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

PROTECT THE PENINSULA'S FUTURE, CLALLAM COUNTY
CITIZENS FOR SAFE DRINKING WATER, and ELOISE KAILIN

Appellants,

v.

CITY OF PORT ANGELES and CITY OF FORKS

Respondents/Cross-Appellants,

ANSWER OF RESPONDENTS/CROSS-APPELLANTS CITY OF
PORT ANGELES AND CITY OF FORKS
TO AMICUS BRIEF OF OWOC! AND WASW

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1. INTRODUCTION

Respondents/Cross-Appellants City of Port Angeles and City of Forks (“Cities”) operate public drinking water utilities that are regulated comprehensively by the Washington Department of Health and Board of Health. The Cities provide fluoridated drinking water, as do most of the larger drinking water utilities in the State of Washington. In 2010, the Washington Supreme Court held that fluoridated public drinking water is expressly allowed, that the U. S. Food and Drug Administration (“FDA”) does not regulate public drinking water, and that fluoride “is one of the permitted chemicals” that may be added to public drinking water. *City of Port Angeles v. Our Water—Our Choice!*, 170 Wn.2d 1 (2010); see WAC 246-290-460.

2. SUMMARY OF RESPONSE ARGUMENT

In this lawsuit, petitioners have attempted to characterize the Cities’ fluoridated public drinking water and permitted fluoridation additives as prescription drugs in violation of Chapter 69.41 RCW. These frivolous claims are directly contradicted by the Supreme Court’s holdings in *City of Port Angeles* and the Supreme Court’s earlier holding in *Kaul v. City of Chehalis*, 45 Wn.2d 616, 625, 277 P.2d 352 (1955) (a city providing fluoridated public drinking water “is not engaged in selling drugs”).¹ Petitioners’ claims are also frivolous because they knew that:

¹ The holding in the *Kaul* case directly disposed of one of the assignments of error in that case, and is not *dicta* as falsely claimed by petitioners.

1) The FDA is the federal agency that designates products as drugs, and the FDA has determined that it does not regulate public drinking water – rather the Environmental Protection Agency (“EPA”) has exclusive responsibility “for direct and indirect additives to and other substances in drinking water.” MOU 225-79-2001; published at 44 FR 42775;² and

2) Petitioners cannot possibly show that fluoridated drinking water and the City’s fluoridation additives meet the controlling definition of “legend drug” adopted by the Board of Pharmacy, which requires legend drugs to be “designated as legend drugs under federal law” and requires legend drugs to be listed in the 2009 *Drug Topics Red Book*.

The brief of amici OWOC! and WASW, through same counsel as petitioners, has merely repeated the conclusory allegations and baseless arguments made by petitioners. The trial court correctly dismissed petitioners for failure to state a claim under CR 12(b)(6). On motion to dismiss, neither the trial court nor this Court is required to accept petitioners’ conclusory allegations that the FDA and the Board of Pharmacy regulate fluoride in public drinking water as a prescription drug. *E.g., Shutt v. Moore*, 26 Wn. App. 450, 453, 613 P.2d 1188 (1980) (court

² A copy of MOU 225-79-2001 is attached as **Appendix A**. This MOU is listed on the FDA’s website as a currently applicable document at: <http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm116216.htm>.

is not required to accept “[g]eneral conclusory allegations” on 12(b)(6) motion). Amici’s continued claims to the contrary are meritless.

The only new argument in the amicus brief is a sham. They assert new testimony from outside the record on review, regarding a letter from petitioner Kailin that was addressed to the Secretary of U. S. Housing and Human Services (“HHS”) Kathleen Sibelius. They claim that this letter somehow compels the FDA to regulate fluoridated drinking water as a drug.³ This argument is frivolous. The statute relied on by amici only applies to applicants and sponsors of products seeking FDA approval. 21 U.S.C. 360bbb-2; *see* 21 C.F.R. Part 3, §§ 3.1 through 3.10. Even if petitioners were a product sponsor, they completely failed to follow FDA’s required submittal process in the federal regulations implementing that statute and adopted by the FDA. 21 C.F.R. §3.7.

