used in food and for food processing.
2. To provide assistance to EPA to facilitate the transition of responsibilities, including:
 - a) To review existing FDA approvals in order to identify their applicability to additives in drinking water.
 - b) To provide a mutually agreed upon level of assistance in conducting literature searches related to toxicological decision making.
 - c) To provide a senior toxicologist to help EPA devise new procedures and protocols to be used in formulating advice on direct and indirect additives to drinking water.

IV. Duration of Agreement:

This Memorandum of Understanding shall continue in effect unless modified by mutual consent of both parties or terminated by either party upon thirty (30) days advance written notice to the other.

This Memorandum of Understanding will become effective on the date of the last signature.

Approved and Accepted
for the Environmental Protection Agency
Signed by: Douglas P. Costle
Administrator
Environmental Protection Agency
Date: June 12, 1979

Approved and Accepted
for the Food and Drug Administration
Signed by: Donald Kennedy
Administrator
Food and Drug Administration

memo-of-understanding-fda-epa-225-79-2001-epa-to-regulate-water-additives
Date: June 22, 1979

HIGHLIGHTS IN NORTH AMERICAN LITIGATION
DURING THE TWENTIETH CENTURY ON
ARTIFICIAL FLUORIDATION OF PUBLIC WATER
SUPPLIES

JOHN REMINGTON GRAHAM* AND PIERRE-JEAN MORIN**

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I. INTRODUCTION***

Fluoride is an ubiquitous substance in our environment. It is naturally present in public water supplies, bound with calcium, iron, magnesium, or other minerals, usually at a level of around 0.2-0.4 ppm. Except incidentally, this article will not address the natural

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*** The authors wish to express their gratitude to J. William Hirzy, Ph.D., Senior Vice President of the National Treasury Employees Union, Chapter 280, at the National Headquarters of the United States Environmental Protection Agency (EPA) for documentation concerning developments at EPA from 1986 through 1998, and also to Rt. Hon. Edward Baldwin, Earl of Bewdley, for his assistance in securing records of important debates on fluoridation in the British House of Lords.

Appendix B

presence of fluoride in drinking water, which is a distinct question. The focus of this article will be the artificial fluoridation of public water supplies which occurs when the fluoride content of drinking water is artificially adjusted from its natural level to a desired level of 0.9-1.2 ppm. This change is effected by adding sodium silico fluoride, hydrofluosilicic acid, or some such industrial waste product, which releases free fluoride ions into water consumed by human beings.¹

The theory behind this practice, which now affects about 130 million people in the United States, is that the ingestion of fluoride will harden the surfaces of teeth and make them less susceptible to dental caries. The literature is extensive on whether this practice does or does not reduce tooth decay, and whether it is or is not safe.² The standard work, done under auspices of the American Dental Association (ADA) and the United States Public Health Service (USPHS), is the *Newburgh-Kingston Caries-Fluorine Study: Final Report*.³ Published over forty years ago, it proudly concluded that artificial fluoridation of public water supplies dramatically reduces tooth decay in humans, at no risk to human health.⁴ In language tinged with contemporary fanaticism, the *Final Report* announced, "The opposition stems from several sources, chiefly food faddists, cultists, chiropractors, misguided and misinformed persons who are ignorant of the scientific facts on the ingestion of water fluorides, and, strange as it may seem, even among a few uninformed physicians and dentists."⁵

1. See GEORGE L. WALDBOTT, M.D. ET AL., FLUORIDATION: THE GREAT DILEMMA 47-54, 148-74 (1978) for a detailed discussion of the absorption of fluoride, mainly as free ions, into the soft tissues of the human body. On the other hand, when fluoride is naturally present in public water supplies, it is generally bound with calcium and other minerals and, in such form, it does not readily dissociate and so is more readily excreted. Experiments with trout indicate that fluoride in water so bound tends to be less toxic. See Joseph W. Angelovic et al., *Temperature and Fluorosis in Rainbow Trout*, 33 J. WATER POLLUTION CONTROL FED'N 371 (1961). Hence, the artificial presence of fluoride in drinking water should be considered separately from its natural presence, at least in connection with questions about whether or not fluoride in drinking water produces harmful side effects.

2. The most respected scientific works, published during the twentieth century in support of artificial fluoridation of public water supplies, are WORLD HEALTH ORGANIZATION, FLUORIDES AND HUMAN HEALTH (1970), and FRANK J. MCCLURE, U.S. DEP'T OF HEALTH, EDUCATION, AND WELFARE, WATER FLUORIDATION: THE SEARCH AND THE VICTORY (1970). The work of WALDBOTT ET AL., *supra* note 1, is a comprehensive and powerful rebuttal. Considerable research has been done since these classic treatises were published.

3. Herman E. Hilleboe et al., *Newburgh-Kingston Caries Fluorine Study: Final Report*, 52 J. AM. DENTAL ASS'N 290 (1956).

4. See *id.* at 313-14, 316-19 (1956).

5. *Id.* at 294.

From the beginning, this ostentatious pronouncement has set the tone of ADA and USPHS activists and others promoting this practice in the face of growing opposition, from eminent scientists and physicians. The ultimate merits of the issues in science and medicine aside, there has always been learned and respectable opposition to artificial fluoridation of public water supplies,⁶ and all attempts to deny it can only be characterised as irresponsible.

A few preliminary questions need to be asked. The first is whether the natural or artificial level of fluoride in public water supplies really has any beneficial effect in reducing tooth decay. The main difficulty with the experimental runs at Newburgh and Kingston in New York and elsewhere is that tooth decay is enhanced or diminished by innumerable factors including dietary, socio-economic, environmental, hygienic, and many others. Thus, criticism was voiced, initially in a doctoral dissertation,⁷ that there was no control for known and unknown variables and, consequently, the conclusions on the reduction of tooth decay associated with fluoridation were invalid.

Subsequent research, involving vastly more data and sophistication, has entirely upset the Newburgh-Kingston orthodoxy.⁸ It has since been persuasively demonstrated that the lowest rates of tooth decay in children occur in areas where the fluoride level is about 0.2-0.4 ppm, which is the normal level in most parts of the world.⁹ From

6. See, e.g., *Hearings on H.R. 2341 Before the House Comm. on Interstate and Foreign Commerce*, 83d Cong. 62-86 (1954) (statement of Frederick Exner, M.D.). In his time, George Waldbott, M.D., was the dean of physicians against fluoridation. His pioneering book, *A STRUGGLE WITH TITANS* (1965), is bound to be of great interest to scientific historians in future years. He was a founder of the International Society for Fluoride Research, a learned society of about five hundred scientists who specialize in the field, publishing a quarterly journal entitled *Fluoride*.

7. See Edward S. Groth III, *Two Issues of Science and Public Policy: Air Pollution Control in the San Francisco Bay Area and Fluoridation of Community Water Supplies* 146-462 (1973) (unpublished Ph.D. dissertation, Stanford University) (on file with University Microfilms in Ann Arbor, Michigan).

8. See, e.g., H. Kalsbeek & G.H.W. Verrips, *Dental Caries Prevalence and the Use of Fluorides in Different European Countries*, 69 J. DENTAL RES. 728 (1990); Rudolph Ziegelbecker, *WHO Data on Dental Caries and Natural Water Fluoride Levels*, 26 FLUORIDE 263 (1993) (setting forth impressive analyses of data published by the World Health Organization). Trends now evident in Newburgh and Kingston indicate no significant differences in tooth decay rates between the two cities, although dental mottling is somewhat higher in fluoridated Newburgh. See, e.g., Jayanth V. Kumer et al., *Trends in Dental Fluorosis and Dental Caries Prevalences in Newburgh and Kingston, NY*, 79 AM. J. PUB. HEALTH 565 (1989); Jayanth V. Kumer et al., *Changes in Dental Fluorosis and Dental Caries in Newburgh and Kingston, New York*, 88 AM. J. PUB. HEALTH 1866 (1998); Jayanth V. Kumer et al., *Recommendations for Fluoride Use in Children*, N.Y.S. DENTAL J., Feb. 1998, at 40.

9. See, e.g., Yoshitsugu Imai, *Relationship Between Fluoride Concentration in Drinking Water and Dental Caries in Japan*, 6 FLUORIDE 248 (1973).

all published studies on the question in Europe and North America, it has been shown that, while there is a strong positive relationship between dental mottling and the natural level of fluoride in drinking water, there is no statistical relationship between the extent of tooth decay and the natural level of fluoride in drinking water.¹⁰ In more recent years, it has been observed that tooth decay rates have decreased as fast in unfluoridated areas as in fluoridated areas.¹¹ From massive data gathered by the government of the United States, it has been revealed that there is no statistical relationship between rates of tooth decay in children and the extent or duration of artificial fluoridation of public water supplies.¹²

Another question is whether public officials of the United States have been honest in levelling with the American people about the potential harmful effects of artificially releasing fluoride into the environment. In this regard, some attention needs to be given to the seminal work of Dr. Alfred Taylor, a biochemist at the University of Texas. The facts have been written up by reputable scholars¹³ and make up an important episode in scientific history.

In the early 1950s, Dr. Taylor undertook a series of preliminary experiments by which it appeared that cancer-prone mice consuming water treated with sodium fluoride had shorter life spans than mice drinking distilled water.¹⁴ Because the mice in both the control and experimental groups ate chow containing measurable fluoride, probably as CaF, as he learned after his initial runs, Dr. Taylor replicated his earlier work, but used chow containing negligible fluoride. He ran twelve experiments using 645 cancer-prone mice. He found that, as measured for statistical significance, cancer-prone mice drinking water containing fluoride, introduced as NaF, had shorter life spans than mice drinking distilled water.¹⁵ In 1954, the results of Dr. Taylor's reruns were published in a refereed journal.¹⁶

Dr. Taylor's work was published at a politically sensitive time, because the last stages of the much-boasted surveys at Newburgh

10. Rudolph Ziegelbecker, *Natürlicher Fluoridgehalt des Trinkwassers und Karies* [Natural Fluoridation of Drinking Water and Caries], 122 GWF WASSER/ABWASSER 495 (1981), translated in 14 FLUORIDE 123 (1981).

11. John Colquhoun, *Child Dental Health Differences in New Zealand*, 9 COMM. HEALTH STUD. 85 (1987).

12. John Yiamouyiannis, *Water Fluoridation and Tooth Decay: Results from the 1986-1987 National Survey of U.S. Schoolchildren*, 23 FLUORIDE 55 (1990)

13. See, e.g., WALDBOTT ET AL., *supra* note 1, at 222-25.

14. See *id.* at 222.

15. See *id.* at 222-23.

16. See Alfred Taylor, *Sodium Fluoride in the Drinking Water of Mice*, 60 DENTAL Dig. 170 (1954).

and Kingston were underway. The obvious meaning of Dr. Taylor's results was that a possible danger to public health had been overlooked, and that widespread fluoridation should be delayed until the situation had been clarified. However, the ADA and the USPHS had already endorsed and begun the drive to promote fluoridation.

The embarrassment, therefore, had to be addressed. In the *Final Report*, reference was made to Dr. Taylor's original tests two years after the positive results of his reruns had been peer-reviewed and published. Then it was said, contrary to the known state of world literature:

The reports by Alfred Taylor, a biochemist at the University of Texas, on the increased incidence of cancer in mice drinking fluoride-treated water have been shown to be unfounded, since the food that he was giving the mice had many times the fluoride content of the drinking water, and the food was supplied both to the control and experimental groups. Subsequent tests did not confirm the differences.¹⁷

Ever since, USPHS officials have insisted, contrary to known facts, that Dr. Taylor's reruns were never done and never published, and that no work supporting Taylor's results exists or has ever been published. For example, in a standard history of the National Institute of Dental Health, published thirty-five years after Dr. Taylor's work first appeared in a refereed journal, Ruth Roy Harris said, "Alfred Taylor, an investigator with a doctorate in biochemistry, indicated that he would not publish his findings because he was unable to confirm those results in a second experiment."¹⁸ Harris added still another misrepresentation, also contrary to known facts, "A literature search of scientific journals failed to show any publication of this work by Taylor -- an indication that it was not subjected to review by his peers."¹⁹ The importance of Dr. Taylor's work is revealed by what USPHS officials have done to conceal it.

After his first study, Dr. Taylor and his wife, also a Ph.D. biochemist, published the results of yet another large-scale study, in which fluoride in water, introduced as NaF, was shown to induce growth in implanted tumors in mice.²⁰ Dr. Taylor's pioneering work

17. Hilleboe et al., *supra* note 4, at 313.

18. RUTH ROY HARRIS, DENTAL SCIENCE IN A NEW AGE, HISTORY OF THE NATIONAL INSTITUTE OF DENTAL RESEARCH 112 (1989).

19. *Id.* at 396 n.33.

20. See Alfred Taylor & Nell Carmichael Taylor, *Effect of Sodium Fluoride on Tumor Growth*, 119 PROC. OF SOC'Y FOR EXPERIMENTAL BIOLOGY AND MED. 252 (1965).

has been confirmed and reconfirmed by a considerable multitude of laboratory studies done by world class scientists, all published in peer-reviewed journals.²¹ Meanwhile, it has been held in some environmental litigation during the twentieth century that, if laboratory tests indicate the capacity of a certain substance to produce harmful side effects in laboratory animals, the same substance may also be presumed deleterious to man in the environment.²²

The main inquiry of this article will be whether the several States have constitutional authority to impose artificial fluoridation of public water supplies. The question depends in part on scientific and medical facts. As we shall relate in detail, trial judges over the past twenty years have repeatedly found, after hearing experts, that fluoridation is injurious to public health. We proceed, first, to review the legal fundamentals.

II. THE NATURE OF POLICE POWER

The first clause of Article I, Section 8 of the United States Constitution states that Congress shall have the power to "provide for the common Defence and general Welfare." James Madison showed that this provision was intended to define the objects of

21. See, e.g., Irwin H. Herskowitz & Isabel L. Norton, *Increased Incidence of Melanotic Tumors in Two Strains of Drosophila Melanogaster Following Treatment with Sodium Fluoride*, 43 GENETICS 307 (1963); Chong Chang, *Effect of Fluoride on Nucleotides and Ribonucleic Acid in Germinating Corn Seedling Roots*, 43 PLANT PHYSIOLOGY 669 (1968); Danuta Jachimczak & Bogumila Skotarczak, *The Effect of Fluorine and Lead Ions on the Chromosomes of Human Leucocytes in Vitro*, 19 GENETICA POLONICA 353 (1978); John Emsley et al., *An Unexpectedly Strong Hydrogen Bond: Ab Initio Calculations and Spectroscopic Studies of Amide-Fluoride Systems*, 103 J. AM. CHEM. SOC'Y 24 (1981); John Emsley et al., *The Uracil-Fluoride Interaction: Ab Initio Calculations including Solvation*, 8 J. CHEMICAL SOC'Y CHEMICAL COMMUN. 476 (1982); A.H. Mohamed & M.E. Chandler, *Cytological Effects of Sodium Fluoride on Mice*, 15 FLUORIDE 110 (1982); Toshio Imai et al., *The Effects of Fluoride on Cell Growth of Two Human Cell Lines and on DNA and Protein Synthesis in HeLa Cells*, 52 ACTA PHARMACOLOGICA ET TOXICOLOGICA 8 (1983); Takeki Tsutsui et al., *Cytotoxicity, Chromosome Aberrations and Unscheduled DNA Synthesis in Cultured Human Diploid Fibroblasts Induced by Sodium Fluoride*, 139 MUTATION RES. 193 (1984); Takeki Tsutsui et al., *Induction of Unscheduled DNA Synthesis in Cultured Human Oral Keratinocytes by Sodium Fluoride*, 140 MUTATION RES. 43 (1984); Takeki Tsutsui et al., *Sodium Fluoride-induced Morphological and Neoplastic Transformation, Chromosome Aberrations, Sister Chromatid Exchanges, and Unscheduled DNA Synthesis in Cultured Syrian Hamster Embryo Cells*, 44 CANCER RES. 938 (1984); Carol A. Jones et al., *Sodium Fluoride Promotes Morphological Transformation of Syrian Hamster Embryo Cells*, 9 CARCINOGENESIS 2279 (1988); Marilyn J. Aardema et al., *Sodium Fluoride-induced Chromosome Aberrations in Different Stages of the Cell Cycle: A Proposed Mechanism*, 223 MUTATION RES. 191 (1989); Takeki Tsutsui et al., *Cytotoxicity and Chromosome Aberrations in Normal Human Oral Keratinocytes Induced by Chemical Carcinogens: Comparison of Inter-Individual Variations*, 5 TOXICOLOGY IN VITRO 353 (1991).

22. See e.g., *Environmental Defense Fund v. Environmental Protection Agency*, 548 F.2d 998, 1006 (D.C. Cir. 1976).

federal spending, not to confer a general legislative authority upon Congress, because, if this clause conferred such a general legislative authority, it would render the enumeration of specific legislative powers redundant and pointless.²³

Madison's observation was important because he showed that, if Congress had a general legislative authority as such, it would be nothing other than a power to provide for the common defense and the general welfare. It would be a power, subject to the limitations inherent and implied in every republican form of government,²⁴ to enact only by laws necessary and proper or, in other words, laws fairly proportioned to and consistent with the common defense and general welfare, in keeping with legal principle and legal tradition.²⁵ Alexander Hamilton made unmistakably clear that a bill of rights, including all essential privileges and immunities of a free people, is always implied, if not expressed, in every republican form of government.²⁶ And every republican form of government, as an outgrowth of the American Revolution, necessarily presupposes the essential truths of the Declaration of Independence, which begins, before all else, with a tribute to the "Laws of Nature and Nature's God."²⁷

So it was that Justice Samuel Chase of the United States Supreme Court, one of the signers of the Declaration of Independence, thus

23. See THE FEDERALIST NO. 41, at 276-77 (Clinton Rossiter ed., 1961). In reaching this conclusion, Madison applied the rule of construction from the common law that clauses dealing with the same general subject or question should be construed together, if possible, to give every distinct provision some useful purpose and to coalesce into a harmonious whole with the others. See THE FEDERALIST NO. 40, at 260 (Clinton Rossiter ed., 1961). The same idea is advanced in the 7th of the Kentucky Resolutions of 1798, authored by Thomas Jefferson. See 4 DEBATES ON THE FEDERAL CONSTITUTION 542 (Elliot ed., Lippencott & Co., Philadelphia) (2d ed. 1859).

24. James Madison emphasized that the government of the Union, like the government of every State, is a republican form of government which has its origin in the people and features distinctive of the American Revolution. See THE FEDERALIST NO. 39, at 240-42 (Clinton Rossiter ed., 1961). The first mature prototype of such a republican form of government, see the Virginia Bill of Rights and Constitution of 1776, reprinted in 9 Hening's Statutes at Large, at 109-19.

25. See THE FEDERALIST NO. 33, at 203-04 (Alexander Hamilton) (Clinton Rossiter ed., 1961); THE FEDERALIST NO. 44, at 285 (James Madison) (Clinton Rossiter ed., 1961). Both Hamilton and Madison agreed that the eighteenth clause of Article I, Section 8, of the United States Constitution, granting Congress the power to enact necessary and proper laws, would have been implied if it had not been expressed. Also, while it allows implied powers, it also imposes implied limits on powers of just legislation. The standard judicial definition of necessary and proper laws is found in *M'Colloch v. Maryland*, 17 U.S. (4 Wheat.) 316, 421 (1819).

26. See THE FEDERALIST NO. 84, at 512-14 (Clinton Rossiter ed., 1961).

27. THE DECLARATION OF INDEPENDENCE para. 1 (U.S. 1776). Sir William Blackstone gave incomparable exposition to the meaning of natural law as the foundation of constitutional government in 1 COMMENTARIES ON THE LAWS OF ENGLAND 38-43 (1765) [hereinafter BLACKSTONE].

expounded in a celebrated case the inherent limitations on general legislative authority under any republican form of government:

The nature and ends of legislative power will limit the exercise of it. This fundamental principle flows from the very nature of our free Republican governments, that no man should be compelled to do what the laws do not require; nor to refrain from acts which the laws permit. There are acts which the Federal, or State, Legislatures cannot do, without exceeding their authority. There are certain vital principles in our free Republican governments, which will determine and over-rule an apparent and flagrant abuse of legislative power; as to authorize manifest injustice by positive law; or to take away that security for personal liberty, or private property, for the protection whereof the government was established.²⁸

There can be no serious dispute as to the nature of the original idea. In view of the transformations accomplished by the American Revolution, general legislative authority was understood to be the power of enacting necessary and proper laws to provide for the common defense and general welfare, in conformity with natural law and legal tradition. And this idea, fully justiciable, was imposed before the Fourteenth Amendment was ever thought of, by the so-called Guarantee Clause in of the United States Constitution, which demands that in and for every State of the Union there shall be a "Republican Form of Government."²⁹

The term "police power" later appeared as a term of jurisprudence in antebellum litigation which arose under the Guarantee Clause, used to describe the legislative powers of the several States to enact regulations of domestic life.³⁰ The Guarantee Clause largely disappeared as a restraint upon the several States as a consequence of misunderstanding the interesting old case of *Luther v. Borden*.³¹ Many generations of judges and lawyers have been deeply confused about it.

In 1842, there was a civil war between two state governments in Rhode Island, each claiming to be lawful.³² Both the majority and the dissent agreed that the court could not resolve this question³³, which was said to be nonjusticiable, because of the enormous

28. *Calder v. Bull*, 3 U.S. (3 Dal.) 386, 388 (1798).

29. U.S. CONST. art IV, § 4.

30. See *Thurlow v. Massachusetts*, 46 U.S. (5 How.) 504, 582-83 (1847).

31. 48 U.S. (7 How.) 1 (1849).

32. See *id.* 34-38, 48-57.

33. See *id.* at 39-47, 51-58.

practical difficulties involved. Thus began the doctrine of political questions which says that a question is nonjusticiable and so cannot be judicially decided if, in the circumstances, a practical remedy cannot be given by the courts, or if there are no objective legal standards upon which a judicial decision can be made, or if the question is plainly referred by fundamental law to the political organs of government or society.³⁴ Nothing could ever be so likely to injure the dignity or reputation of the bench than failure of judges to honor these inherent limits to their power.

But there was another important question in the case which most students have overlooked. This question was whether the charter government of Rhode Island, assumed legitimate, could impose martial law during the unrest which appears in retrospect to have been remarkably trivial. This question was decided on the merits.³⁵ The majority held that the charter government could impose martial law, but there was a strong dissent, mainly based on the Petition of Right.³⁶

In any event, there has never been any reason for saying, as has sometimes been held,³⁷ that any constitutional question arising under the Guarantee Clause is per se nonjusticiable. And a number of courts have occasionally recognized the Guarantee Clause as an appropriate basis of judicial decision,³⁸ as clearly suggested by Justice Samuel Chase when John Adams was President. During the twentieth century, the Guarantee Clause has been a sleeping giant of the United States Constitution, yet there is no reason why, if the need becomes urgent in future years, the giant cannot be awakened and put to good use.

The Fourteenth Amendment followed the American Civil War and has since been the main basis in the United States Constitution for judicial decisions restraining the exercise of police power by the several States. There are some well-kept secrets about the Fourteenth Amendment, which are highly pertinent to the question of police power, and these may conceivably become more widely understood or even become legal orthodoxy in the twenty-first century.

34. See *Baker v. Carr*, 369 U.S. 186, 208-37(1962).

35. See *Luther v. Borden*, 48 U.S. (7 How.) at 46, 58-88.

36. 3 Car. I, ch. 1 (1628).

37. See, e.g., *Taylor v. Beckham*, 178 U.S. 548, 578-79 (1900); *Pacific States Tel. & Tel. Co. v. Oregon*, 223 U.S. 118, 142-53 (1912).

38. See, e.g., *Harrington v. Plainview*, 6 N.W. 777 (Minn. 1880).

In the *Slaughter House Cases*,³⁹ the majority spoke the dark language of police power and upheld a Louisiana statute which required all slaughtering of animals as food for consumption in and around New Orleans to be done in facilities maintained under the auspices of a certain corporation.⁴⁰ The holding rests mainly on a notoriously unconvincing rationalization to accommodate an unwillingness to face the full impact of the Fourteenth Amendment.

The first well-kept secret about the Fourteenth Amendment is found in the four dissenting votes to the *Slaughter House Cases*, which rest mainly on the very capable and powerful opinions of Justice Stephen Field⁴¹ and Justice Joseph Bradley.⁴² Section 1 of the Fourteenth Amendment restrains the several States from abridging the privileges and immunities of citizens of the United States. Most certainly these dissenters were right in maintaining that this clause serves to incorporate all guarantees of civil liberty found in the United States Constitution as further restraints on the several States, including the First through Ninth Amendments.⁴³ And in light of legal tradition, they were right in maintaining that the Fourteenth Amendment, by incorporating the Ninth Amendment, imposes the old Statute of Monopolies⁴⁴ upon the several States.

Another well-kept secret about the Fourteenth Amendment, which may be unpleasant to some people yet ever so true, is that the article was never lawfully adopted,⁴⁵ mainly because it was proposed by a Congress which unlawfully excluded representatives and senators from ten States for having had the temerity of holding views not to the liking of an impassioned and factious majority.⁴⁶ Moreover, adoption was unlawful because ratification by those ten States, essential to adoption, was coerced by keeping them under

39. 83 U.S. (16 Wall.) 36 (1873).

40. *See id.* at 58-82.

41. *See id.* at 83-111.

42. *See id.* at 111-24.

43. It is impossible to attribute any other cogent meaning to this clause in light of *Corfield v. Coryell*, 6 F. Cas. 546 (C.C.E.D. Pa. 1823) (No. 3230), and *Barron v. Baltimore*, 32 U.S. (7 Pet.) 243 (1833).

44. *See* 21 Jac., ch. 3 (1623). The Statute of Monopolies expressly ordained that monopolies granted by the Crown were "contrary to the ancient and fundamental laws of the realm, and are utterly void." *Id.* at § 1. The statute created an express proviso allowing patents of invention for terms of fourteen years. *See id.* at § 6. Royal grants of monopoly had previously been declared unlawful in the *Case of Monopolies*, 11 Coke 84a (K.B. 1603).

45. This unhappy truth has been subject to protest from the most respectable quarters. *See, e.g., Dyett v. Turner*, 439 P.2d 266 (Utah 1968).

46. Such exclusion was unconstitutional for reasons then clearly understood and long since judicially settled. *See, e.g., Powell v. McCormick*, 395 U.S. 486 (1969).

martial law until they ratified,⁴⁷ contrary to principles already known and adjudicated to be unconstitutional.⁴⁸ Because time is a wonderful solvent of truth, we may anticipate that in the twenty-first century the Fourteenth Amendment may well be stricken from the United States Constitution.

The final well-kept secret about the Fourteenth Amendment is this: if and when it is finally acknowledged that the Fourteenth Amendment was never lawfully adopted, we shall not be deprived of means, under the fundamental law of the Union, to restrain the several States from acts of invidious discrimination or other forms of injustice. The reason is that everything worthwhile so far done in the name of the Fourteenth Amendment, and much more besides, can also be done upon a more enlightened view of the American Revolution, in the name of the Guarantee Clause.⁴⁹ *E pluribus unum. Annuit coeptis novus ordo seclorum.*

III. NATURAL LAW JURISPRUDENCE

Between now and the hopeful future of clearer vision, we can use principles common both to the Guarantee Clause or the Fourteenth Amendment as a constitutional restraint on the "police power" of the several States, and we may be guided by judicial decisions rendered under either provision. And for this purpose, especially as it relates to artificial fluoridation of public water supplies, it is important to understand what has been done right, what has been done wrong, and why there has consequently been both progress and deterioration in American jurisprudence.

We first need to understand what has been done wrong and learn from it. With this objective in mind, we need to pay attention to Justice Hugo Black. During his tenure on the United States Supreme Court, Justice Black managed to sow more confusion, yet with important kernels of truth and distinguished erudition, than almost

47. The Reconstruction Act was passed over a veto based on constitutional grounds. See 14 Stat. 428 (1867). The unanswerable veto message of President Andrew Johnson is reprinted in, 1 DOCUMENTS OF AMERICAN HISTORY 481-85 (Henry Steele Commager ed., 9th ed. 1973).

48. Although the Reconstruction Act imposed martial law under circumstances disallowed in *Ex Parte Milligan*, 71 U.S. (4 Wall.) 2 (1866), the constitutional infraction was allowed by systematic evasion of the question by the judiciary. See generally *Texas v. White*, 74 U.S. (7 Wall.) 700 (1869); *Georgia v. Stanton*, 73 U.S. (6 Wall.) 50 (1868); *Ex Parte McCordle*, 73 U.S. (6 Wall.) 318 (1868); *Ex Parte Yerger*, 75 U.S. (8 Wall.) 85 (1868); *Mississippi v. Johnson*, 71 U.S. (4 Wall.) 475 (1867).

49. The possibilities for this development have already been considered in two articles by Arthur E. Bonfield, *Baker v. Carr: New Light on the Constitutional Guarantee of Republican Government*, 50 CAL. L. REV. 245 (1962) and *The Guarantee Clause of Article IV, Section 4: A Study in Constitutional Desuetude*, 46 MINN. L. REV. 513 (1962).

any judicial figure in the world during the twentieth century. His mistakes have pronounced characteristics which are particularly instructive when viewed in retrospect.

His trademark position, stated in his famous dissent in *Adamson v. California*,⁵⁰ was that the Fourteenth Amendment incorporates the Federal Bill of Rights, including the First through Eighth Amendments.⁵¹ But, if the Fourteenth Amendment incorporates the Federal Bill of Rights, it necessarily also incorporates the Ninth Amendment which says that the enumeration of certain rights "shall not be construed to deny or disparage others retained by the people."⁵² Why no mention of the Ninth Amendment?

Throughout his dissent, Justice Black fairly radiated hostility against the ancient and venerable idea of natural law,⁵³ which he plainly did not understand either as a force shaping legal tradition or as a category of jurisprudence.⁵⁴ He acted as if the Ninth Amendment did not exist, because this article of fundamental law, construed in light of constitutional history, cannot possibly exclude those "certain unalienable Rights" with which all human beings are "endowed by their Creator" under the "Laws of Nature and Nature's God."⁵⁵

Justice Black carried his hostility to natural law even further in his majority opinion in *Ferguson v. Skrupa*.⁵⁶ At issue in that case was a Kansas statute prohibiting any person from engaging in the business of debt adjusting, except as incident to the authorized practice of law.⁵⁷ At the time, there was a venerable precedent which held that, under the 14th Amendment, no State has constitutional

50. 332 U.S. 46, 68-123 (1947).

51. The historical evidence supporting this thesis is found in the appendix to Justice Black's opinion. *See id.* at 92-123.

52. This provision was intended to meet the objection of Alexander Hamilton in THE FEDERALIST NO. 84, at 513-14 (Clinton Rossiter ed., 1961), that an enumeration of rights was dangerous, because it might be used as a false pretext to claim power for seizing rights not mentioned. See the observations of James Madison in the United States House of Representatives on June 8, 1789, recorded in 1 ANNALS OF CONGRESS 439-40 (Gales & Seaton 1834).

53. *See Adamson v. California*, 332 U.S. at 79-80, 91.

54. Justice Black was plainly not aware of such distinguished works on natural law as HEINRICH A. ROMMEN, *DIE EWIGE WIEDERKEHR DES NATURRECHTS* (1936), translated as THE NATURAL LAW (Thomas R. Hanley trans., 1955). Hanley's introduction movingly relates how Rommen as a lawyer in Nazi Germany discovered the reality of natural law and was led to reject legal positivism in resisting Hitler's violations of human rights. *See id.* at xi-xxxviii.

55. THE DECLARATION OF INDEPENDENCE para. 1, 2 (U.S. 1776). This language obviously corresponds to those "certain inherent rights" which are mentioned in the first article of the Virginia Bill of Rights of 1776, reprinted in 9 Hening's Statutes at Large, at 109.

56. 372 U.S. 726 (1963).

57. *See id.* at 727.

authority to prohibit a useful business which is not inherently immoral or dangerous to public welfare.⁵⁸ Black flippantly overruled this old case with the remark, "Whether the legislature takes for its textbook Adam Smith, Herbert Spencer, Lord Keynes, or some other is no concern of ours."⁵⁹

Black's attitude was founded upon one of the most unfortunate falsehoods ever to pollute American jurisprudence. He assumed, out of ignorance, that cases like *Lochner v. New York*,⁶⁰ were founded on political prejudice, not legal standards. In *Lochner*, the court held that a law limiting the right of bakers to contract for their hours of work was unconstitutional.⁶¹ No reason was even suggested on the record why bakers should not enjoy such discretion, or why they needed the protection of the law, as might have been true if, say, it had been shown that the bakers are typically in an uneven bargaining position in dealing with their employers. If such a showing had been at least attempted, as might well have been easily done, the statute would certainly have been upheld.⁶²

It is true that the freedom to contract, cited as the justification for holding the statute unconstitutional, came from natural law jurisprudence. But the theory was not woven out of thin air. It came from venerable and historic roots, ultimately the decision of Lord Mansfield in *Sommersett's Case*⁶³ which held that, because slavery runs against natural law, it could be sustained only by acts of Parliament,

58. See *Adams v. Tanner*, 244 U.S. 590 (1917). As with many other cases like it, this case turned on the clause of the Fourteenth Amendment which forbids any state from denying life, liberty, or property without due process of law. The clause is ultimately traceable to the 39th Article of the Magna Carta of King John. It was probably added to the Fourteenth Amendment to cure the unfortunate holding of the majority in *Satterlee v. Matthewson*, 27 U.S. (2 Pet.) 380 (1829), and drew inspiration from cases such as *University of North Carolina v. Fox*, 5 N.C. (1 Mur.) 83 (1805).

59. 372 U.S. at 732. This case echoed of the thoughtless satyrism of Oliver Wendell Holmes in *Lochner v. New York*, 198 U.S. 45, 75 (1905) ("The Fourteenth Amendment does not enact Mr. Herbert Spencer's Social Statics"). Under this theory, we should be equally indifferent as to whether the legislature of a State were to take guidance from Maximilien de Robespierre, Vladimir Lenin, Adolf Hitler, Joseph Stalin, Mao Tse Tung, or Pol Pot.

60. 198 U.S. 45 (1905).

61. See *id.* at 64-65.

62. Pope Leo XIII issued the encyclical *Rerum Novarum* (1891), which was one of the greatest statements on natural law in history. He expounded rights of labor and the duty of governments to enact legislation protecting labor from unjust exploitation. It was on this basis that legislation protecting labor from unjust exploitation was repeatedly approved as constitutional in natural law jurisprudence, whenever a plausible justification of legislative judgment was made to appear on the record. See, e.g., *Bunting v. Oregon*, 243 U.S. 426 (1917); *Muller v. Oregon*, 208 U.S. 412 (1908); *Holden v. Hardy*, 169 U.S. 366 (1898).

63. 20 How. St. Tr. 1, 82 (K.B. 1771).

and all statutes allowing it had to be strictly construed so as to make a slave free the moment he set foot on the free soil of England.⁶⁴

This idea was, of course, adopted and expanded by the Thirteenth Amendment. It follows, by legal inference, that nobody in the United States may be denied a liberal right to earn a livelihood or to engage in business as he or she sees fit. Thus, it has been held under the Fourteenth Amendment that, unless a statute limiting the right of a citizen to contract freely can be plausibly justified, it is unconstitutional.⁶⁵ The idea does not embrace irresponsible freedom and it does not outlaw legislation to prevent unjust exploitation of labor or activity harmful to the public good. The right is confirmed by natural law and legal tradition and is suited to the circumstances of a free people. There has always been just cause to apply this notion with judicious caution,⁶⁶ but there never has been any reason to reject or overrule it altogether.⁶⁷

Black took his extremism to the *ne plus ultra* in his bitter dissent in *Griswold v. Connecticut*.⁶⁸ Complaining that natural law is mysterious and uncertain and that the Ninth Amendment has only nominal but no substantive meaning, Black insisted that even a statute intruding into the sexual intimacy of husband and wife, disallowing them to be instructed by their physician on artificial methods of birth control, could not be struck down as unconstitutional.⁶⁹ Fortunately, his fellow justices had no trouble in

64. This principle originated in the policy of the common law which favored liberty, and thus nudged villeinage into extinction. See, e.g., *Figg v. Caley*, Noy 27 (K.B. 1618). Strict construction of laws allowing slavery was adopted by judges of the old South, and many slaves were freed because of it. See, e.g., *Murray v. M'Carty*, 16 Va. (2 Mun.) 393 (1811). It was also applied by the circuit court of Missouri in granting Dred Scott and his family their freedom, and was the main basis of the dissent of Justice Benjamin Curtis in *Dred Scott v. Sandford*, 60 U.S. (19 How.) 391, 602-603 (1857).

65. See *Allgeyer v. Louisiana*, 165 U.S. 578 (1897).

66. So as to avoid unfortunate decisions like *Coppage v. Kansas*, 236 U.S. 1 (1915), which was simply a mistake. No apology can be offered for it in any school of thought.