3. ARGUMENT

3.1 Amici’s Argument that FDA Automatically Designated Fluoridated Drinking Water as a Drug Is Frivolous.

In 1997, Congress passed the Food and Drug Modernization Act of 1997 (“Modernization Act”). Pub. L. 105-115. The Modernization Act amended the Federal Food, Drug and Cosmetics Act (“FFDCA”). The FDA is the federal agency that administers the FFDCA and that has primary jurisdiction to classify products under the FFDCA. *E.g.*, *Weinberger, v. Hynson, Westcot & Dunning, Inc.*, 412 U.S. 609 – 626-27,

³ The FDA is one of the 11 operating divisions under HHS.

93 S. Ct. 2469 (1973) (FDA has “primary jurisdiction to determine whether a product is a drug”). One goal of the Modernization Act was the prompt approval of new products submitted to the FDA, including combination products and products that might be subject to regulation by more than one division of the FDA. Pub. L. 105-115, Section 101.

As part of the Modernization Act, the Congress directed HHS to implement streamlined procedures for the resolution of disputes regarding products and for product classification requests. 21 U.S.C. § 360bbb-1; 21 U.S.C. § 360bbb-2. The first section allows a “sponsor, applicant or manufacturer” to request a review of any scientific controversy. 21 U.S.C. § 360bbb-1 (attached as **Appendix B**). The second provisions allows a person “who submits an application or submission ... under this Act [the FFDCA]” to also submit a request regarding how that product should be classified and which department of FDA should regulate the product. 21 U.S.C. § 360bbb-2 (attached as **Appendix C**). The FDA, which has been delegated authority by the Secretary to administer the FFDCA,⁴ will respond within 60 days to the request or accept the project sponsor’s recommendation regarding classification. *Id.*

The FDA adopted detailed regulations implementing 21 U.S.C. § 360bbb-2. 21 C.F.R. Part 3, §§ 3.1 – 3.10 (attached as **Appendix D**). Those regulations make it clear that this request procedure is intended for sponsors of products – defined as applicants for FDA premarket review –

⁴ 21 C.F.R. §5.10.

and not for the general public. 21 C.F.R §3.2, §3.7. The regulations require all requests to include detailed and specific information about the product, including: identity of sponsor, identification of any premarket approvals, chemical composition information, status and reports on all testing, proposed dosages and administration, and descriptions of all related products. 21 C.F.R. §3.7. The request must be filed with the FDA product jurisdiction officer (as defined in 21 C.F.R §3.2) not the HHS Secretary.

Amici claim that petitioner Eloise Kailin and attorney Gerald Steel sent letters addressed personally to Kathleen Sibelius, Secretary of HHS.⁵ Secretary Sibelius is a cabinet level official, who oversees the 11 operating divisions of HHS, 300 programs, a \$698 Billion budget, and 65,000 employees.⁶ Because Secretary Sibelius did personally respond to their letter within 60 days, amici naively claim that the Secretary of HHS has decided to regulate fluoride drinking water additives as prescription drugs.

Ms. Kailin's and Mr. Steel's letters were ineffective under 21 U.S.C. 360bbb-2. First, neither Ms. Kailin nor Mr. Steel is a product sponsor to whom that section applies.⁷ Second, Ms. Kailin and Mr. Steel did not include the information required by 21 C.F.R. §3.7 in their letters.

⁵ Declaration of Gerald Steel accompanying amicus brief. As discussed later in this response, Mr. Steel's declaration should be stricken.

⁶ <http://www.hhs.gov/about/>

⁷ This does not mean petitioners are without a federal remedy. Any person may submit a petition to the FDA under 21 C.F.R. §§10.25 and 10.30 to request rule-making. Petitioners have failed to pursue this remedy.