67. *Nebbia v. New York*, 291 U.S. 502 (1934), is sometimes cited as the beginning of the end of natural law jurisprudence in the field of economic regulation, but the case is better understood as a just extension of *Munn v. Illinois*, 94 U.S. 113 (1877), in light of pressing economic circumstances not existing at the time of *Fairmont Creamery Co. v. Minnesota*, 274 U.S. 1 (1926). Likewise, *West Coast Hotel Co. v. Parrish*, 300 U.S. 379 (1937), is often cited as the definitive end of natural law jurisprudence in the field of economic regulation. Yet in *Parrish*, the majority disregarded the intended meaning of the Nineteenth Amendment as expounded in *Adkins v. Children's Hospital of the District of Columbia*, 261 U.S. 525, 552-53 (1923), and later revived in *Frontiero v. Richardson*, 411 U.S. 677, 686-88 (1977). *Parrish* allowed a kind of sex discrimination which would never be allowed today and may be considered virtually overruled.

68. 381 U.S. 479, 507-27 (1965).

69. See *id.* at 523-25.

understanding privacy as a liberty protected by fundamental law, and they declared the statute unconstitutional.⁷⁰

If Hugo Black condemned natural law because he did not understand it, the founding fathers of the United States did understand it, and they built a new constitutional order upon it. They knew that natural law is a timeless moral and physical order which enforces itself and can be discovered by natural reason.⁷¹ They knew that it constrains governments no less than markets. They knew that, if its lofty commands were disobeyed, there would be misfortunes in public affairs, requiring the accommodations of temporal law. They knew, therefore, that natural law was elaborated and given objective form by legal tradition.

The dissenters in the *Slaughter House Cases* rested their erudite opinions on the facts of history. They did not make things up to suit their political fancies but relied instead on legal custom acknowledged by the King's Bench and an organic statute of the English Parliament. In light of long experience, it became clear in the past, as it is impossible to deny today, that, by the wonderful operation of unseen but undeniable forces of nature, the practice of monopoly creates painful economic congestions. So it was that legal tradition accommodated and expressed the reality of natural law.

Likewise, if the statute in *Griswold* had not been left to fade in desuetude, but had been actively enforced, Connecticut would have faced political upheaval or revolution. Hence, the reality of natural law, which, fortunately, did not produce unhappy consequences, but only because prosecutors had the good sense not to file accusations, and the statute was eventually found unconstitutional. In this way temporal law honored privacy as an unenumerated constitutional immunity which had always existed by natural law. After transi-

70. See *id.* at 484-86 (penumbras of the Bill of Rights), 498-99 (the Ninth Amendment), 500-04 (due process of law under the Fourteenth Amendment). By acknowledging a constitutional right of privacy on the basis of natural law jurisprudence, the Court in no way committed itself to *Roe v. Wade*, 410 U.S. 113 (1973), which did not rest on natural law jurisprudence but rather overthrew the traditional protection of the unborn by both the common law and the civil law. See *e.g.*, *Thulluson v. Woodford*, 4 Ves. Jr. 227, 321-22 (Ch. 1799); *Montreal Tramways v. Leveille*, [1933] 4 D. L. R. 337, 340-41 (Can.). Nor did the Court contradict the moral teaching of Pope Paul VI against artificial birth control in the encyclical *HUMANE VITAE* (1968). Natural law jurisprudence actually restrains temporal law from attempting to prohibit some activities, especially those of a private nature, which, right or wrong, are not proper subjects for public regulation. See, *e.g.*, THOMAS AQUINAS, *SUMMA THEOLOGICA*, Ia IIae, q. 93, art. 3, ad 3, translated in, *BASIC WRITINGS OF SAINT THOMAS AQUINAS*, 766 (Anton Pegis ed. 1945).

71. For abundant references to natural law, see the opening passages of *THE DECLARATION OF INDEPENDENCE* (U.S. 1776) and the corresponding language of Sir William Blackstone, *supra* note 27, at 38-43.

tions and adjustments, legal tradition will mature into a sturdier and sounder landmark which can be used with greater wisdom and confidence in future years.

IV. HEALTH FREEDOM

One of the most distinguished civil liberties decisions of the twentieth century, never overruled and often cited,⁷² rests on the opinion of Justice James McReynolds in *Meyer v. Nebraska*.⁷³ Citing the duty of government to promote education, founded on the Northwest Ordinance, McReynolds struck down as unconstitutional under the Fourteenth Amendment a law prohibiting the teaching of German to children in the primary grades of public schools in Nebraska. His general formula is particularly worthy of notice:

While this court has not attempted to define with exactness the liberty thus guaranteed, the term has received much consideration, and some of the included things have been definitively stated. Without doubt, it denotes not merely freedom from bodily restraint, but also the right of the individual to contract, to engage in any of the common occupations in life, to acquire useful knowledge, to marry, to establish a home and bring up children, to worship God according to the dictates of conscience, and, generally, to enjoy privileges long recognized at common law as essential to the orderly pursuit of happiness by free men.⁷⁴

It is noteworthy that Sir William Blackstone mentioned the "preservation of man's health from such practices as may prejudice or annoy it" not as a legislative power, but as among "absolute rights of individuals,"⁷⁵ -- in other words, as among "those privileges long recognized at common law as essential to the orderly pursuit of happiness by free men."⁷⁶

Therefore, it is clear enough that there are natural rights protected by fundamental law, even if not constitutionally enumerated. As there are such natural rights to marry and have children, to seek knowledge, to enjoy personal privacy, and to earn a livelihood by honest work of choice, subject only to such regulation as may be reasonably needed to protect the rights of others and the common good, so too there is a domain of personal freedom, which limits the

72. See, e.g., *Griswold v. Connecticut*, 381 U.S. at 481-82, 495, 502.

73. 261 U.S. 390 (1923).

74. See *id.* at 399-400.

75. BLACKSTONE, *supra* note 27, at 134.

76. 261 U.S. at 400.

"police power" of a State in regulating health. It is an area given some but not full judicial development in the twentieth century.

Two classic cases stand out like beacons, the first being *Jacobson v. Massachusetts*,⁷⁷ in which a citizen challenged a statute compelling small pox vaccinations to counteract a pending epidemic of deadly disease. The act of the legislature was upheld under the Fourteenth Amendment. The holding is understandable, because the statute addressed a public danger, and failure to comply might have tangibly increased the chances that an offender might become a carrier of disease which thereby could infect others. Public emergency has always justified intrusions, even upon incomplete knowledge, which normal situations will not.

Of much interest in this case is the discussion of the fact that, while the general belief of the legislature on the need for smallpox vaccinations was supported by respectable medical authority, there was nevertheless responsible dissent within the medical profession over the efficacy and in some degree even of the safety of this particular measure. In *Jacobson*, the court reasoned, "The possibility that the belief [favoring smallpox vaccinations] may be wrong, and that science may yet show it to be wrong is not conclusive; for the legislature has the right to pass laws which, according to [reasonable belief] are adapted to prevent the spread of contagious diseases."⁷⁸

No less of interest is an exception to the general principle of the judgment. The court plainly said that the statute could never be interpreted to compel a vaccination where it could be shown "with reasonable certainty" that application of the statute to an objecting citizen "would seriously impair his health or probably cause his death."⁷⁹ This observation was added as an essential feature of the *ratio decidendi* to avoid misinterpretation.

The court did not define what exactly it meant in saying that a statutory regulation of public health may not be extended to situations in which serious impairment of personal health is shown with "reasonable certainty." But this characteristic phrase has long been a term of art in the law of damages. It has long been used to

77. 197 U.S. 11 (1905).

78. *Id.* at 35. Language has been substituted in brackets for the phrase "the common belief of the people" in the opinion, because the obvious intent of the court was that the belief of the legislature acting on behalf of the people must at least be reasonable in view of available knowledge and evidence. The court said, "if a statute purporting to have been enacted to protect the public health, the public morals, or the public safety, has no real or substantial relation to those objects," then it is the duty of the judiciary to intervene and declare such statute unconstitutional. *Id.* at 31.

79. *Id.* at 39.

describe the legal standard of proving an injury in civil proceedings: while damages may not be based on speculation or guess, it will be enough to show the approximate degree of harm by fair preponderance of the evidence adduced in a judicial hearing.⁸⁰ And, in such case, injury may be proved by the opinions of experts who can demonstrate that they are well informed on the subject investigated.⁸¹

The other outstanding case on generic principles of health freedom is *Toronto v. Forest Hill*,⁸² in which the majority opinion was written by Justice Ivan Rand, who was probably the most eminent jurist on the Supreme Court of Canada, in any event one of the finest natural law judges in the world, during the twentieth century.⁸³ This case arose under the British North America Act of 1867, before it was possible, except on a very limited basis,⁸⁴ for the judiciary of Canada to strike down acts of the dominion Parliament or of the provincial Legislatures as unconstitutional and thus null and void.⁸⁵ The judiciary of Canada was then obliged to protect civil liberties by strict construction of statutes, as far as possible, so as to avoid collision with natural law and legal tradition.⁸⁶ It was by

80. See, e.g., *Bigelow v. RKO Radio Pictures Inc.*, 327 U.S. 251 (1946); *Story Parchment Co. v. Paterson Parchment Paper Co.*, 282 U.S. 555 (1930); *Eastman Kodak Co. v. Southern Photo Material Co.*, 273 U.S. 359 (1927).

81. See, e.g., *Julian Petroleum Corp. v. Courtney Petroleum Co.*, 22 F.2d 360, 362 (9th Cir. 1927).

82. [1957] 9 D.L.R. 2d 113 (Can.).

83. See, e.g., Michael Schneiderman, *The Positivism of Hugo Black v. The Natural Law of Ivan Rand: A Study in Contrasting Judicial Philosophies*, 33 SASKATCHEWAN LAW REV. 267 (1968). Another great natural law jurist in Canada during the twentieth century was Chief Judge Jules Deschenes of the Superior Court of Quebec. See, e.g., *Nissan Auto. Co. v. Pelletier*, 77 D.L.R. 3d 646 (Que. 1976).

84. Mainly where statutes were enacted contrary to the organic provisions of the British North America Act of 1867, as held by the British Privy Council in *In re Initiative and Referendum Act* [1919] App.Cas. 935, and the Supreme Court of Canada in *Saumer v. Quebec*, [1953] 4 D.L.R. 641 (Can.).

85. The situation has since changed beginning with the Canadian Bill of Rights of 1960, an organic statute of the dominion Parliament, which unlike the English Bill of Rights of 1689, was more than a venerable guide for the interpretation of statutes. In *Queen v. Drybones* [1970] 9 D.L.R. 3d 473 (Can.), the Canadian Bill of Rights of 1960 was held to be a statutory directive to restrain federal laws from operation. Later came the Canadian Charter of Rights and Freedoms consisting of sections 1 through 35 of the Constitution Act of 1982, which restrains the federal and provincial governments, and cannot be repealed by legislative act. Even so, section 33 of the Constitution Act of 1982 concedes to legislative power the prerogative of making statutes operable for five-year intervals, notwithstanding important provisions of the Canadian Charter. The Constitution Act of 1982 is part of the Canada Act of 1982, an organic statute of the British Parliament which renounced the last vestiges of imperial control over Canada.

86. Lord Coke held in *Dr. Bonham's Case*, 8 Coke 114a (C.P. 1610), that the courts of common law could declare acts of Parliament null and void. This doctrine was overthrown on the weight of the principle that the Commons, Lords, and King in Parliament are omnipotent and sovereign, and that, therefore, the judiciary cannot declare an act of Parliament null and void. Even so, the judges can and must construe acts in keeping with the principle that the

using such conservative yet effective principles that Justice Rand became distinguished as a civil libertarian on the bench.

In *Forest Hill*, a provincial law allowed municipal corporations to treat public water supplies so as to make the vended water "pure and wholesome."⁸⁷ Justice Rand construed this statute strictly, so as to disallow fluoridation. He protested,

But it is not to promote the ordinary use of water as a physical requisite for the body that fluoridation is proposed. That process has a distinct and different purpose; it is not a means to an end of wholesome water for water's function but to an end of a special health purpose for which water supply is made use of as a means.⁸⁸

Similar language appears in the concurring opinion of Justice Cartwright, regarding the municipal by-law to initiate fluoridation then in question:

In pith and substance the by-law relates not to the provision of a water supply but to the compulsory preventative medication of the inhabitants of the area. In my opinion, the words of the statutory provisions on which the appellant relies do not confer upon the council the power to make by-laws in relation to matters of this sort.⁸⁹

Jacobson and *Forest Hill* expound complementary principles of natural law jurisprudence, and thereby supply a cogent idea of health freedom which is inherent in the respected constitutional formulation expressed in *Meyer v. Nebraska*.⁹⁰

Under the Guarantee Clause, the Ninth Amendment, and the Fourteenth Amendment, understood in light of natural law and legal tradition, "police power" to regulate public health includes discretion to compel submission of citizens to medical intervention, but only if three necessary conditions are met. First, legislative judgment underlying the statute may discount responsible professional dissent,

King can do no wrong, and thus that all acts of Parliament must be construed, if possible, in keeping with natural law and legal tradition. The judges should do so, even if they must read statutes *quoad hoc* or contrary to their literal meaning in unusual situations. See, e.g., BLACKSTONE, *supra* note 27, at 91, 160, 246.

87. *Forest Hill*, 9 D.L.R. 2d at 114-15.

88. *Id.* at 118. The same distinction appears in the Safe Drinking Water Act, 42 U.S.C. § 300g-1(b)(11), which states, "No national primary drinking water regulation may require the addition of any substance for preventative health care purposes unrelated to contamination of drinking water." This provision was intended by Congress to prohibit the use of the Safe Drinking Water Act as a means of imposing artificial fluoridation of public water supplies throughout the United States.

89. *Id.* at 124.

90. 261 U.S. 390 (1923).

yet must at least rest upon reasonable medical or scientific evidence. Second, it must be fairly justified by grave cause or public emergency, such as the need to prevent the spread of a contagious disease. Third, the intervention prescribed cannot be imposed upon protesting citizens who are able to prove, by a fair preponderance of the evidence, a tangible danger of serious injury to their health. But the legislative power cannot otherwise impose compulsory medication on protesting citizens. This much is the ideal of natural law jurisprudence which is inseparable from the intended meaning of the United States Constitution.

V. THE KEY DECISIONS SUSTAINING FLUORIDATION

It is not our purpose to provide a general review of all judicial decisions that have touched upon the constitutionality of imposing fluoridation on the general public.⁹¹ Suffice it to say that the great majority of cases sustain it, we think wrongly, but there can be no doubt about the clear trend of American jurisprudence.

Our objective here is to note highly important developments in the last twenty-five years, which strenuous efforts have been made to camouflage behind smiling propaganda orchestrated by the ADA and the USPHS to promote fluoridation, as if all were well. In fact an end to this episode of public health malpractice is foreseeable. If we consider scientific and legal revolutions of the past, say from the discovery of the true cause of puerperal fever by Dr. Ignaz Semmelweiss until his eventual posthumous vindication, or in the development of freedom of the press from the founding of the Star Chamber to the adoption of the First Amendment, we should not be astonished to see the passing of considerable time in the rise and fall of fluoridation, and not a little confusion along the way.

Among all others, the most distinguished judgment sustaining the constitutionality of mandatory fluoridation of public water supplies has always been, and still is *Paduano v. City of New York*,⁹² which arose upon a suit brought in 1965 to enjoin the practice in New York City.⁹³ At that time the clear weight of available medical and scientific evidence, then respectable but long since shown to be

91. A recent article reviewing many such cases is by Douglas Balog, *Fluoridation of Public Water Systems: Valid Exercise of State Police Power or Constitutional Violation?*, 14 PACE ENVTL. L. REV. 645 (1997).

92. 257 N.Y.S. 2d 531 (S.Ct. N.Y. County 1965), *aff'd* 24 App. Div. 2d 437, 260 N.Y. S. 2d 831 (1965), *aff'd* 17 N. Y. 2d 875, 271 N. Y. S. 2d 305 (1966), *cert. denied* 385 U.S. 1026 (1967).

93. *See id.* at 533.

unfounded,⁹⁴ suggested that fluoridation was effective in reducing tooth decay in children.⁹⁵ Evidence of potential danger then existed,⁹⁶ but it was little known, in an undeveloped state, and effectively concealed by ADA-USPHS disinformation.⁹⁷ Most physicians and dentists then believed that fluoridation was beneficial and safe. It is fair to say that most available evidence -- at least what could be easily orchestrated into a courtroom appearance of the most available evidence -- then suggested that fluoridation was beneficial and safe.

True enough, then available evidence suggested the need for caution among the wise. But there were not many in those days who had good credentials, independent means, leisure time for deep study, the persuasiveness to expose the slick sales pitches of ADA-USPHS spokesmen, the capacity to survive assaults on their careers and reputations mounted by fluoridation promoters,⁹⁸ -- and wisdom besides.

It is wrong to justify fluoridation by reference to *Jacobson*, because fluoridation, unlike small pox vaccinations, does not address a contagious disease, but it is at least understandable that the Supreme Court of New York should have cited it as persuasive legal authority.⁹⁹ The court said:

The question of the desirability of fluoridation is immaterial. In the face of the overwhelming precedents previously cited, and in accordance with general principles of stare decisis, this court sitting at Special Term, feels constrained to deny plaintiffs' application for a temporary injunction and to grant defendants' motion for a dismissal of the complaint. *Until the scientific evidence as to the deleterious effects of fluoridation reaches beyond the purely speculative state now existing, decisional law mandates the holding that the controversy should remain within the realm of the legislative and executive branches of government. While the courts do not have a right to impose fluoridation upon anyone, judicial restraint requires us to adhere to the uniform decisions holding that the executive and legislative branches of government do -- at least*

94. See Kalsbeek & Verrips, *supra* note 8; Ziegelbecker, *supra* note 10; Kumer, *supra* note 8; Imai, *supra* note 9; Colquhoun, *supra* note 11; Yiamouyiannis, *supra* note 12, and accompanying text.

95. See, e.g., Hillboe et al., *supra* note 4, at 314-24.

96. See Taylor, *supra* note 16, and accompanying text.

97. See, e.g., Hillboe et al., *supra* note 4; HARRIS, *supra* note 18, and accompanying text.

98. Literally volumes could be written on the notorious and ruthless tactics of fluoridation promoters seeking to silence all credible opposition. A sober and factual introduction to this subject of political intrigue can be found in WALDBOTT, ET AL., *supra* note 1, at 258-352.

99. *Paduano v. New York*, 257 N.Y.S. 2d 531, 539 (S. Ct. N.Y. County 1965).

until some proof is adduced that fluoridation has harmful side effects and therefore is not in the interests of the community.¹⁰⁰

The court obviously had in mind the qualifying dictum in *Jacobson* that a public health regulation, obliging a citizen to accept a medical remedy, cannot be extended to a situation in which it is shown with reasonable certainty, or by a fair preponderance of the evidence exceeding speculation or guess, that the remedy will impose a danger of serious injury to the personal health of protesting citizens. Note clearly what the court did not say, should not have said, and, in light of its reliance on *Jacobson*, cannot be interpreted to have said: -- that such danger or injury must be proven by evidence so powerful as to eliminate all reasonable controversy on the subject. Such a burden of proof is legally impossible on any question of public health, nor does it comport with public justice or safety, nor does it have any legitimate basis in legal authority.

Another key judgment sustaining imposed fluoridation merits passing notice because it concerns legal ideals of the type suggested by the natural law jurisprudence of Ivan Rand. In *State Board of Health v. Brainerd*,¹⁰¹ a mandatory fluoridation law was applied to a community which protested as a whole body politic in a special referendum¹⁰² by a vote of 9 to 1 against implementing the law, and by a vote of 5 to 1 authorizing the city fathers to sit as a convention which met and declared the statute unconstitutional.

The state board of health sued the municipal government which pleaded the express and formal protest of the residents and voters of the city, the want of a public emergency occasioned by a pending epidemic of contagious disease, the existence of a responsible medical and scientific controversy over the effectiveness and safety of fluoridation, the availability of fluoride to persons desiring it by less intrusive means, and, therefore, the invasion of a natural right of the people, protected by fundamental law under these circumstances, to enjoy freedom of choice in maintaining personal health.¹⁰³ The Minnesota Supreme Court upheld the constitutionality of the mandatory fluoridation law, and sustained the writ of mandamus

100. *Id.* at 542 (emphasis added).

101. 241 N.W.2d 624, 626 (Minn. 1976), *appeal dismissed* 429 U.S. 803 (1976).

102. See *State Board of Health v. City of Brainerd*, No. 38183, Respondents' Answer, part VII, plea in avoidance, filed Oct. 31, 1974 (Crow Wing County District Court, Minn.). Judge John Alexander Jameson expressed his warm approbation of such citizen assemblies in his classic *TREATISE ON CONSTITUTIONAL CONVENTIONS* 4-5 (4th ed. 1887, reprint 1972).

103. See *City of Brainerd*, Respondent's Answer, part VIII, plea in avoidance and demurrer, filed Oct. 31, 1974.

ordering city officers to implement the statute.¹⁰⁴ But there was a compelling dissent that speaks to the future.¹⁰⁵

If it can be established "with reasonable certainty" that fluoridation is dangerous to human health, and has caused massive injury to the health of the American people, two very important legal consequences should ultimately follow: (1) the standard of unconstitutionality set forth in *Jacobson* and *Paduano* will have been met, and fluoridation will be unlawful throughout the United States; and (2) the wisdom of a broader constitutional principle of health freedom, envisioned by the majority in *Forest Hill* and the dissent in *Brainerd*, will then be evident, and its eventual judicial recognition as a blessing of liberty may be anticipated for our children, grandchildren, and great grandchildren.

VI. THE EPIDEMIOLOGICAL EVIDENCE

The question now to be addressed is whether, in keeping with *Jacobson* and *Paduano*, it can be proved with "reasonable certainty" in judicial proceedings that fluoridation is dangerous to public health by causing cancer and other ailments in man. In assessing trends in human cancer, we have two main sources of information which can be used as evidence.

Laboratory studies enable us to view a disease at the molecular and cellular levels, and to consider reactions in living plants, insects and animals. The advantage of laboratory studies is that precise experimental conditions can be designed and implemented to control for known and unknown variables, which is critical in the identification of causal operations in the empirical sciences.¹⁰⁶ Whatever legitimate doubt may once have been voiced on the subject, it is now abundantly clear that a significant body of laboratory research reveals carcinogenic potential in fluoride artificially introduced in water at 1.0 ppm.¹⁰⁷

The disadvantage of laboratory studies is that some caution is required in extrapolating results to human beings, and here is where

104. See *Brainerd*, 241 N.W.2d at 629-34.

105. See *id.* at 634-35.

106. Sir Francis Bacon expounded this demand of inductive logic in the third, fourteenth, nineteenth, twenty-second, eighty-second, and ninety-ninth aphorisms in Book I of *Novum Organum*. The meaning of these aphorisms is discussed in 3 COPELSTON, A HISTORY OF PHILOSOPHY, pt. II, 112-22 (1963) [hereinafter COPELSTON].

107. See, e.g., Taylor, *supra* note 16; Taylor & Taylor, *supra* note 20; sources cited *supra* note 21.

epidemiology comes into the picture. Epidemiology is the branch of medicine which studies the diseases of man in his actual environment. If the controls in epidemiological surveys are not as precise, the results are more pertinent to human experience. Therefore, both laboratory studies and epidemiological surveys can profitably be considered together, and, when parallels between them become striking, causal relationships between agents in the environment and human disease can be more readily identified and explained.

Hence the question: Has the carcinogenic potential of fluoride observed in laboratory studies been reflected in human experience? The answer, based on very extensive epidemiological data, is certainly in the affirmative.¹⁰⁸ This fact removes the speculative character of objections previously expressed by physicians and other learned persons when the world first hailed fluoride as a wonder of modern science.

The leader in gathering pertinent epidemiological data and organizing it in a usable form was Dr. Dean Burk, who retired in 1974 as the head of the cytochemistry section of the National Cancer Institute (NCI) of the United States.¹⁰⁹ In his time, he was one of the most famous cancer research scientists in the world. He was well read, highly cultured, disarmingly humble, and had a delicious sense of humor. But standing out above every other trait was his ability to view a problem of empirical observation with clear insight and to give reality, as he put in conversation with those who knew him, "the simplest rational expression."¹¹⁰

108. The most important versions of the epidemiological data here in question, including reference to related laboratory studies, and conventional adjustments for age, race, and sex, are the following: Dean Burk & John Yiamouyiannis, *Fluoridation and Cancer: Age Dependence of Cancer Mortality Related to Artificial Fluoridation*, 10 FLUORIDE 123 (1977) [hereinafter Burk & Yiamouyiannis]; Dean Burk and J. R. Graham, *Lord Jauncey and Justice Flaherty: Opposing Views of the Fluoridation-Cancer Link*, 17 FLUORIDE 63 (1984) [hereinafter Burk & Graham]; Pierre Morin et al., *Les fluorures versus le cancer et les maladies congénitales: l'image globale*, GOUVERNEMENT DU QUÉBEC, MINISTÈRE DES AFFAIRES SOCIALES (1984); Pierre Morin et al., *Fluorides, Water Fluoridation, Cancer, and Genetic Diseases*, 12 SCI. & PUB. POL'Y 36 (1985); Rudolf Ziegelbecker, *Zur Frage eines Zusammenhanges zwischen Trinkwasserfluoridierung, Krebs, und Leberzirrhose*, 218 GWF WASSER/ABWASSER 111 (1987); Dean Burk et al., *A Current Restatement and Continuing Reappraisal Concerning Demographic Variables in American Time-Trend Studies on Water Fluoridation and Human Cancer*, 61 PROC. PA. ACAD. OF SCI. 138 (1988) [hereinafter Burk, Graham, & Morin].

109. See WHO'S WHO IN THE WORLD 1974-1975 161 (2d ed., Marquis Who's Who, Inc., 1975); *National Cancer Program (Part 2), Hearings Before the Subcomm. of the Comm. on Government Operations, 95th Cong.* 471 (1977) [hereinafter *National Cancer Program*].

110. Dr. Burk's capacity to view and characterize phenomenal reality is illustrated in his trademark paper, Dean Burk & Hans Lineweaver, *The Determination of Enzyme Dissociation Constants*, 56 J. AM. CHEM. SOC'Y 658 (1934), which has been one of the most often cited and discussed papers in biochemistry during the twentieth century.

The epidemiological work here in question was done under the direction of Dr. Burk from his retirement until his death in 1988. As with so much of his work before his retirement, he was years ahead of his time.

On December 16, 1975, Congressman James Delaney of New York inserted into the *Congressional Record* data gathered and organized under the direction of Dr. Burk, showing a striking association between fluoridation and cancer.¹¹¹ It is important to appreciate the basic data, because it was the principal and decisive focus of the judicial hearings that followed.¹¹²

The year-by-year average observed cancer death rates of ten large central cities of the United States, which served as the control group and remained unfluoridated from 1940 through 1968, were compared for the years 1940 through 1968 with the year-by-year average observed cancer death rates of ten large central cities of the United States which served as the experimental group and remained unfluoridated from 1940 through 1951, but fluoridated between 1952 and 1956, and remained fluoridated through 1968 and thereafter.¹¹³ The experiment came to an end in 1968 because fluoridation was introduced in the control cities step-by-step from and after 1969. The necessary data are available for all years except for 1951 and 1952.

The central cities in question are all very large, comparable in size, and spread out across the whole country. In the control group were: Los Angeles; Boston; New Orleans; Seattle; Cincinnati; Atlanta; Kansas City (Missouri); Columbus (Ohio); Newark; and Portland.¹¹⁴ In the experimental group were: Chicago; Philadelphia; Baltimore; Cleveland; Washington D.C.; Milwaukee; St. Louis; San Francisco; Pittsburgh; and Buffalo.¹¹⁵

Roughly speaking, the comparison is between about seven million people in the ten control cities and about eleven million people in the ten experimental cities over about thirty years.¹¹⁶

¹¹¹ See 121 CONG. REC. 40773-75 (1975).

¹¹² The technical particulars of the selection, derivation, and arrangement of the basic data are precisely described in the method section of Burk & Yiamouyiannis, *supra* note 108, at 103-05, and Burk, Graham, & Morin, *supra* note 108, at 138-39.

¹¹³ See Burk & Yiamouyiannis, *supra* note 108, at 104; Burk, Graham, & Morin, *supra* note 108, at 138.

¹¹⁴ See Burk & Yiamouyiannis, *supra* note 108, at 104; Burk, Graham, & Morin, *supra* note 108, at 138.

¹¹⁵ See Burk & Yiamouyiannis, *supra* note 108, at 104; Burk, Graham, & Morin, *supra* note 108, at 138.

¹¹⁶ See Burk, Graham, & Morin, *supra* note 108, at 139.

There has hardly ever been a published epidemiological study using so much data, arranged in such powerful experimental design.

The basic data can be expressed as unweighted averages (giving each city equal weight, regardless of size) and as weighted averages (giving each city weight according to size). All cancer death rates here discussed are expressed as so many cancer deaths per 100,000 persons.

The basic data are given in detail in the appendix of this article.¹¹⁷ For the sake of convenience an observed or crude cancer death rate for all sites in an entire population will be designated as CDRo. It does not matter in this case whether unweighted or weighted averages are used. The pattern is numerically and visibly the same, and the differences emerging from mathematical analysis of the figures for the two types of averages are trivial. Either way the possibility of chance occurrence is far less than 1 in 1000. The weighted averages will be used here because weighted averages have been used by all critics of Dr. Burk's work, and Dr. Burk frequently used weighted averages himself.

The data are arranged in standard experimental design, comparing like with like along a base line from 1940-50 in which cancer death rates grew equally, then continuing the comparison after fluoridation was introduced in the experimental cities. It was after fluoridation began that there was a pronounced acceleration in cancer mortality in the experimental group (+F) as compared with the control group (-F). The resulting association between fluoridation and cancer can be conveniently quantified by linear regression¹¹⁸ analysis for the data for 1940-50, also for 1953-68 then extending the resulting lines to achieve values for 1950 and 1970.¹¹⁹

117. The figures and tables set forth in the appendix are taken from Burk, Graham, & Morin, *supra* note 108, at 139-40. The basic data can be recapitulated by any informed and impartial investigator drawing from census figures and vital statistics published by the government of the United States.

118. Linear regression is a standard technique in statistics for characterization of a field of points on a two-dimensional graph as a straight line. This line is so drawn that the sum of the squares of the distances of the several points to the line is the lowest possible number. Such line is assumed in the product moment formula for the linear correlation coefficient, designated "r" to express the degree of association between the two axes. By use of related operations, a statistical confidence level, represented by the coefficient "P" can be derived. P determines the extent to which an observed association may or may not have occurred by chance. The subject is discussed in standard textbooks. See, e.g., SIR AUSTIN BRADFORD-HILL, A SHORT TEXTBOOK OF MEDICAL STATISTICS 161-67, 173-80 (10th ed. 1977); MURRAY SPIEGEL, THEORY AND PROBLEMS OF STATISTICS 218-20, 226-28, 244-45, 253-54 (1961).

119. See Burk & Graham, *supra* note 108, at 65; Burk, Graham, & Morin, *supra* note 108, at 142-43.

	1940	1950	1950	1970
CDRo(+F)	154.2	181.8	186.3	222.6
CDRo(- F)	153.5	181.3	183.6	188.8

The size of the association between fluoridation and cancer can be expressed as follows: $[(222.6-188.8) - (186.3-183.6)] + [(154.2-153.5) - (181.8-181.3)]$ or 31.3 excess cancer deaths per 100,000 persons exposed within fifteen to twenty years after fluoridation began in the experimental group of cities. If this figure is multiplied against 130 million Americans who have been drinking fluoridated water over the past fifteen to twenty years or more, an excess of over 40,000 cancer deaths in the United States every year is attributable to fluoridation.

Not long after the foregoing figures were first called to the public's attention, Dr. Burk was called to testify before Congress on April 6, 1976. And testify he did:

Oliver Wendell Holmes Sr., M.D., of Civil War medical fame, and professor of anatomy at Harvard University, in 1843 and 1855 described then prevailing treatment of puerperal fever in lying-in hospitals as criminal manslaughter. It was only manslaughter, however, not murder because the physicians of that day did not have, and could not have had a sufficiently knowledgeable idea of the bacteriological basis of the doctor-nurse-patient transmission of the disease until the work of Pastuer and Lister decades later.

The scientific and medical status of artificial fluoridation or public water supplies has now advanced to the stage of the possibility of socially imposed mass murder on an unexpectedly large scale involving tens of thousands of cancer deaths of Americans annually.¹²⁰

The shock resulting from this firm statement by a world-renowned cancer research scientist evoked an emergency response from the USPHS. Needless to say, the USPHS did not admit that they had exposed the American people to an environmental hazard which produced "tens of thousands of cancer deaths of Americans annually." As night follows day, they claimed that Dr. Burk had failed to take elementary precautions.¹²¹

120. *Departments of Labor and Health, Education, and Welfare Appropriations for 1977 (Part 7), Hearings Before a Subcomm. of the Comm. on Appropriations, 94th Cong. 1063-64 (1976)* (statement of Dr. Burk).

121. This protest first appeared in a letter of February 6, 1976, from Dr. Donald Frederickson, Director of the National Institutes of Health, to Congressman James Delaney of New York. This letter has not been officially published, but the particulars are set forth in the

Their pretext was that he and his associates had not adjusted the basic data for age, race and sex, and that, when such adjustments were done, there was no association between fluoridation and cancer.¹²² Their claim essentially was that, among 18 million people in twenty large cities over thirty years, it so happened that the experimental cities grew older faster just as they were fluoridated, and that this aging occurred precisely to the extent necessary to create the shocking appearance of an association between fluoridation and cancer.¹²³ This association, they held, was merely an illusion deceiving the ignorant. It sounds far-fetched. It was worse than far-fetched.

It is obligatory to note that Dr. Burk and those working with him adjusted for demographic variables on numerous occasions.¹²⁴ Beyond his published scholarship, he repeatedly gave detailed testimony on these questions in public hearings¹²⁵ and courts of justice.¹²⁶ But his view was that the basic data are best not adjusted in this particular case, because the base line established by the data for 1940 through 1950 already controls for all known and unknown variables.¹²⁷

Cancer incidence and mortality are influenced by countless demographic, environmental, dietary, socio-economic, and other factors, some tending to increase, others tending the decrease the extent of the disease. It is known, for example, that older people tend to experience more cancer than younger people, yet good diet and environment can significantly offset the effects of age. Adjustments

prepared statement of Dr. Arthur Upton, Director of the NCI, to Congress on October 12, 1977. See *National Cancer Program*, *supra* note 109 at 104-20.

122. See *id.* at 98-103 (statement of Dr. Guy Newell, Deputy Director of NCI).

123. See *id.* at 80-83 (statement of Dr. Robert Hoover, NCI).

124. Dr. Burk's interest in such adjustments first surfaced at the meeting of the American Society of Biological Chemists in San Francisco on June 6-10, 1976, where he joined Dr. John Yiamouyiannis in a paper setting forth partial adjustments of the basic data for age and race by the direct method. See Dean Burk & John Yiamouyiannis, *Fluoridation of Public Water Supplies and Cancer Death Rates*, 35 FED. PROC. AM. SOC. BIOL. CHEM. 1707, (1976). Dr. Burk's more advanced adjustments of the basic data for demographic variables absorbed twelve years of his life's work and included, among others, articles published by the International Society of Fluoride Research and the Pennsylvania Academy of Science. See Burk & Yiamouyiannis, *supra* note 108; Burk & Graham, *supra* note 108; Burk, Graham, & Morin, *supra* note 108. He was the major inspiration of these several articles. His matured views are best expressed in the last, published in 1988 not long before his death.

125. For example, see his formal statement to a hearing panel of the EPA on June 17, 1985, including nineteen tables outlining multiple adjustments by the indirect method for age, race and sex, *reprinted in* NATIONAL FLUORIDATION NEWS, Vol. XXXI, no. 4 (1985).

126. See *Safe Water Found. of Tex. v. City of Houston*, No. 80-52271, Trial Transcript, Jan. 13-14, 1982, at 48-105 (151st Jud. Dist., Tex.)

127. See *id.* at 46-48, 105-07.

for age in particular, and perhaps also for race and sex, may be important in comparing two populations at one point in time, because such adjustments may serve as a control for such demographic variables.¹²⁸ Yet a very different situation emerges when, as in the case of the basic data here in question, there is a comparison of trends over time, including a long base line.¹²⁹

There are established principles of inductive logic which are associated historically with William of Ockham¹³⁰ and Sir Isaac Newton.¹³¹ They are used in the empirical sciences for the discovery or identification of causes in nature. Given a strong trend or association observed in nature, take the simplest and most fitting explanation as the cause, unless and until the contrary be shown. Likewise, attribute like causes to like effects, unless and until the contrary be shown. Finally, where cause and effect in certain circumstances are fairly ascertained by proper experiment, such cause and effect may be generalized throughout the universe, unless and until the contrary be shown.

Given these principles of natural reason, and given what is known about fluoride, including especially its demonstrated carcinogenic potential,¹³² the simplest and most fitting explanation of the basic data is that all cancer-influencing factors counterbalanced each other during the long base line period before 1950; that all these factors continued to counterbalance each other after 1950 except for the one factor known to be new, viz., fluoridation; and that, therefore, the entire observed association between fluoridation and cancer in the basic data, i.e., 31.3 excess CDs/100,000 after 15-20 years of exposure, is attributable to fluoridation as the cause.¹³³ We can then generalize by saying that artificial fluoridation of public water supplies causes an immense amount of cancer in the United

128. See, e.g., Burk & Graham, *supra* note 108, at 65; Burk, Graham, & Morin, *supra* note 108, at 139-40.

129. See, e.g., Burk & Graham, *supra* note 108, at 65; Burk, Graham, & Morin, *supra* note 108, at 140.

130. Ockham's emphasis on the simplest explanation as the best explanation, often called "Ockham's razor," grew out of his philosophical treatment of universals, relations, causation, and motion. See COPLESTON, *supra* note 106, pt. I, at 69-71, 80-81, 83-88.