Third, Ms. Kailin and Mr. Steel did not send their letter to the correct party – the FDA product jurisdiction officer. In fact, this supposed “gotcha” letter sent to Secretary Sibelius is a sham. Both Ms. Kailin and Mr. Steel know that a Cabinet-level officer does not answer personal letters about one of the hundreds of programs administered by her extensive, multi-agency department. Rather, the Secretary of HHS and her Vice-Secretary for Health have delegated all administration and duties under the FFDCA to the FDA Commissioner. 21 C.F.R. §5.10. The supposed letters to Secretary Sibelius are a dissembling pretense, and the Cities should be awarded costs and fees for having to respond to such a baseless argument.

Moreover, as discussed in the prior briefs of the Cities, the FDA does not regulate public drinking water. The FDA determined that passage of the Safe Drinking Water Act (SDWA) “implicitly repealed FDA’s authority under the FFDCA over water used for drinking water purposes” and that “EPA will have responsibility for direct and indirect additives to and other substances in drinking water.” MOU 225-79-2001; 44 FR 42775 (Appendix A hereto). Our Supreme Court ruled the same in *City of Port Angeles*, 170 Wn.2d at 6, f.n. 1.

3.2 This Court Should Not Accept Petitioner’s Misrepresentations Regarding The Regulation Of Fluoridated Drinking Water.

The trial court dismissed petitioners’ complaint under CR 12(b)(6) for failure to state a claim. Neither the trial court nor this Court on appeal is required accept petitioners misrepresentations of fact or law on motion

to dismiss. *West v. State*, 162 Wn. App. 120, 128, 252 P.3d 406 (2011) (court is “not required to accept the complaint’s legal conclusions as true”); *Shutt v. Moore*, 26 Wn. App. 450, 453, 613 P.2d 1188 (1980) (court is not required to accept “[g]eneral conclusory allegations” on 12(b)(6) motion); see *Farm Credit Services of America v. American State Bank*, 339 F.3d 764, 767 (8th Cir., 2003) (court is not required to assume “unwarranted inferences and sweeping legal conclusions cast in the form of factual allegations”); *Anderson v. Clow*, 89 F.3d 1399, 1403 (9th Cir. 1996) (conclusory allegations and unwarranted inferences are insufficient to defeat motion to dismiss for failure to state a claim).

The amicus brief continues petitioners’ misrepresentations – demanding this Court accept as true petitioners’ “allegations” that fluoridated drinking water and the Cities’ bulk fluoridation additives are regulated as prescription drugs. In fact, the Complaint does not mention public drinking water and the Cities’ bulk fluoridations when it alleges that the FDA and the Board of Pharmacy regulate fluoride under some circumstances.⁸ This Court must reject those conclusory allegations about how drinking water is regulated. And under the controlling law, including Washington Supreme Court precedent, there is no set of facts petitioners can show that would prove the Cities’ drinking water or drinking water additives are prescription drugs.

⁸ AR 259 (Complaint ¶¶5 and 6).

3.3 Petitioners and Amici Intentionally Misrepresent That Fluoridated Drinking Water And The Cities' Bulk Additives Are Legend Drug.

The Washington Board of Pharmacy adopts regulations to administer the legend drug statute. RCW 69.41.075. The Board has adopted the controlling definition of “legend drugs” at WAC 246-883-020(2). Under that regulation, substances must be “designated as legend drugs under federal law” and “listed as such in the 2009 Drug Topics Red Book.” *Id.* Neither of those standards can be met.