131. At the beginning of the third book of his *PHILOSOPHIAE NATURALIS PRINCIPIA MATHEMATICA*, Sir Isaac Newton laid down his "rules of reasoning in natural philosophy" for the identification of causes in phenomenal reality, including the simplicity principle, sometimes called "Ockham's Razor." See 5 COPLESTON, *A HISTORY OF PHILOSOPHY*, pt. I, 162-64 (1964).

132. See generally Taylor, *supra* note 16; Taylor & Taylor, *supra* note 20; sources cited *supra* note 21.

133. See Burk & Graham, *supra* note 108, at 65; Burk, Graham, & Morin, *supra* note 108, at 139-40.

States, "involving tens of thousands of cancer deaths of Americans annually."

Adjustments for age, race, and sex are here meant to account for demographic factors which have already been addressed by the base line. Such adjustments will therefore tend to control more than once for the same factors and so, in this context, will tend to understate reality. Changes in the demographic composition of the control and experimental cities have in some degree been counteracted by other factors, and the adjusted figures will not reflect this counteracting effect. So again, adjustments will tend to understate reality.

Dr. Burk respected conventional opinion, but he did not adore it. And since conventional opinion demands adjustments for age, race, and sex, not because he thought they clarified the meaning of the basic data, he cheerfully went along. It is ironic that the scientist who thought these adjustments least useful did more than all others to assure that they were properly done. His guiding principle in dealing with the subject was that, if adjustments were to be executed, they should rest upon standard methods, and be carried out as comprehensively and thoroughly as possible, otherwise not at all.

It is no less ironic that the attack against his epidemiological work was spearheaded by the National Cancer Institute which he had served with such distinction before his retirement. The confrontation initially developed in hearings on September 21 and October 12, 1977, in Congress.¹³⁴

In these hearings, the National Cancer Institute came forth with its objections in a definitive, 17-page document.¹³⁵ It was presented under the signature of the director Dr. Arthur Upton, and introduced in committee by the deputy director Dr. Guy Newell. This "Upton Statement" was then and still is the official position of the government of the United States. It is reputed to be the irrefutable answer to the thesis of Dr. Burk and his colleagues. The scientific debate since then has turned upon the Upton Statement, which lays down a characteristic adjustment of the basic data for age, race, and sex by the indirect method, an orthodox procedure for this purpose.¹³⁶

In this procedure, we ordinarily compare two populations at a certain point in time in terms of the ratio of the observed cancer death rate (which we have called CDRo) to the "index" or

134. The key contributions of historic significance on both sides are reprinted in *National Cancer Program*, *supra* note 109, at 3-60, 75-83, 98-140, 181-212, 219-30, 305-18 (1977).

135. *See id.* at 104-20.

136. *See* BRADFORD-HILL, *supra* note 118, at 190-96.

"expected" cancer death rate (which we shall call CDR_e) of each population.

In deriving an "expected" CDR, we ascertain from census figures the number of persons in each demographic category of the observed populations. In addressing Dr. Burk's basic data, the staff at NCI used forty such categories, viz., age groups 0-4, 5-14, 15-24, 25-34, 35-44, 45-54, 55-64, 65-74, 75-84, and 85+, each divided into white male, white female, nonwhite male, and nonwhite female.

We must then select a "standard population," drawn from census figures and vital statistics for a certain territory and year: this standard population really consists of a set of known cancer death rates for each category in the population. The choice of this standard population requires some judgment. The staff at NCI selected the United States in 1950,¹³⁷ which is not, in our view, an unreasonable choice, because it represents a fair estimate of what cancer experience should be, category by category, in the absence of anything tending to make cancer deaths higher or lower than usual.

For each population compared, the number of persons in each category is multiplied by the corresponding rate in the standard population. Expected cancer deaths so determined are added up, then divided by the total population, and reduced to a common denominator of 100,000. The resulting "expected" CDR will be what may be anticipated for the population in view of its demographic composition.

The fraction CDR_o/CDR_e is called a standardized mortality ratio or SMR. If based on good judgment, it will indicate the extent to which the observed cancer death rate of a given population is higher or lower than what should be expected under normal circumstances in view of its demographic structure.

The Upton Statement sets forth an adjustment of the basic data expressed in weighted averages. The SMRs are as follows:¹³⁸

	1950	1970	Change
CDR _o /CDR _e (+F)	1.23	1.24	+ .01
CDR _o /CDR _e (-F)	1.15	1.17	+ .02

Using these figures, the NCI asked Congress to believe that, relative to what may be expected in light of the age structure of the two

137. See *National Cancer Program*, *supra* note 109, at 112, 224.

138. See *National Cancer Program*, *supra* note 109, at 118.

groups of cities observed, cancer mortality actually grew 1% faster in the unfluoridated cities than in the fluoridated cities.¹³⁹

Dr. Burk and his colleagues had a remarkable answer:¹⁴⁰ The available and pertinent data for the years after 1950 were 1953-1968. Without the trends in these years, nobody would suspect that there is a causal relationship between fluoridation and cancer. In its adjustment, the NCI considered 1950 before fluoridation began in the experimental cities, and 1970 after fluoridation had already been initiated in the control cities, and did not consider the years 1953-1968 which were the whole basis of concern. In other words, the NCI simply derived their CDRo values from data reported for 1950 and 1970, and ignored all else, as if 1953-1968 were unimportant.

Having omitted all available and pertinent data in their adjustment, it is not surprising that the NCI came up with the wrong answer. In the same hearings before Congress, it was demonstrated by a colleague of Dr. Burk that, if the adjustment proposed by the NCI is undertaken using all available and pertinent data after 1950, there emerges an impressive association between fluoridation and age-race-sex adjusted cancer mortality.¹⁴¹

139. See *id.* at 81, 112.

140. See *id.* at 64-65. See also Burk & Graham, *supra* note 108, at 67-68; Burk, Graham, & Morin, *supra* note 108, at 142-43.

141. Dr. John Yiamouyiannis executed an adjustment of the basic data, using weighted averages and US-1950 as the standard population, exactly as stipulated in the Upton Statement. He adjusted only for the years after 1950, deriving CDRo values for 1950 and 1970, by linear regression analysis of the CDRo data for 1950 and 1953-1969, and showed an association in terms of CDRo/CDRe = +.042, and in terms of CDRo-CDRe = 12.4 cancer deaths per 100,00 persons exposed within after fifteen to twenty years after the introduction of fluoridation in the experimental cities. See *National Cancer Program*, *supra* note 109, at 64-65. The main objection to this technique came from Dr. David Newell of the Royal Statistical Society in defense of the Upton Statement. He claimed that, because populations between census years and thus denominators in intercensal CDRs must be estimated by linear interpolation, they are not reliable data, and therefore not suitable for linear regression analysis. See *Aitkenhead v. Borough of West View*, No. GD-4585, Trial Transcript, May 8, 1978, at 72, 72A, 73-76 (Allegheny Court of Common Pleas, Pa). This criticism was exploded by none other than Dr. Guy Newell, Deputy Director of the NCI, who supervised preparation of the Upton Statement and introduced it before Congress. Later speaking as a professor of epidemiology at the University of Texas, he stated emphatically that use of linear interpolation to derive denominators in intercensal CDRs is "accepted procedure" in modern applied epidemiology, and, therefore, perfectly reliable. See *Safe Water Found. of Texas v. City of Houston*, No. 80-52271, Trial Transcript, Jan. 26, 1982, at 1648-54 (151st Jud. Dist., Tex.). The correctness of undertaking a linear regression analysis of intercensal CDRs in which the denominators were estimated by linear interpolation was further confirmed by Dr. Hubert Arnold, professor of statistics at the University of California, Davis. See *National Cancer Program*, *supra* note 109, at 580. The propriety and necessity of such use of interpolated data, based on fundamental principles of inductive logic, is discussed in Burk & Graham, *supra* note 108, at 68-69, and Burk, Graham, & Morin, *supra* note 108, at 143-44.

Dr. Burk developed even more comprehensive adjustments. In doing so, he considered the years before and after 1950, because the observed CDRs portray a change in trends after 1950 and a change from trends before 1950.¹⁴² The data representing 1953-1968 were important, but they were especially important in view of what happened in 1940-1950. The need to consider the years before and after 1950 became clearer from the fact that there were demographic fluctuations before and after 1950: it appeared that these fluctuations both before and after 1950 could materially influence the size the association adjusted for age, race, and sex.

Dr. Burk derived CDR_o values for 1940 and 1950 by linear regression analysis of the data for 1940-1950, and for 1950 and 1970 by linear regression analysis of the data for 1953-1968.¹⁴³ He derived CDR_e values, using US-1950 as the standard population, exactly as stipulated in the Upton statement.¹⁴⁴ He used the SMR or CDR_o/CDR_e, and also the difference between observed and expected CDRs, i.e., CDR_o-CDR_e, which is also used by conventional epidemiologists.¹⁴⁵ His results can be summarized as follows:¹⁴⁶

Cities	1940	1950	1950	1970
CDR _o (+F)	154.2	181.8	186.3	222.6
CDR _e (+F)	128.1	146.9	146.9	174.7
CDR _o /CDR _e (+F)	1.204	1.238	1.268	1.274
CDR _o -CDR _e (+F)	26.1	34.9	39.4	47.9
CDR _o (-F)	153.5	181.3	183.6	188.8
CDR _e (-F)	140.3	155.5	155.5	166.0
CDR _o /CDR _e (-F)	1.094	1.166	1.181	1.137
CDR _o -CDR _e (-F)	13.2	25.8	28.1	22.8

142. On the importance of adjusting both for the period before fluoridation was begun in the experimental cities and the period after, then reaching a combined result, see Burk & Graham, *supra* note 108, at 67, and Burk, Graham, & Morin, *supra* note 108, at 142-43.

143. See Burk & Graham, *supra* note 108, at 67; Burk, Graham, & Morin, *supra* note 108, at 142.

144. The particulars of the NCI adjustments are laid out more clearly in the paper of the Royal Statistical Society defending the Upton Statement. See *National Cancer Program*, *supra* note 109, at 224-29.

145. See *id.* at 227-28 (Royal Statistical Society).

146. See Burk & Graham, *supra* note 108, at 67-68. Dr. Burk preferred another similar adjustment based on the indirect method, using weighted averages, and US-1940 as the standard population, then combining the impact of changes both before and after 1950 in "time independent" terms. This adjustment yields the conclusion that 69.2% of the observed association between fluoridation and cancer, as reflected in the basic data, cannot be explained by demographic differences. See Burk, Graham, & Morin, *supra* note 108, at 142-43.

These figures can be transformed into coefficients which reflect an association between fluoridation and CDRs adjusted for age, race, and sex, as it developed from 1940 to 1970:

The change in $CDRo/CDRe = [(1.274-1.137) - (1.268-1.181)] + [(1.204-1.094) - (1.238-1.166)] = +.088$. This coefficient means that, relative to what might be expected in light of the demographic structure of the two populations here in question, adjusted cancer mortality grew about 9% faster in the fluoridated cities.

In terms of $CDRo-CDRe$, fluoridation is associated with $[(47.9-22.8) - (39.4-28.1)] + [(26.1-13.2) - (34.9-25.8)] = 17.6$ excess cancer deaths per 100,000 persons exposed after 15-20 years. This adjusted figure, multiplied against 130 million Americans now drinking fluoridated water 15-20 years, works out to something on the order of 23,000 excess cancer deaths every year in the United States.

Whether adjusted or unadjusted figures are preferred, the size of the human casualty is so large and tragic that it is almost indecent to quibble over the numbers. Over twenty years have passed, and the casualty has mounted, since the NCI represented to Congress, on the basis of demographic adjustments which left out all available and pertinent data, that there is no association between fluoridation and cancer.

VII. THE JUDICIAL FINDINGS CONDEMNING FLUORIDATION

In the wake of the hearings in Congress just discussed, litigation seeking to resist or restrain further implementation of fluoridation began in several places in the United States. In Ohio it had recently been held that fluoridation was a constitutional exercise of police power.¹⁴⁷

But in light of the recent publication of the basic data gathered under the direction of Dean Burk, opportunities for a new judicial hearing vastly improved. When such a hearing was sought, the Ohio Supreme Court commented:

A more difficult question is raised by the claim that fluoride is a carcinogen based on statistics that the cancer death rate has increased in certain cities with fluoridated water, while remaining the same in certain other cities which do not fluoridate. The evidence for this claim has not been tested by litigation and is disputed by other authorities. This evidence has also been submitted to federal agencies and to the Congress. If scientifically proved,

147. See *City of Canton v. Whitman*, 337 N.E.2d 766 (Ohio 1975); *City of Cincinnati v. Whitman*, 337 N.E. 2d 773 (Ohio 1975).

these claims could raise legitimate questions as to the constitutionality of fluoridation as a public health measure, and, since these claims are based upon very recent studies, the purposes underlying the principle of *res judicata* would probably not be served by barring litigation to determine the validity of these claims.¹⁴⁸

Reading this statement side by side with *Jacobson v. Massachusetts*,¹⁴⁹ and *Paduano v. City of New York*¹⁵⁰, a suit before the judiciary attacking the constitutionality of mandatory fluoridation should succeed if it could be established by a fair preponderance of the evidence that the measure causes or contributes to the cause of cancer in man. But the court held that the judiciary had no original jurisdiction to consider the question, ostensibly because, in Ohio, the power to find the facts was vested by statute in an administrative agency.¹⁵¹ The holding seems to have been created post hoc to avoid a touchy question.

It would have been easy for the court to rely on respectable authority to the effect that, where a constitutional question is fairly raised, and the outcome depends on facts, especially where personal rights are involved, exhaustion of administrative remedies is not necessary, and the judiciary can take jurisdiction to hear the evidence and decide the controversy on the merits.¹⁵² No further headway was made in Ohio because the plaintiffs too well understood that impartial consideration by the administrative agency, where fluoridation was institutional policy, was as hopeless as an unbiased attitude by the NCI and other institutes in the USPHS.

A. The Pittsburgh Case

However, it was not necessary to wait very long for the opportunity to be fairly heard on the new evidence in Pittsburgh in the case of *Aitkendedead v. Borough of West View*.¹⁵³ The case was assigned to Judge John Flaherty who has since become the Chief Justice of Pennsylvania. The suit rested on a theory of nuisance, and

148. *City of Cincinnati ex rel. Crotty v. City of Cincinnati*, 361 N.E.2d 1340, 1341-42 (Ohio 1977).

149. See 197 U.S. 11, 39 (1905).

150. 257 N.Y.S.2d 531, 542 (N.Y. Sup. Ct. 1965)

151. See 361 N.E.2d at 1342.

152. See, e.g., *United States v. Sisson*, 297 F. Supp. 902, 906 (D. Mass. 1969) *appeal dismissed*, 399 U.S. 267 (1970); *Bare v. Gorton*, 526 P.2d 379, 383-84 (Wash. 1974). This exception to the rule on exhaustion of administrative remedies is ultimately rooted in the "constitutional fact" doctrine in *Ng Fung Ho v. White*, 259 U.S. 276, 282-83 (1922) and *Ohio Valley Water Co. v. Ben Avon Borough*, 253 U.S. 287, 289 (1920).

153. No. GD-4585-78 (Allegheny County Court of Common Pleas, Pa.).

went to hearing on a motion for a preliminary injunction. Expert witnesses from the National Cancer Institute, the National Academy of Sciences, the Royal Statistical Society, and the Royal College of Physicians appeared to oppose the testimony of Dr. Burk and his colleagues, as had occurred in Congress.¹⁵⁴ After many sessions, followed by extensive summations on both sides, Judge Flaherty made his findings on November 16, 1978. He first described the main evidence by stating:

Over the course of five months, the court held periodic hearings which consisted of extensive expert testimony from as far away as England. At issue was the most recent time trend study of Dr. Burk and Dr. Yiamouyiannis, which compared the cancer mortality of 10 cities which fluoridated their water systems with 10 cities which did not fluoridate over a period of 28 years from 1940 to 1968. The study concluded that there was a significant increase in cancer mortality in the fluoridated cities.¹⁵⁵

He defined the sole issue of fact as "whether fluoride may be a carcinogen."¹⁵⁶ He then found that "[p]oint by point, every criticism made of the Burk-Yiamouyiannis study was met and explained by the plaintiffs. Often, the point was turned around against defendants. In short, this court was compellingly convinced of the evidence in favor of plaintiffs."¹⁵⁷

Judge Flaherty entered a preliminary injunction. Since the facts of the case had been fully tried, a motion was prepared for an amended complaint to attack the constitutionality of imposed fluoridation, and for a permanent injunction, based on danger to public health. The motion was about to be filed when raw power showed itself with lightning speed and impressive clout to limit the political

154. The most critical dispute in the trial was whether the basic data (set forth in the appendix of this article) should be adjusted for age, race, and sex by the methods proposed by Dr. Dean Burk or Dr. John Yiamouyiannis in *National Cancer Program*, *supra* note 109, at 18-40, 61-72, or by the method proposed in the Upton Statement, *id.* at 104-20, 220-30. The defense of the Upton Statement collapsed when Dr. David Newell of the RSS conceded that he used data only for 1950 and 1970, and considered nothing in between "for the main and simple reason" that he was sent his data from the NCI. See *Aitkenhead v. Borough of West View*, No. GD-4585-78, Trial Transcript, May 9, 1978, at 72-72A, 75-6 (Allegheny County Court of Common Pleas, Pa.). Dr. Marvin Schneiderman of NCI admitted that such intermediate data should be used, but could give no specific alternative to linear regression analysis of intercensal CDRs between 1950 and 1970. See *id.* Trial Transcript, May 9, 1978, at 47-56.

155. See No. GD-4585-78, Opinion, Nov. 16, 1978, at 6.

156. *Id.* at 6.

157. *Id.* at 9.

damage.¹⁵⁸ The Chief Judge of the Commonwealth Court of Pennsylvania quickly stayed the preliminary injunction, ignoring the facts judicially found, as if public safety were not an issue.¹⁵⁹

An administrative agency, which favored fluoridation as institutional policy, quickly and summarily entered "findings" which parroted USPHS propaganda.¹⁶⁰ Another administrative agency, which had a similar institutional policy, then entered an "order" which purported to deny the Borough of West View "permission" to obey Judge Flaherty's injunction.¹⁶¹ Events thus took bizarre turns to save a sacred cow.

Jurisdiction to enter the findings supporting the preliminary decree of November 16, 1978, was sustained on appeal shortly before Judge Flaherty was elevated to the Supreme Court of Pennsylvania.¹⁶² The Commonwealth Court then held that the cause could go no further before the judiciary under the pretext that exclusive jurisdiction belonged to the administrative agency.¹⁶³ That was the end of the case, for all understood the notorious bias of the administrative agency which was not about to admit that it had promoted the dumping of carcinogenic agents into the environment. The appellate decisions left the findings of Judge Flaherty untouched, but departed widely from the traditional rule that, once a court of equity takes jurisdiction over the subject matter of a suit, such jurisdiction continues until the final decree, even though a basis for legal or administrative jurisdiction might later appear.¹⁶⁴

As the USPHS tried to press-release its way out of the crisis in the United States, the findings of Judge Flaherty became highly influential abroad. In the British House of Lords, the Earl of Yarborough accurately summed up the meaning of the case:

158. The odd appellate history of the cause is summarized in *Aitkenhead v. West View*, 442 A.2d 364 (Pa. Commw. Ct. 1982), and *Aitkenhead v. West View*, 397 A.2d 878, 878-79 (Pa. Commw. Ct. 1979)

159. See 397 A.2d at 879-80.

160. See *Aitkenhead v. Borough of West View*, No. GD-4585-78, Exhibit C (Pa. Dept. of Health, Dec. 21, 1978), Plaintiffs' Motion to Dismiss Preliminary Objections, Feb. 21, 1979 (Allegheny County Court of Common Pleas, Pa.).

161. See *id.* Exhibit A (Pa. Dept. of Env. Res., Jan. 8, 1979), Plaintiffs' Motion to Dismiss Preliminary Objections, Feb. 21, 1979. See also *id.* Order Dismissing Preliminary Objections, May 25, 1979.

162. See *Aitkenhead*, 397 A.2d at 880.

163. See *Aitkenhead*, 442 A.2d at 366.

164. The rule can be traced to Lord Eldon in *Eyre v. Everett*, 2 Russ. 381 (Ch. 1826), and *Adley v. Whitstable*, 17 Ves. Jr. 316 (Ch. 1810). See also *Gulbenkian v. Gulbenkian*, 147 F.2d 173, 176 (2d Cir. 1945); *Rosen v. Mayer*, 113 N.E. 217 (Mass. 1916).

Already this evening examples have been quoted of what occurred in America. What I read was rather different from the picture painted this evening. It was my understanding—if the case quoted was the case in Allegheny [County] in Pennsylvania—that it was found proven that fluoride was a danger to health. I know that there was some legal wrangle about jurisdiction but I thought, on the facts presented by a number of experts, that that was the finding and that the facts had not been challenged but merely the jurisdiction of the court.¹⁶⁵

So important was the meaning of this case that it also attracted the attention of an investigative commission of the Environment Ministry of Quebec, chaired by Dr. Benoît Bundock who had been the principal medical officer for special projects in the Canadian Ministry of Health. The commission had been diligently studying world literature on fluoridation for over a year when Judge Flaherty returned his findings. They obtained the entire record of the proceedings in Pittsburgh.

Dr. Bundock and his colleagues returned a comprehensive report on November 30, 1979, acknowledging the laboratory studies of Dr. Taylor and the basic data of Dr. Burk, specifically concurred with the findings of Judge Flaherty, and recommended executive suspension of all efforts to enforce the mandatory fluoridation law of Quebec.¹⁶⁶ This recommendation was accepted, and the moratorium has now continued almost twenty years through no less than six governments both pequist and liberal. So well regarded is this report that a standard ecology textbook, widely used in the secondary schools of Quebec, forthrightly acknowledges that fluoride in drinking water, as introduced through artificial fluoridation of public water supplies, is an environmental pollutant which causes cancer in man.¹⁶⁷

B. *The Alton Case*

One important early case sustaining the constitutionality of imposed fluoridation on sweeping notions of police power came out

165. 402 PARL. DEB. H.L. (5th ser.) 1446-50 (1979). Another important contribution on the same occasion, including learned discussion on the epidemiological work of Dr. Dean Burk, came from the Deputy Speaker, Lord Douglas of Barloch. *See id.* at 1461-68. *See also* the recent and informed speeches by the Earl Baldwin of Bewdley in 593 PARL. DEB. H. L. (5th ser.) 1394-99, 1427-29 (1998).

166. *See* Jean-Benoît Bundock et al., *Les fluorures, la fluoruration, et la qualité de l'environnement*, MINISTÈRE DE L'ENVIRONNEMENT, GOUVERNEMENT DU QUÉBEC, at 1-2, 103-04, 107-08, 116-17, 197-200 (1979).

167. *See* JACQUES VIEL ET PAUL DARVÉAU, *POUR UNE PENSÉE ÉCOLOGIQUE* 35 (1984).

of the Illinois Supreme Court.¹⁶⁸ Some years later a suit was brought to enjoin fluoridation on allegations of new evidence not previously considered. The complaint was dismissed on demurrer, but the Appellate Court of Illinois held that, taking the facts alleged as true, *res judicata* did not bar the suit, because *res judicata* cannot bar reconsideration of an issue on the basis of evidence which did not exist when the judgment was initially entered.¹⁶⁹ The remand occurred in 1972, and the case floundered in legal horseplay in the circuit court until a trial was forced eight years later in Alton, where Lincoln and Douglas had debated the Dred Scott case before the Civil War.

*Illinois Pure Water Committee v. Director of Public Health*¹⁷⁰ was tried from April through June 1980 before Judge Ronald Niemann. It was a case of uncommon ferocity with endless dilatory motions and preposterous contentions by the State, causing the trial to move at a snail's pace.

Judge Niemann endured the experience with almost inhuman patience. He had a highly skeptical attitude about the testimony offered on behalf of the plaintiffs and he reacted to the large numbers generated by the basic data with astonishment and disbelief. He discounted much of what he heard, but at length was satisfied that the plaintiffs had at least made a *prima facie* case of danger to public safety.¹⁷¹

Judge Niemann turned to the State and asked it to account for the association between fluoridation and cancer reflected by the basic data.¹⁷² It should be kept in mind that Chicago is the home of the ADA which has at its command every expert in the world to support fluoridation as a public health measure. Even so, no world class scientists appeared to defend fluoridation as in the hearings before Congress and the trial in Pittsburgh.¹⁷³

168. See *Schuringa v. City of Chicago*, 198 N.E.2d 326 (Ill. 1964).

169. See *Illinois Pure Water Comm. v. Yoder*, 286 N.E.2d 155, 157-58 (Ill. App. Ct. 1972).

170. See No. 68-E-128 (Madison County Circuit Court, Ill.). The full record of the proceedings is not available to us, but the final decree entered by Judge Nieman on February 24, 1982, is fairly detailed in describing the procedural history and the scientific evidence presented on both sides. Moreover, the summations of the evidence and the legal arguments on both sides, only slightly abridged, have been conveniently and accurately published by the National Health Action Committee in 2 HEALTH ACTION, NO. 11-12 (1981) [hereinafter HEALTH ACTION].

171. See *Illinois Pure Water Comm'n v. Dir. of Pub. Health*, No. 68-E-128, Final Decree, Feb. 24, 1982, at 9-10, 20-1, 29 (Madison County Circuit Court, Ill.).

172. See *id.* at 10, 29, 33.

173. See *id.* at 10.

data. A state-hired epidemiologist went so far as to claim that Dr. Burk's work was invalid because the basic data linking fluoridation with cancer had been selected and organized to meet the requirements of experimental design. In other words, he condemned the comparison of like with like before introducing fluoridation in the experimental cities, then observing the subsequent difference in cancer mortality between the two groups invalidated the data. Instead, he said, it was statistically necessary to select fluoridated and unfluoridated cities of the country at random,¹⁷⁴ which, of course, would have assured no control for known and unknown variables.

The same epidemiologist spoke of the need for adjustments for age, race, and sex, yet the plaintiffs' case in chief was full of detailed demographic adjustments of the basic data by the direct and indirect methods.¹⁷⁵ A large box of original data, rows of government publications, and a thick bundle of sheets of calculations were brought into the courtroom for inspection. The same epidemiologist made generalized claims that his adjustments wiped away any association between fluoridation and cancer, yet he conspicuously offered no specific figures or documented calculations in support of his projections.¹⁷⁶

"What causes cancer?" asked the attorney general of Illinois in his summation, "Apparently, nobody knows."¹⁷⁷ Judge Niemann pondered the case for almost two years. On February 24, 1982, he entered judgment. He thus stated the law:

The presumption of the validity of legislation is overcome when the plaintiff makes a prima facie case. The traditional concept of burden of proof resting on the plaintiff, once met, shifts to the government to justify its intrusion into the life and health of the individual. When the State is involved, the traditional view is that the 'King can do no wrong.' Although the King must constantly act for his subjects, certainly he has been wrong a time or two.¹⁷⁸

Judge Niemann specifically found, "[This legislation] exposes the public to the risk, uncertain in its scope, of unhealthy side effects of artificial fluoridation of public water supplies, is unreasonable, and

174. See *HEALTH ACTION*, *supra* note 170, 16-19 (Plaintiffs' Summation), and 53-54 (Defendant's Summation).

175. See *id.* at 20-26 (Plaintiffs' Summation).

176. See *id.* at 56-58 (Defendant's Summation).

177. *Id.* at 62 (Defendant's conclusion in final argument).

178. *Illinois Pure Water Comm. v. Director of Pub. Health*, No. 68-E-128, Final Decree, Feb. 24, 1982, at 29 (Madison County Circuit Court, Ill.).

[is] a violation of the due process clause of the Illinois Constitution of 1970."¹⁷⁹ He added with disappointment, "This record is barren of any credible and reputable scientific epidemiological studies and/or analysis of statistical data which would support the Illinois Legislature's determination that fluoridation of public water supplies is both a safe and effective means of promoting public health."¹⁸⁰ Accordingly, Judge Niemann entered a permanent injunction enjoining the State and its subdivisions from further implementation of fluoridation in Illinois.¹⁸¹

A direct appeal was immediately taken to the Illinois Supreme Court. Like lightning, the injunction was stayed without any consideration of the evidence, as if power, and not public health, were the name of the game.¹⁸² As night follows day, the Illinois Supreme Court reversed the judgment of the circuit court citing broad notions of police power.¹⁸³ Particularly offensive about the opinion were numerous petty and vindictive comments made against the plaintiffs' witnesses,¹⁸⁴ harmful to the dignity of the bench.

There was also dissimulation regarding the record, as may be illustrated. Judge Niemann had specifically found that the statute was "unreasonable," and therefore unconstitutional, because a prima facie case had been made that fluoridation exposes the population to a tangible risk, albeit uncertain in extent, of unhealthy side effects, and that no "credible and reputable" evidence had been given to justify the intrusion.¹⁸⁵ Yet the Illinois Supreme Court attempted to characterize Judge Niemann's position to be "not that the risk was so great that fluoridation was unreasonable, but that the question was shown to be debatable. Under these circumstances the plaintiffs have failed to show an unreasonable exercise of the police power."¹⁸⁶

C. The Houston Case

A third case arose in the Lone Star State, entitled *Safe Water Foundation of Texas v. City of Houston*.¹⁸⁷ The case brought to trial in January 1982, before Judge Anthony Farris. The petition prayed for a

179. *Id.* at 32.

180. *Id.* at 33.

181. *See id.* at 44.

182. *See Illinois Pure Water Comm. v. Director of Pub. Health*, 470 N.E.2d 988-89 (Ill. 1984).

183. *See id.* at 991-92.

184. *See id.* at 989-90.

185. *See id.* No. 68-E-128, Final Decree, Feb. 24, 1982, at 29, 32, 33.

186. 470 N.E.2d at 992.

187. No. 80-52271 (151st Jud. Dist., Tex.).

declaratory judgment that a recently enacted city ordinance imposing fluoridation in Houston was unconstitutional, and it sought an injunction prohibiting implementation of the ordinance within the municipality.¹⁸⁸

The trial before Judge Farris moved at an energetic pace, not atypical of judicial proceedings in Texas. It was distinguished by polished testimony on both sides. The best available witnesses from several universities defended fluoridation. Cross-examination was crisp and businesslike. The rules of evidence were somewhat relaxed¹⁸⁹ so as to permit practical inclusion of more information in less time. The bench firmly managed the proceedings. The trial was efficient, ample, rigorous, and thorough.

Whereas in Pittsburgh and Alton the issue was reduced to whether or not fluoridation induces cancer in man, in Houston a larger range of evidence was considered. These issues included, aside from cancer, whether fluoridation induces genetic damage,¹⁹⁰ intolerant reactions,¹⁹¹ and chronic toxicity,¹⁹² not to mention other disputed points

Counsel and witnesses for the plaintiffs conceded that a rational controversy exists over the effectiveness and safety of fluoridation.¹⁹³ It was so stipulated, because a good measure of knowledge is awareness of both sides of the question. There were a few fanatical pro-fluoridation witnesses who made fabulous claims of Newburgh-Kingston orthodoxy, but they did not do well. Pro-fluoridation

188. See *id.* in Second Amended Petition, Dec. 3, 1980, at 6-8.

189. See *id.* Trial Transcript, Jan. 14, 1982, at 280-287. Relying on *Urquhart v. Barnes*, 335 S.W.2d 666, 669 (Tex. Civ. App. 1960), Judge Farris held that learned treatises could be marked, introduced and received to prove their existence and the basis of the opinion offered. This ruling was made during the testimony of Doctor Albert Burgstahler, one of the foremost scholars in the world on fluoride and fluoridation. The impact of Judge Farris' ruling was to promote an excellent record for this kind of case, as illustrated by Dr. Burgstahler's testimony on direct examination. See No. 80-52271, Trial Transcript, Jan. 14-15, 1982, at 276-429.

190. See, e.g., No. 80-52271, Trial Transcript, Jan. 18, 1982, at 539-59 (testimony of Dr. Pierre Morin). Dr. Morin testified on the laboratory studies of fluoride and mutagenesis noted by Dyson Rose and John Maurier in *Environmental Fluoride*, NAT'L RES. COUNCIL OF CANADA PUBL. NO. 16081 69-70 (1977), as confirmed by epidemiological data linking fluoride in drinking water and mongoloid births. See Ionel Rapaport, *Les opacifications du cristallin mongolisme et cataracte sénile*, 2 REV. ANTHROP. (Paris) 133 (1954); Ionel Rapaport *Contribution a l'étude du mongolisme. Rôle pathogénique du fluor*, 140 BULL. ACAD. NAT'L. MED. (Paris) 529 (1956).

191. See, e.g., No. 80-52271, Trial Transcript, Jan. 19, 1982, at 579-96 (testimony of John Lee, M.D., on the work of Dr. George L. Waldbott in *Fluoridation: A Clinician's Experience*, 73 SO. MED. J. 301 (1980), and his own clinical experience).

192. See No. 80-52271, Trial Transcript, Jan. 19, 1982, at 609-14 (testimony of Dr. Lee on the strong association between the fluoride content of public water supplies and dental fluorosis, described by Rudolf Ziegelbecker, *Natürlicher Fluoridgehalt des Trinkwassers und Karies*, 122 GWF WASSER/ABWASSER 495 (1981)).

193. See No. 80-52271, Plaintiffs' Summation, Feb. 4, 1982, at 4.

witnesses who displayed broader understanding were more appreciated.

At the conclusion of the trial, plaintiffs argued that they proved serious injury to the public health by a fair preponderance of the evidence, and that for this reason they were entitled to an injunction.¹⁹⁴ On the other side, counsel argued that there was a reasonable debate, and that for this reason the City was entitled to a judgment of dismissal.¹⁹⁵

On February 22, 1982, Judge Farris denied the plaintiff's motion for permanent injunction, holding that the plaintiffs "had the burden to introduce overwhelming evidence in this case. Plaintiffs had to prove that no rational relationship exists between fluoridation of city surface water and the public health. Plaintiffs had to prove that no controversial facts exist."¹⁹⁶

The plaintiffs immediately made a motion for new trial or amended order.¹⁹⁷ The argument on the motion, heard on April 19, 1982, centered on the burden of proof necessary to prevail. Judge Farris stated from the bench that the plaintiffs had proven harm by a fair preponderance of the evidence.¹⁹⁸ "If this were your run-of-the-mill litigation asking for injunctive relief," he said, "plaintiffs would have prevailed, but this is not the run-of-the-mill case."¹⁹⁹

The question was one of burden of proof, a pure question of law. It was agreed by the court and counsel that "[t]hat is why we have appellate courts."²⁰⁰ Counsel for the plaintiffs then asked for findings based on a fair preponderance of the evidence to prepare the record for appeal.²⁰¹ The court acceded to the suggestion, asking for proposals from both sides.²⁰² On May 24, 1982, Judge Farris entered his findings which were about as comprehensive and

194. See *id.* Plaintiffs' Summation, Feb. 4, 1982, at 4, 25.

195. See *id.* Defendant's Summation, Feb. 4, 1982, at 12-13.

196. See *id.* Opinion, Feb. 22, 1982, at 8. Judge Farris relied on *City of Houston v. Johnny Frank's Auto Parts Co.*, 480 S.W.2d 774 (Tex. Civ. App. 1972), which rests squarely of *Ferguson v. Skrupa*, 372 U.S. 726 (1963).

197. See No. 80-52271, Plaintiffs' Amended Motion for New Trial, Etc., April 14, 1982, at 1 (stating that, while the evidence at trial "did not eliminate the existence of a rational controversy, and was not intended or claimed to do so, the preponderance of the said evidence tended to show" that fluoridation causes or contributes to the cause of "cancer, genetic damage, intolerant reactions, and chronic toxicity, including dental mottling in man.").

198. See *id.* Hearing Transcript, Apr. 19, 1982, at 11.

199. See *id.* at 10.

200. See *id.* at 12.

201. See *id.* at 12-13.

202. See *id.* at 13-14.

desirable as any judicial findings have been in environmental law.²⁰³
The court found:

[That] the artificial fluoridation of public water supplies, such as is contemplated by [Houston] City Ordinance No. 80-2530 may cause or contribute to the cause of cancer, genetic damage, intolerant reactions, and chronic toxicity, including dental mottling, in man; that the said artificial fluoridation may aggravate malnutrition and existing illnesses in man; and that the value of said artificial fluoridation is in some doubt as to the reduction of tooth decay in man.²⁰⁴

This assessment of the facts, based on a fair preponderance of the evidence, was a reasonable and impartial picture of scientific reality as it was then understood.