3.3.1 Fluoridated Drinking Water and the Cities' Bulk Additives Are Not Designated As Legend Drugs Under Federal Law.

There are no facts amici or petitioners can prove to show the Cities' drinking water and additives are “designated as legend drugs under federal law,” and they intentionally seek to mislead the Court. The FFDCA is the federal statute governing drugs. 21 U.S.C. §301 *et seq.* There is no mention of public drinking water in the FFDCA. Instead, Congress regulates public drinking water under the SDWA, and granted the EPA jurisdiction to regulate public drinking water systems in that statute. 42 U.S.C. §300 *et seq.*

The United States Supreme Court and other federal courts (in an unbroken line of cases) hold that the FDA has “primary jurisdiction” to determine whether a product is a drug under the FFDCA. *Hynson, Westcott & Dunning*, 42 U.S. at 626-627; *Weinberger v. Bentex Pharmaceuticals*, 412 U.S. 640, 643-644; 93 S. Ct. 2469 (1973). Amici argue that the Cities have not proven that FDA has primary jurisdiction.

Cities do not need to do so. The United States Supreme Court and 9th Circuit Court of Appeals have already decided that question.

Moreover, because the FDA has primary jurisdiction, the courts will not even rule on whether a product is a drug under the FFDCA until all administrative remedies are exhausted before the FDA. *Dietary Supplements Coalition, Inc. v. Sullivan*, 978 F.2d 560, 563-564 (9th Cir. 1992); *Biotics Research Corp. v. Heckler*, 710 F.2d 1375, 1376-1377 (9th Cir. 1982). This means that petitioners must petition the FDA under 21 C.F.R. Part 10, and then sue FDA if they disagree. Rather than follow that required process, petitioners have chosen to bring this nuisance lawsuit against the Cities.

More directly, the Washington Supreme Court has already held that the FDA does not regulate public drinking water. *City of Port Angeles*, 170 Wn.2d at 6, f.n. 1. The FDA itself has entered into a MOU with the EPA stating that the SDWA “repealed FDA’s authority under the FFDCA over water used for drinking water purposes” and that “EPA will have responsibility for direct and indirect additives to and other substances in drinking water.” MOU 225-79-2001. This MOU has been repeatedly affirmed by EPA and FDA⁹ and is listed as an active MOU on the FDA

⁹ 58 FR 378 (January 5, 1993); 63 FR 54532 (October 9, 1998); 68 FR 58894 (October 10, 2003).

website.¹⁰ Amici and petitioners intentionally misrepresent the MOU's status to the Court.

Like petitioners, amici's only argument is that fluoridated drinking water meets the broad definition of a "drug" in the FFDCA. *See* 21 U.S.C. 321(g)(1). But under controlling law, only the FDA can determine what is a drug (or a prescription drug) under the FFDCA. E.g., *Dietary Supplements Coalition* 978 F.2d at 563-564. Clearly, the FDA has not designated the Cities' fluoridated drinking or bulk fluoridation additives as "legend drugs under federal law."

Amici continue to assert as "evidence" an 2000 letter from an FDA staffperson to a congressional committee. CP 352-354. That letter merely stated that FDA regulates some fluorides and has published a rule for over-the-counter anticaries products. In the same paragraph, the letter concludes: "As you know, the Environmental Protection Agency regulates fluoride in the water supply." CP 352. So amici's own evidence shows that the FDA does not regulate drinking water and its additives.

Amici's argument that EPA does not regulate fluoridation additives is both incorrect and irrelevant (even if true, it does not show that FDA has designated drinking water additives as federal legend drugs). EPA regulates additives by regulating the drinking water itself. Any substance in drinking water, whether it is added to the water or naturally

¹⁰<http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm116216.htm>.

occurring, is regulated by EPA if that substance might adversely affect human health.¹¹ 40 C.F.R. Part 141, Subpart O, App. A; 40 C.F.R. Part 143. EPA has authority to set standards for additives and treatment techniques under Section 1431 of the SDWA. *See* 44 FR 42775. EPA has chosen to work with the National Science Foundation to develop standards for drinking water additives. The resulting standard has been adopted as a controlling regulation by the Washington Board of Health. WAC 246-290-020 (adopting ANSI/NSF Standard 60).