If the municipal government of Houston had acted rationally in the face of these findings of fact, effectively a declaratory judgment on the weight of the evidence, the city council would have noted the danger, repealed the ordinance in the public interest, and perhaps established an investigative commission as had occurred in Quebec. But a city councilwoman, smiling broadly as cameras flashed, started the machinery which injected into public drinking water a substance judicially found, after an intensive and disciplined trial of the facts, to be carcinogenic and mutagenic.²⁰⁵

An appeal was taken, based mainly on a venerable old case decided by the Texas Supreme Court which held that, where exercise of police power rests on assumed facts, those facts may be judicially examined and, if upon such inquiry it fairly appears that the means chosen are disproportionate to the end desired, the ordinance should be declared unconstitutional.²⁰⁶ This principle is typical of the best natural law jurisprudence which prevailed earlier in the twentieth century. Given the findings of Judge Farris, fluoridation was unconstitutional under this principle, because endangering the public with cancer and other ailments cannot be justified by a dubious possibility of reducing tooth decay. The Texas Court of Appeals

203. The findings of Judge Farris, based on a fair preponderance of the evidence, are similar to the findings of Judge Miles Lord in *United States v. Reserve Mining Co.*, 380 F. Supp 11, 15-17 (D. Minn. 1974), and *United States v. Reserve Mining Co.*, 417 F. Supp 789 (D. Minn. 1976), affirmed 543 F. 2d 1210 (8th Cir. 1976). The dumping of taconite tailings was terminated on the principle that, where substantial evidence shows harm to human health, a question of public health should be judicially determined by resolving doubt against the introduction of foreign material into environment.

204. See No. 80-52271, Findings of Fact, May 24, 1982, at 1-2.

205. See *id.* at 1-2.

206. See *Houston & T. C. Ry. v. City of Dallas*, 84 S.W. 648, 653-54 (Tex. 1905).

expressly found that a fair preponderance of the evidence showed "the injection of fluoride into the City's water system would be harmful,"²⁰⁷ but, with the full support of higher tribunals, held that such proof of harm was not enough to arrest an exercise of police power.²⁰⁸

Therefore, it is evident that, at least for the time being, we are saddled with Hugo Black's positivist and anti-libertarian doctrines, and some years must pass before our judiciary sees the need for a change of course. Years must pass as surely as years had to pass from the death of Sir John Elliot following his arrest in 1630 for a speech in Parliament, and the grand day in 1667 when the House of Lords reversed the judgment of the King's Bench which denied Sir John release on a writ of habeas corpus.²⁰⁹ Meanwhile, the findings of Judge Flaherty, Judge Niemann, and Judge Farris have since been quoted to legislative bodies from Montreal to Honolulu and from London to Canberra. Not always, but occasionally legislators have listened.

There has been other interesting political fallout from these judicial findings. On August 9-10, 1983, a strategic conference of pro-fluoridation activists, most of them deeply involved in ADA and USPHS politics, took place at the University of Michigan.²¹⁰

The proceedings began with a presentation by a special counsel of the American Dental Association.²¹¹ The gentleman was introduced as a member of the rules committee of the Illinois Supreme Court, so it is clear that he was a powerful insider.²¹² He told the audience that it was he who had secured the stay of the injunction from the Illinois Supreme Court issued by Judge Niemann.²¹³

Counsel did not clearly inform his listeners that, from 1978 through 1982, three American judges in courts of superior jurisdiction had fully heard evidence on both sides: the first of these judges, by then a supreme court justice of eminent standing, entered findings undisturbed on appeal, saying he was compellingly convinced

207. *Safe Water Found. of Tex. v. City of Houston*, 661 S.W.2d 190, 192 (Tex. App. 1983), writ *ref'd n.r.e.* (Tex. 1984), appeal dismissed 469 U.S. 801 (1984).

208. *See id.* at 192-93.

209. *See, e.g.*, HENRY HALLAM, *CONSTITUTIONAL HISTORY OF ENGLAND* 299-300 (Garland Pub. 1978) (1846).

210. The proceedings were recorded verbatim in *FLUORIDATION: LITIGATION & CHANGING PUBLIC POLICY*, (Michael W. Easley et al. eds. 1983) [hereinafter *CHANGING PUBLIC POLICY*].

211. *See id.* at 3-11.

212. *See id.* at 3.

213. *See id.* at 5-6; *see also Illinois Pure Water Comm., Inc. v. Director of Pub. Health*, 470 N.E.2d 988, 989 (Ill. 1984).

of the danger of cancer; the second entered findings of no credible or reputable evidence to redeem fluoridation; and the third had entered comprehensive findings based on a preponderance of the evidence, expressly sustained on appeal, condemning fluoridation as posing a tangible danger of cancer and a good many other human diseases, while expressing doubt even of its capacity to reduce tooth decay.

Another speaker at the University of Michigan announced a significant change of litigation policy to perpetuate and expand fluoridation in future years. Whereas in earlier years it had been standard practice to invite trials, as had occurred in a number of earlier fluoridation cases, a new policy, following the trials in Pittsburgh, Alton, and Houston, was announced: "By avoiding a trial on the merits of fluoridation, we prevent the subjection of what we feel is a purely scientific issue to scrutiny by a judge who is likely not to have proper scientific training with which to make an objective ruling."²¹⁴ To recapitulate this interesting phase of legal and scientific history, in the trials in Pittsburgh, Alton, and Houston, one trial judge after another heard the evidence and found that fluoridation appears to be injurious to human health. Therefore, the new ADA-USPHS policy is to avoid, by all means, a trial on the merits.

This policy has been remarkably successful for over fifteen years. No case has ever gotten to trial. No pro-fluoridation witness has been cross-examined in court. Sales pitches continue before legislative bodies with a fair degree of success in the sense that mandatory or imposed fluoridation has considerably expanded. In legislative committees, witnesses usually cannot be effectively held to account for what they say.

We understand that the judicial process is far from perfect. But, now, the "purely scientific issue" mentioned at the University of Michigan -- and fluoridation is a purely scientific issue until legally imposed -- is tried in legislative proceedings by frantic political lobbying, maneuvers, ambushes, speechifying, applause, horse-trading, buttonholing, demagoguery, infighting, and posturing.

VIII. THE COMING END OF FLUORIDATION

One of the results of the hearings in Congress on September 21 and October 12, 1977, was a suggestion that the National Toxicology Program (NTP) should investigate fluoride.²¹⁵ Over twelve years,

214. CHANGING PUBLIC POLICY, *supra* note 210, at 84.

215. See *National Cancer Program*, *supra* note 109, at 319.

the NTP sputtered. At last some news was leaked to the press. On December 28, 1989, the *Medical Tribune* reported on the front page:

Fluoride appears to have caused bone cancer in rodents in a recently completed National Toxicology Program study, and the chemical is now at risk of being classified as a carcinogen, according to internal documents and statements obtained by the *Medical Tribune* from the Environmental Protection Agency.²¹⁶

Press fanfare erupted, and the main feature of this media blitz was the impression that there had been a discovery of something entirely new and previously unknown, as if the work of Alfred Taylor, Dean Burk and many others had never been done. Soon, however, the public was assured that all is well.²¹⁷

The "official" evaluation, while leaving much to be desired, gives a very different impression. The authors conceded that, although the numbers were small, the data gathered by the NTP study reveal a statistically significant dose-response trend of osteosarcomas of bone in male rats.²¹⁸ Additionally, the authors cited no less than eleven studies published in good journals, showing that fluoride is capable of inducing genetic mutation in mammalian cells and fruit flies, aggravating chromosomal aberrations in animal systems, and causing morphological transformations in Syrian hamster ovary cells.²¹⁹

The article concludes with the sedate comment that "it would appear prudent to re-examine previous animal studies and human epidemiological studies, and perform further studies as needed to evaluate more fully any possible association between exposure to fluorides and the occurrence of osteocarcomas of bone."²²⁰ We join this recommendation, adding that meanwhile artificial fluoridation of public water supplies ought to be halted across the country pending such review of the evidence, as was recommended by Dr. Bundock and his colleagues in Quebec, and that nobody having any direct or indirect interest in the conclusions ought to participate.

The recommendation for reevaluation has not been fulfilled. There are interesting reasons why.

216. Joel Griffiths, *Fluoride Linked to Bone Cancer in Fed Study*, 30 MED TRIB., DEC. 28, 1989, 1, 6.

217. See e.g., *Additive approved, Federal study says fluoride no threat*, PITTSBURGH POST-GAZETTE, Feb. 20, 1991, at 1-2.

218. See John Bucher et al., *Results and Conclusions of the National Toxicology Program's Rodent Carcinogenicity Studies with Sodium Fluoride*, 48 INT. JOUR. CANCER 733, 734-35 (1991).

219. See *id.* at 736.

220. *Id.*

On May 1, 1990, the acting Director of the Criteria and Standards Division, Office of Drinking Water in the United States Environmental Protection Agency, received a memorandum from Dr. William Marcus, Senior Scientific Advisor in the Criteria and Standards Division.²²¹ Dr. Marcus reviewed the NTP study and pointed to results suggesting carcinogenic potential of fluoride.²²² He also cited the most recent published version of the epidemiological data gathered and adjusted under the direction of Dr. Burk.²²³ Dr. Marcus urgently recommended an independent review by the EPA.²²⁴

To put it mildly, Dr. Marcus' memorandum did not inspire a warm and friendly response from the management of the EPA. In due course, Dr. Marcus sent his document to the Administrator of the EPA and to his union representative who in turn released it to the press. The public reaction was rather agitated, causing a bureaucrat from the "health effects branch" within the agency to approach Dr. Marcus' supervisor with the suggestion that he memorandum sent "the wrong message to the public."²²⁵ Shortly thereafter, Dr. Marcus was accused of "violent and aberrant behavior" and discharged.²²⁶

On December 3, 1992, following extended hearings, an administrative law judge found that Dr. Marcus had been fired on false pretexts because of his warnings against artificial fluoridation of public water supplies.²²⁷ The ALJ ordered Dr. Marcus reinstated with back salary, money damages, and attorney's fees,²²⁸ and, on February 7, 1994, the Secretary of Labor affirmed the reinstatement as ordered.

The simple and blunt meaning of this episode is impossible to misunderstand. The scientists, lawyers, and engineers at the national headquarters of the EPA have since used their union for protection against their administrators who, as the case of Dr. Marcus demonstrates, have a political agenda not necessarily in the public interest, and certainly not in the interest of the professionals at EPA

221. Dr. Marcus' historic memorandum of May 1, 1990, is a matter of public record. See *Marcus v. Environmental Protection Agency*, No. 92-TSC-5, Complainant's Exhibit 56, mentioned in the Recommended Decision and Order, Dec. 3, 1992, at 5 (U.S. Dep't Labor).

222. See *id.* at 1-3.

223. See *id.* at 3.

224. See *id.* at 4.

225. *Id.*, Recommended Decision and Order, Dec. 3, 1992, at 5.

226. See *id.* at 6-9.

227. See *id.* at 25-28.

228. See *id.* at 30-31.

who desire the independence required to act honestly for the general welfare.

Under the protection of their union they have made plain that their administrators may set policy, but that they as professionals refuse to conceal the errors of policy set. The subject of fluoridation has come to their attention. On July 2, 1997, the union members, at a duly called meeting,²²⁹ voted unanimously in support of a resolution that read:

Our members review of evidence over the last eleven years, including animal and human epidemiology studies, indicate a causal link between fluoride/fluoridation and cancer, genetic damage, neurological impairment, and bone pathology. Of particular concern are recent epidemiology studies linking fluoride exposures to lower I.Q. in children. As professionals who are charged with assessing the safety of drinking water, we conclude that the health and welfare of the public are not served by the addition of this substance to the public water supply.²³⁰

If artificial fluoridation of public water supplies causes cancer in man, as the published laboratory studies and epidemiological surveys indicate, and as judicial findings confirm, then nobody should be surprised to see that it produces a host of other human ailments. Who should be surprised to learn that dumping a

229. At the time of this resolution, scientists, lawyers, and engineers at the national headquarters of EPA were organized in the National Federation of Federal Employees, Local 2050. These professional people are now organized as the National Treasury Employees Union, Chapter 280.

230. This resolution has been released to the press by the professional union at the national headquarters of EPA, but, not surprisingly, the government of the United States has not seen fit to publish the document. We are indebted to Dr. J. William Hirzy at EPA for our copy. Aside from the material cited in this article, the evidence considered in support of this resolution included, on the question of cancer, PERRY COHN, NEW JERSEY DEPARTMENT OF HEALTH, A BRIEF REPORT ON THE ASSOCIATION OF DRINKING WATER FLUORIDATION AND THE INCIDENCE OF OSTEOSARCOMA AMONG WHITE MALES (1992). This epidemiological survey is particularly important because its finding with respect to human males parallels the NTP study which suggests that sodium fluoride induces osteosarcomas in male rats. To the same effect, is John Yiamouyiannis, *Fluoridation and Cancer: The Biology and Epidemiology of Bone and Oral Cancer Related to Fluoridation*, 26 FLUORIDE 83 (1993). Also considered in support of the resolution of July 2, 1997, on the question of bone pathology was Lawrence Riggs et al., *Effect of Fluoride Treatment on the Fracture Rate in Postmenopausal Women with Osteoporosis*, 322 NEW ENG. J. MED. 802 (1990). Taken into account on the question of neurological impairment was Phyllis J. Mullenix et al., *Neurotoxicity of Sodium Fluoride in Rats*, 17 NEUROT. & TERAT. 169 (1995). Since published to the same effect is Julie Varner et al., *Chronic Administration of Aluminum Fluoride or Sodium Fluoride to Rats in Drinking Water: Alterations in Neuronal and Cerebrovascular Integrity*, BRAIN RES. 784 (1998) 284-98. The epidemiological studies on fluoride exposure and the I.Q.'s of children were done in China. They are abstracted in English as X. S. Li et al., *Effect of Fluoride Exposure on Intelligence in Children*, 28 FLUORIDE 189 (1995), and L.B. Zhao et al., *Effect of a High Fluoride Water Supply on Children's Intelligence*, 29 FLUORIDE 190 (1996).

carcinogen and mutagen in public drinking water has not only been accompanied by devastating increases in cancer mortality, but may also reduce human intelligence?

The end of fluoridation will take time, but not because time is necessary to develop essential scientific information. We already know enough to appreciate the enormity of the risk. We knew enough many years ago.

But the end will finally arrive, because, as Aristotle said at the beginning of the *Metaphysics*, all men by nature desire to know.²³¹ Ignorance cannot be perpetuated forever. The necessary legal and scientific reforms will come in the twenty-first century. Our descendants will look back on us, and they will be amazed.

231. See BASIC WORKS OF ARISTOTLE 689 (W.D. Ross trans., Richard McKeon ed. 1941).

APPENDIX

TABLE 1. The Basic Data in Unweighted Averages for 1940-1950 and 1953-1968.

Year	CDRo Control Cities (-F)	CDRo Experimental Cities (+F)
1940	158.4	155.5
1941	152.4	155.2
1942	153.9	157.2
1943	159.2	161.6
1944	162.5	162.3
1945	165.6	168.4
1946	168.5	171.6
1947	174.5	172.6
1948	178.0	173.2
1949	179.5	179.4
1950	178.9	179.6
1953	188.2	191.3
1954	185.6	194.1
1955	189.5	196.3
1956	189.1	203.6
1957	188.4	207.1
1958	188.6	203.5
1959	193.0	204.7
1960	191.1	207.0
1961	190.4	209.3
1962	190.2	207.2
1963	189.4	210.9
1964	190.3	212.6
1965	194.3	218.6
1966	193.4	224.8
1967	198.8	224.4
1968	199.4	226.4

FIGURE 1. The Basic Data in Unweighted Averages for 1940-1950 and 1953-1968.^a

a The vertical axis represents observed cancer death rates per 100,000 (CDRo). The horizontal axis represents years. The white diamonds represent the control (-F) cities. The black diamonds represent the experimental (+F) cities. The vertical lines touching the horizontal axis at 1952 and 1956 represent the period during which fluoridation was started in the experimental cities.

TABLE 2. The Basic Data in Weighted Averages for 1940-1950 and 1953-1968.

Year	CDRo Control Cities (-F)	CDRo Experimental Cities (+F)
1940	159.9	155.6
1941	154.5	156.3
1942	154.7	158.3
1943	159.8	162.4
1944	163.2	164.2
1945	167.0	168.9
1946	169.9	171.8
1947	175.0	173.9
1948	177.8	174.3
1949	180.4	181.1
1950	179.0	180.8
1953	185.9	190.2
1954	182.6	192.3
1955	186.1	193.9
1956	187.6	201.6
1957	185.2	204.5
1958	184.3	199.7
1959	188.8	201.0
1960	185.0	205.8
1961	185.7	206.0
1962	183.8	204.6
1963	184.8	208.6
1964	184.8	208.7
1965	187.0	212.5
1966	188.2	218.5
1967	190.1	218.4
1968	191.1	219.7

FIGURE 2. The Basic Data in Weighted Averages for 1940-1950 and 1953-1968.^b

^b The vertical axis represents observed cancer death rates per 100,000 (CDRo). The horizontal axis represents years. The white diamonds represent the control (-F) cities. The black diamonds represent the experimental (+F) cities. The vertical lines touching the horizontal axis at 1952 and 1956 represent the period during which fluoridation was started in the experimental cities.

WAC 246-290-001
Purpose and scope.

(1) The purpose of this chapter is to define basic regulatory requirements and to protect the health of consumers using public drinking water supplies.

(2) The rules of this chapter are specifically designed to ensure:

- (a) Adequate design, construction, sampling, management, maintenance, and operation practices; and
- (b) Provision of safe and high quality drinking water in a reliable manner and in a quantity suitable for intended use.
- (3) Purveyors shall be responsible for complying with the regulatory requirements of this chapter.

(4) These rules are intended to conform with Public Law 93-523, the Federal Safe Drinking Water Act of 1974, and Public Law 99-339, the Safe Drinking Water Act Amendments of 1986, and certain provisions of Public Law 104-182, the Safe Drinking Water Act Amendments of 1996.

(5) The rules set forth are adopted under chapter 43.20 RCW. Other statutes relating to this chapter are:

- (a) RCW 43.20B.020, Fees for services -- Department of health and department of social and health services;
- (b) Chapter 43.70 RCW, Department of health;
- (c) Chapter 70.05 RCW, Local health department, boards, officers -- Regulations;
- (d) Chapter 70.116 RCW, Public Water System Coordination Act of 1977;
- (e) Chapter 70.119 RCW, Public water supply systems -- Certification and regulation of operators;
- (f) Chapter 70.119A RCW, Public water systems -- Penalties and compliance; and
- (g) Chapter 70.142 RCW, Chemical contaminants and water quality.

[Statutory Authority: RCW 43.02.050 [43.20.050]. 99-07-021, § 246-290-001, filed 3/9/99, effective 4/9/99. Statutory Authority: RCW 43.20.050. 93-08-011 (Order 352B), § 246-290-001, filed 3/25/93, effective 4/25/93; 91-02-051 (Order 124B), recodified as § 246-290-001, filed 12/27/90, effective 1/31/91. Statutory Authority: P.L. 99-339. 89-21-020 (Order 336), § 248-54-005, filed 10/10/89, effective 11/10/89. Statutory Authority: RCW 34.04.045. 88-05-057 (Order 307), § 248-54-005, filed 2/17/88. Statutory Authority: RCW 43.20.050. 83-19-002 (Order 266), § 248-54-005, filed 9/8/83.]