3.3.2 Fluoridated Drinking Water and the Cities Bulk Additives Are Not Listed in the 2009 *Drug Topics Red Book*.

Amici and plaintiffs do not even argue that the second mandatory element of the Board of Pharmacy definition is met. Neither fluoridated public drinking water nor the bulk fluoridation additives used by the Cities are listed in the 2009 *Drug Topics Red Book*. CP 366-374. Because they are not listed, they are not legend drugs under Washington law.

Amici's only argument is to repeat misrepresentations based on a 2009 staff letter to one of petitioners, Bill Osmunson. Mr. Osmunson had requested the Board of Pharmacy to regulate fluoride as a poison. The Board of Pharmacy replied that fluorides were regulated as legend drugs

¹¹ The Court should note that the Cities do not, of course, distribute the additives themselves, which are bulk hydrofluorosilicic acid (Port Angeles) and bulk sodium fluoride (Forks). Rather, these chemicals are dissolved in the water to achieve a concentration of fluoride ions that meets Board of Health standards for fluoridation. WAC 246-290-460.

pursuant to the definition in WAC 246-883-020(2) **and** enclosed the pages of the *Drug Topics Red Book* containing **all** the fluoride legend drugs in Washington. Neither fluoridated public drinking water nor the Cities' bulk additives were listed in those pages from the *Drug Topics Red Book*. Amici's attempt to mislead the Court, by claiming the Board of Pharmacy regulates public drinking water, is unsupportable. There are **no** regulations from the Board of Pharmacy regulating drinking water or drinking water additives. Drinking water and additives are, however, comprehensively regulated by the Washington Board of Health and Department of Health. Amici and petitioners know this, but they continue their misrepresentations to this Court.

3.4 Motion to Strike Declaration of Gerald Steel and Fourth Declaration of Eloise Kailin, M.D.

The attorney for petitioners and petitioner Eloise Kailin have submitted testimony in the form of declarations attached to the Brief of Amici. Those declarations and attachments should be stricken and not considered for at least four independent reasons.

First, none of amici's testimony or documents attached are in the record on review. The testimony and exhibits concern letters allegedly sent to the Secretary of the United States Department of HHS. Neither petitioners nor amici have shown that any of the standards for new evidence on appeal in RAP 9.11 have been met.

Second, amici claim that the Court can take judicial notice of their testimony and new evidence. But judicial notice applies to self-evident

truths that no reasonable person could question, such as official records of when sunrise occurred. *State v. Bishop*, 90 Wn.2d 185, 580 P.2d 259 (1978). Amici's new evidence is testimony that depends on the veracity of the witnesses and is not proper for judicial notice.

Third, with respect to Mr. Steel, his testimony goes beyond identifying documents that have been otherwise authenticated by witnesses and are in the record. Instead, he is seeking to authenticate documents and testify about whether replies were received from the Secretary of HHS. Mr. Steel cannot make himself a necessary witness in this matter without violating RPC Rule 3.7 (Lawyer as Witness). This Court should prevent a violation of the Rules of Professional Conduct by striking his declaration.

Fourth, the evidence presented by Steel and Kailin is irrelevant. Mr. Steel and Ms. Kailin claim to have sent letters to the Secretary of HHS requesting regulation of fluoridated drinking water and fluoridation additives as drugs.¹² As discussed supra in Section 3.1 of this brief, Mr. Steel and Ms. Kailin are not product sponsors who can petition the FDA under 21 U.S.C. §360bbb-2. Only persons who have made an "application or other submission for a product" can request determinations under that statute. Their letters also did not follow the request procedure required by FDA in 21 C.F.R Part 3. And most telling regarding amici's frivolous

¹² The letter were allegedly sent pursuant to 21 USC 360bbb-2, a portion of the FFDCA, which is administered by FDA.

assertions, the Washington Supreme Court has already determined that fluoridated drinking water is not a drug, *Kaul*, 45 Wn.2d at 625, and that the FDA does not regulate public drinking water, *City of Port Angeles*, 170 Wn.2d at 6, f.n. 1.

For all the above reasons the Steel and Kailin declarations should be stricken and not considered.

3.5 The Cities' Should Be Awarded Costs, Attorneys' Fees and Sanctions Under RAP 18.9.

The Court has authority to award costs and attorneys' fees for frivolous appeals. RAP 18.9(a). An appeal is frivolous if there are no debatable issues and there is no reasonable possibility of reversal. *Eugster v. City of Spokane*, 139 Wn. App. 21, 34, 156 P.3d 912 (2007). Sanctions should also be awarded to the Cities for being required to reply to the frivolous amicus brief, and the City moves for such an award.

Amici merely parrot the arguments already made by petitioners in this matter. For all the reasons stated in the Cities' Brief of Respondents and the Cities' Reply Brief, there are no debatable issues in this case. The petitioners and amici have not produced a single fact showing that the Cities' fluoridated public drinking water or additives are prescription drugs.

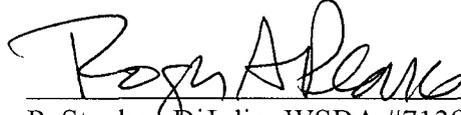
The only new argument raised by amici is that Ms. Kailin's supposed "gotcha" letter to Secretary Sibelius – a claim that FDA must now regulate fluoridated drinking water and fluoridation additives as prescription drugs. That argument relies on improper evidence, which

must be stricken. It also relies on a statute that does not apply to Ms. Kailin. Ms. Kailin and Mr. Steel failed to follow controlling FDA regulations. And their letters not sent to the proper party – as required under FDA regulations. This type of sophistry should not be countenanced by the Court. The Cities and this Court continue to be burdened by the nonsense legal arguments of petitioners and amici. As the trial court found, petitioners' remedy is with the Legislature, not the courts. VRP at 40 (lines 4 – 5). The Court must put a stop to this effort to have the courts make political decisions. The history of this matter shows that only an award of terms will stop petitioners' nuisance lawsuits..

This is the third lawsuit brought by the same group of anti-fluoridation activists against the City of Port Angeles challenging its public water fluoridation. In this third suit, the City of Forks has been sued also – presumably because it had the temerity to submit an amicus brief in lawsuit number two. This action to seize the Cities' fluoridated public drinking water systems as prescription drugs is meritless, seeks intentionally to mislead the Court, and is a clear case for an award of costs, fees and sanctions. This Court should put a stop to petitioners' and amici's frivolous litigation, which has burdened both the Cities' utility ratepayers and the courts.

RESPECTFULLY SUBMITTED this 21st day of December, 2012.

FOSTER PEPPER PLLC

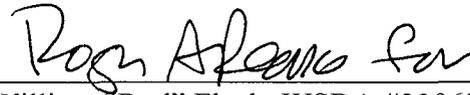


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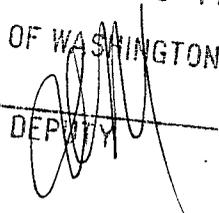


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DECLARATION OF SERVICE

Helen M. Stubbert declares:

I am a legal assistant to Roger A. Pearce. I am now, and at all times hereinafter mentioned was, a resident of the State of Washington, over the age of 18 years, and have personal knowledge of the facts in this declaration.

On December 21, 2012, I caused to be delivered in the manner indicated below a true and correct copy of the foregoing Answer of Respondents/Cross-Appellants City of Port Angeles and City of Forks to Amicus Brief of OWOC! and WASW to the following:

Gerald Steel, PE
Attorney at Law
7303 Young Rd. N.W.
Olympia WA 98502
By email and U.S. Mail

I declare under penalty of perjury under the laws of the State of Washington, that the foregoing is true and correct.

Executed this 21st day of December, 2012, at Seattle, Washington.


Helen M. Stubbert