C-1

WAC 246-290-220
Drinking water materials and additives.

(1) All materials shall conform to the ANSI/NSF Standard 61 if in substantial contact with potable water supplies. For the purposes of this section, "substantial contact" means the elevated degree that a material in contact with water may release leachable contaminants into the water such that levels of these contaminants may be unacceptable with respect to either public health or aesthetic concerns. It should take into consideration the total material/water interface area of exposure, volume of water exposed, length of time water is in contact with the material, and level of public health risk. Examples of water system components that would be considered to be in "substantial contact" with drinking water are filter media, storage tank interiors or liners, distribution piping, membranes, exchange or adsorption media, or other similar components that would have high potential for contacting the water. Materials associated with components such as valves, pipe fittings, debris screens, gaskets, or similar appurtenances would not be considered to be in substantial contact.

(2) Materials or additives in use prior to the effective date of these regulations that have not been listed under ANSI/NSF Standard 60 or 61 may be used for their current applications until the materials are scheduled for replacement, or that stocks of existing additives are depleted and scheduled for reorder.

(3) Any treatment chemicals, with the exception of commercially retailed hypochlorite compounds such as unscented Clorox, Purex, etc., added to water intended for potable use must comply with ANSI/NSF Standard 60. The maximum application dosage recommendation for the product certified by the ANSI/NSF Standard 60 shall not be exceeded in practice.

(4) Any products used to coat, line, seal, patch water contact surfaces or that have substantial water contact within the collection, treatment, or distribution systems must comply with the appropriate ANSI/NSF Standard 60 or 61. Application of these products must comply with recommendations contained in the product certification.

(5) The department may accept continued use of, and proposals involving, certain noncertified chemicals or materials on a case-by-case basis, if all of the following criteria are met:

(a) The chemical or material has an acknowledged and demonstrable history of use in the state for drinking water applications;

(b) There exists no substantial evidence that the use of the chemical or material has caused consumers to register complaints about aesthetic issues, or health related concerns, that could be associated with leachable residues from the material; and

(c) The chemical or material has undergone testing through a protocol acceptable to the department and has been found to not contribute leachable compounds into drinking water at levels that would be of public health concern.

(6) Any pipe, pipe fittings, fittings, fixtures, solder, or flux used in the installation or repair of a public water system shall be lead-free:

(a) This prohibition shall not apply to leaded joints necessary for the repair of cast iron pipes; and

(b) Within the context of this section, lead-free shall mean:

(i) No more than eight percent lead in pipes and pipe fittings;

(ii) No more than two-tenths of one percent lead in solder and flux; and

(iii) Fittings and fixtures that are in compliance with standards established in accordance with 42 USC 300g-6(e).

[Statutory Authority: RCW 43.20.050 (2) and (3) and 70.119A.080 . 03-08-037, § 246-290-220, filed 3/27/03, effective 4/27/03. Statutory Authority: RCW 43.02.050 [43.20.050]. 99-07-021, § 246-290-220, filed 3/9/99, effective 4/9/99. Statutory Authority: RCW 43.20.050. 91-02-051 (Order 124B), recodified as § 246-290-220, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 34.04.045. 88-05-057 (Order 307), § 248-54-131, filed 2/17/88.]

C.2

WAC 246-290-310

Maximum contaminant levels (MCLs) and maximum residual disinfectant levels (MRDLs).

(1) General.

(a) The purveyor shall be responsible for complying with the standards of water quality identified in this section. If a substance exceeds its MCL or its maximum residual disinfectant level (MRDL), the purveyor shall take follow-up action under WAC 246-290-320.

(b) When enforcing the standards described under this section, the department shall enforce compliance with the primary standards as its first priority.

(2) Bacteriological.

(a) MCLs under this subsection shall be considered primary standards.

(b) If coliform presence is detected in any sample, the purveyor shall take follow-up action under WAC 246-290-320(2).

(c) Acute MCL. An acute MCL for coliform bacteria occurs when there is:

(i) Fecal coliform presence in a repeat sample;

(ii) *E. coli* presence in a repeat sample; or

(iii) Coliform presence in any repeat samples collected as a follow-up to a sample with fecal coliform or *E. coli* presence.

Note: For the purposes of the public notification requirements in Part 7, Subpart A of this chapter, an acute MCL is a violation that requires Tier 1 public notification.

(d) Nonacute MCL. A nonacute MCL for coliform bacteria occurs when:

(i) Systems taking less than forty routine samples during the month have more than one sample with coliform presence; or

(ii) Systems taking forty or more routine samples during the month have more than 5.0 percent with coliform presence.

(e) MCL compliance. The purveyor shall determine compliance with the coliform MCL for each month the system provides drinking water to the public. In determining MCL compliance, the purveyor shall:

(i) Include:

(A) Routine samples; and

(B) Repeat samples.

(ii) Not include:

(A) Samples invalidated under WAC 246-290-320 (2)(d); and

(B) Special purpose samples.

(3) Inorganic chemical and physical.

(a) The primary and secondary MCLs are listed in Table 4 and 5:

TABLE 4

INORGANIC CHEMICAL CHARACTERISTICS

Substance	Primary MCLs (mg/L)	
	Antimony (Sb)	
Arsenic (As)		0.010*

C-3

WAC 246-290-416
Sanitary surveys.

(1) All public water systems shall submit to a sanitary survey conducted by the department, or the department's designee, based upon the following schedule:

(a) For community and nontransient noncommunity water systems, every five years, or more frequently as determined by the department. The sanitary surveys shall be consistent with the schedules presented in 40 CFR 141.21; and

(b) For transient noncommunity water systems, every five years unless the system uses only disinfected ground water and has an approved wellhead protection program, in which case the survey shall be every ten years. The sanitary surveys shall be conducted consistent with schedules presented in 40 CFR 141.21.

(c) For community public water systems that use a surface water or GWI source, every three years. Surveys may be reduced to every five years upon written approval from the department.

(2) All public water system purveyors shall be responsible for:

(a) Ensuring cooperation in scheduling sanitary surveys with the department, or its designee; and

(b) Ensuring the unrestricted availability of all facilities and records at the time of the sanitary survey.

(3) All public water systems that use a surface water or GWI source shall, within forty-five days following receipt of a sanitary survey report that identifies significant deficiencies, identify in writing to the department how the system will correct the deficiencies and propose a schedule to complete the corrections. The department may modify the schedule if necessary to protect the health of water system users.

[Statutory Authority: RCW 43.20.050 (2) and (3) and 70.119A.080 . 03-08-037, § 246-290-416, filed 3/27/03, effective 4/27/03. Statutory Authority: RCW 43.02.050 [43.20.050]. 99-07-021, § 246-290-416, filed 3/9/99, effective 4/9/99.]

C-4

WAC 246-290-455

Operation of chemical contaminant treatment facilities.

(1) Purveyors shall ensure finished drinking water from chemical contaminant treatment facilities complies with the minimum water quality standards established in WAC 246-290-310. This section does not apply to facilities used only for corrosion control treatment purposes.

(2) The purveyor shall collect finished drinking water samples at a point directly downstream of the treatment system prior to the first consumer on a monthly basis.

(a) Finished drinking water samples from treatment systems utilized for removal of contaminants with established primary MCLs shall be submitted to a certified laboratory for analysis of the specific contaminant(s) of concern.

(b) Finished drinking water samples from treatment systems utilized for removal of contaminants with established secondary MCLs shall be submitted to a certified laboratory for analysis or analyzed for the specific contaminant(s) of concern by the purveyor through department-approved on-site methods.

(c) Additional finished drinking water monitoring may be required by the department based on the complexity or size of the water system.

(3) If primary MCLs following treatment are exceeded in four or more months of a consecutive twelve-month compliance period, the purveyor shall submit a project report to the department that addresses the failure to maintain compliance. The project report shall include methods and schedules to correct the treatment deficiency and/or indicate schedules for implementing an alternate source of supply or an effective treatment technology.

(4) If secondary MCLs following treatment are exceeded in four or more months of a consecutive twelve-month compliance period, the purveyor shall take action per WAC 246-290-320 (3)(d).

[Statutory Authority: RCW 43.02.050 [43.20.050]. 99-07-021, § 246-290-455, filed 3/9/99, effective 4/9/99.]

C-5

WAC 246-290-460
Fluoridation of drinking water.

- (1) Purveyors shall obtain written department approval of fluoridation treatment facilities before placing them in service.
- (2) Where fluoridation is practiced, purveyors shall maintain fluoride concentrations in the range 0.8 through 1.3 mg/L throughout the distribution system.
- (3) Where fluoridation is practiced, purveyors shall take the following actions to ensure that concentrations remain at optimal levels and that fluoridation facilities and monitoring equipment are operating properly:
 - (a) Daily monitoring.
 - (i) Take daily monitoring samples for each point of fluoride addition and analyze the fluoride concentration. Samples must be taken downstream from each fluoride injection point at the first sample tap where adequate mixing has occurred.
 - (ii) Record the results of daily analyses in a monthly report format acceptable to the department. A report must be made for each point of fluoride addition.
 - (iii) Submit monthly monitoring reports to the department within the first ten days of the month following the month in which the samples were collected.
 - (b) Monthly split sampling.
 - (i) Take a monthly split sample at the same location where routine daily monitoring samples are taken. A monthly split sample must be taken for each point of fluoride addition.
 - (ii) Analyze a portion of the sample and record the results on the lab sample submittal form and on the monthly report form.
 - (iii) Forward the remainder of the sample, along with the completed sample form to the state public health laboratory, or other state-certified laboratory, for fluoride analysis.
 - (iv) If a split sample is found by the certified lab to be:
 - (A) Not within the range of 0.8 to 1.3 mg/l, the purveyor's fluoridation process shall be considered out of compliance.
 - (B) Differing by more than 0.30 mg/l from the purveyor's analytical result, the purveyor's fluoride testing shall be considered out of control.
- (4) Purveyors shall conduct analyses prescribed in subsection (3) of this section in accordance with procedures listed in the most recent edition of *Standard Methods for the Examination of Water and Wastewater*.
- (5) The purveyor may be required by the department to increase the frequency, and/or change the location of sampling prescribed in subsection (3) of this section to ensure the adequacy and consistency of fluoridation.

[Statutory Authority: RCW 43.02.050 [43.20.050], 99-07-021, § 246-290-460, filed 3/9/99, effective 4/9/99. Statutory Authority: RCW 43.20.050. 91-02-051 (Order 124B), recodified as § 246-290-460, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 34.04.045. 88-05-057 (Order 307), § 248-54-235, filed 2/17/88. Statutory Authority: RCW 43.20.050. 83-19-002 (Order 266), § 248-54-235, filed 9/8/83.]

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WAC 246-290-480
Recordkeeping and reporting.

(1) Records. The purveyor shall keep the following records of operation and water quality analyses:

(a) Bacteriological and turbidity analysis results shall be kept for five years. Chemical analysis results shall be kept for as long as the system is in operation. Records of source meter readings shall be kept for ten years. Other records of operation and analyses required by the department shall be kept for three years. All records shall bear the signature of the operator in responsible charge of the water system or his or her representative. Systems shall keep these records available for inspection by the department and shall send the records to the department if requested. Actual laboratory reports may be kept or data may be transferred to tabular summaries, provided the following information is included:

(i) The date, place, and time of sampling, and the name of the person collecting the sample;

(ii) Identification of the sample type (routine distribution system sample, repeat sample, source or finished water sample, or other special purpose sample);

(iii) Date of analysis;

(iv) Laboratory and person responsible for performing analysis;

(v) The analytical method used; and

(vi) The results of the analysis.

(b) Records of action taken by the system to correct violations of primary drinking water standards. For each violation, records of actions taken to correct the violation, and copies of public notifications shall be kept for no less than three years after the last corrective action taken.

(c) Copies of any written reports, summaries, or communications relating to sanitary surveys or SPIs of the system conducted by system personnel, by a consultant or by any local, state, or federal agency, shall be kept for ten years after completion of the sanitary survey or SPI involved.

(d) Copies of project reports, construction documents and related drawings, inspection reports and approvals shall be kept for the life of the facility.

(e) Where applicable, records of the following shall be kept for a minimum of three years:

(i) Chlorine residual;

(ii) Fluoride level;

(iii) Water treatment plant performance including, but not limited to:

(A) Type of chemicals used and quantity;

(B) Amount of water treated;

(C) Results of analyses; and

(iv) Other information as specified by the department.

(f) The purveyor shall retain copies of public notices made under Part 7, Subpart A of this chapter and certifications made to the department under 40 CFR 141.33(e) for a period of at least three years after issuance.

(g) Purveyors using conventional, direct, or in-line filtration that recycle spent filter backwash water, thickener supernatant, or liquids from dewatering processes within their treatment plant shall, beginning no later than June 8, 2004, collect and retain on file the following information for review and evaluation by the department:

(i) A copy of the recycle notification and information submitted to the department under WAC 246-290-660 (4)(a)(i).

(ii) A list of all recycle flows and the frequency with which they are returned.

(iii) Average and maximum backwash flow rate through the filters and the average and maximum duration of the filter backwash process in minutes.

(iv) Typical filter run length and a written summary of how filter run length is determined.

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(v) The type of treatment provided for the recycle flow.

(vi) Data on the physical dimensions of the equalization and/or treatment units, typical and maximum hydraulic loading rates, type of treatment chemicals used and average dose and frequency of use, and frequency at which solids are removed, if applicable.

(h) Purveyors required to conduct disinfection profiling and benchmarking under 40 CFR 141.530 through 141.544 shall retain the results on file indefinitely.

(i) Copies of monitoring plans developed under this chapter shall be kept for the same period of time as the records of analyses taken under the plan are required to be kept under (a) of this subsection.

(j) Purveyors using surface water or GWI sources must keep the records required by 40 CFR 141.722.

(2) Reporting.

(a) Unless otherwise specified in this chapter, the purveyor shall report to the department within forty-eight hours the failure to comply with any national primary drinking water regulation (including failure to comply with any monitoring requirements) as set forth in this chapter. For violations assigned to Tier 1 in WAC 246-290-71001, the department must be notified as soon as possible, but no later than twenty-four hours after the violation is known.

(b) The purveyor shall submit to the department reports required by this chapter, including tests, measurements, and analytic reports. Monthly reports are due before the tenth day of the following month, unless otherwise specified in this chapter.

(c) The purveyor shall submit to the department copies of any written summaries or communications relating to the status of monitoring waivers during each monitoring cycle or as directed by the department.

(d) Source meter readings shall be made available to the department.

(e) Water facilities inventory form (WFI).

(i) Purveyors of **community** and **NTNC** systems shall submit an annual WFI update to the department;

(ii) Purveyors of **TNC** systems shall submit an updated WFI to the department as requested;

(iii) Purveyors shall submit an updated WFI to the department within thirty days of any change in name, category, ownership, or responsibility for management of the water system, or addition of source or storage facilities; and

(iv) At a minimum the completed WFI shall provide the current names, addresses, and telephone numbers of the owners, operators, and emergency contact persons for the system.

(f) Bacteriological. The purveyor shall notify the department of the presence of:

(i) Coliform in a sample, within ten days of notification by the laboratory; and

(ii) Fecal coliform or *E. coli* in a sample, by the end of the business day in which the purveyor is notified by the laboratory. If the purveyor is notified of the results after normal close of business, then the purveyor shall notify the department before the end of the next business day.

(g) Systems monitoring for disinfection byproducts under WAC 246-290-300(6) shall report information to the department as specified in 40 CFR 141.134.

(h) Systems monitoring for disinfectant residuals under WAC 246-290-300(6) shall report information to the department as specified in subsection (2)(b) of this section, and 40 CFR 141.134(b).

(i) Systems required to monitor for disinfection byproduct precursor removal under WAC 246-290-300(6) shall report information to the department as specified in 40 CFR 141.134(d).

(j) Systems required to monitor for disinfection byproducts under WAC 246-290-300(6) shall report information to the department as specified in 40 CFR 141.600 - 629.

(k) Systems subject to the enhanced treatment requirements for *Cryptosporidium* under WAC 246-290-630(4) shall report information to the department as specified in 40 CFR 141.706 and 141.721.

(l) Systems that use acrylamide and epichlorohydrin in the treatment of drinking water, must certify annually in writing to the department that the combination (or product) of dose and monomer level does not exceed the levels specified in (l)(i) and (ii) of this subsection. Certifications shall reference maximum use levels established by an ANSI-accredited listing organization

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approved by the department.

- (i) Acrylamide = 0.05 percent dosed at 1 ppm (or equivalent); and
- (ii) Epichlorohydrin = 0.01 percent dosed at 20 ppm (or equivalent).

(m) Use of products that exceed the specified levels constitutes a treatment technique violation and the public must be notified under the public notice requirements under Part 7, Subpart A of this chapter.

(n) Systems shall submit to the department, in accordance with 40 CFR 141.31(d), a certification that the system has complied with the public notification regulations (Part 7, Subpart A of this chapter) when a public notification is required. Along with the certification, the system shall submit a representative copy of each type of notice.

[Statutory Authority: RCW 43.20.050. 09-21-045, § 246-290-480, filed 10/13/09, effective 1/4/10. Statutory Authority: RCW 70.119A.180 and 43.20.050. 08-03-061, § 246-290-480, filed 1/14/08, effective 2/14/08. Statutory Authority: RCW 70.119A.180. 07-02-025B, § 246-290-480, filed 12/22/06, effective 1/22/07. Statutory Authority: RCW 43.20.050 and 70.119A.080. 04-04-056, § 246-290-480, filed 1/30/04, effective 3/1/04. Statutory Authority: RCW 43.20.050 (2) and (3) and 70.119A.080. 03-08-037, § 246-290-480, filed 3/27/03, effective 4/27/03. Statutory Authority: RCW 43.02.050 [43.20.050]. 99-07-021, § 246-290-480, filed 3/9/99, effective 4/9/99. Statutory Authority: RCW 43.20.050. 94-14-001, § 246-290-480, filed 6/22/94, effective 7/23/94; 93-08-011 (Order 352B), § 246-290-480, filed 3/25/93, effective 4/25/93; 92-04-070 (Order 241B), § 246-290-480, filed 2/4/92, effective 3/6/92; 91-02-051 (Order 124B), recodified as § 246-290-480, filed 12/27/90, effective 1/31/91. Statutory Authority: P.L. 99-339. 89-21-020 (Order 336), § 248-54-265, filed 10/10/89, effective 11/10/89. Statutory Authority: RCW 34.04.045. 88-05-057 (Order 307), § 248-54-265, filed 2/17/88. Statutory Authority: RCW 43.20.050. 83-19-002 (Order 266), § 248-54-265, filed 9/8/83.]

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