WASHINGTON STATE
# Board of Health
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**DATE:** June 9, 2010

**TO:** Washington State Board of Health Members

**FROM:** Environmental Health Committee:
Karen VanDusen, Keith Higman, and John Austin

**SUBJECT:** **PETITION FOR RULE MAKING: WATER FLUORIDATION, WAC 246-290-220 AND WAC 246-290-460**

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## Background and Summary:

On May 11, 2010, the Washington State Board of Health received a petition for rule making in the form of an e-mailed letter from Bill Osmunson, DDS, MPH, president of Washington Action for Safe Water. The petition asks the Board to amend WAC 246-290-460 and WAC 246-290-220, sections in the Board's rules for Group A public water supplies. The first requested amendment would change the allowable concentration of a fluoridation additive from a range specified in rule to a range approved by the U.S. Food and Drug Administration (FDA). The second would change the requirement that drinking water fluoridation additives meet Standard 60 of the National Sanitation Foundation (NSF) and American National Standards Institute (ANSI) to a requirement the additives be approved by FDA under a New Drug Application.

RCW 34.05.330 provides the opportunity for anyone to petition the Board with a request to adopt, amend, or repeal any of its rules. Upon receipt of such a petition, the Board has sixty days to initiate rule making, deny the petition, or address concerns raised by the petitioner by alternate means. Board policy number 2005-001 sets forth the procedures followed by the Board when it receives such a request. According to this policy, the chair may either decide on the request and instruct the executive director to respond or take the request to the full Board for discussion and possible action.

Chair Higman has worked with the Board's Environmental Health (EH) Committee to review the petition and make a recommendation for action. Ned Therien, Board staff, will summarize this rule making petition and EH Committee recommendations for the Board. Please refer to materials behind Tab 16 for additional information.

## Recommended Board Action

The Environmental Health Committee recommends the Board adopt the following motion:

> ***Motion**: The Board denies the petition for rule making from Dr. William Osmunson dated May 11, 2010 because the U.S. Food and Drug Administration has a memorandum of understanding with the U.S. Environmental Protection Agency clarifying that the latter agency has authority for regulating tap water.*

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**Discussion:**

The Board has authority under RCW 43.20-050(2) to adopt rules for Group A public water supplies "necessary to assure safe and reliable public drinking water and to protect public health." The Board has further responsibility under RCW 70.142.010 to establish standards for chemical contaminants in public drinking water and "consider the best available scientific information in establishing the standards." The Board has adopted such rules in chapter 246-290 WAC. These rules set both a maximum contaminant level (MCL) for fluoride in drinking water and a lower allowable concentration range if fluoride is added to drinking water. These rules also require that drinking water additives meet NSF/ANSI Standard 60.

RCW 57.08.012 gives each water district the authority to decide whether to ask the electors of the water district to vote on adding fluoride to its tap water. The Board does not appear to have authority to adopt rules related to a water district deciding whether to fluoridate. The Board's authority is to regulate allowable concentration levels and method of approval of water additives.

Dr. Osmunson asked the Board of Pharmacy in 2009 to designate fluoride a poison under chapter RCW 69.38 RCW, Poisons—sales and manufacturing. Dr. Osmunson asserted that fluoridation of public water supplies was the therapeutic administration of fluoride and should be controlled by the laws for legend drugs. The Pharmacy Board's response was that RCW 57.08.012, by being more specific, supersedes the general statutory authority under which it regulates drugs.

For fluoride in drinking water, this Board has adopted the U.S. Environmental Protection Agency (EPA) primary MCL of 4 parts per million (ppm) and secondary MCL of 2 ppm under WAC 246-290-310. These standards are primarily intended for naturally occurring fluoride. The Board has adopted under WAC 246-290-460 an allowable concentration range for artificial fluoridation of public tap water. This range is 0.8–1.3 ppm and is based on the Centers for Disease Control and Prevention (CDC) "optimal" recommended levels to help prevent tooth decay. The Board has adopted under WAC 246-290-220 requirements that drinking water additives meet NSF/ANSI Standard 60. These organizations have developed these standards in association with EPA and the American Water Works Association.

CDC recommends public tap water be fluoridated to an "optimal" target concentration of 0.7–1.2 ppm to help prevent cavities. This is a range of target concentrations and the actual target for a given water supplier would be based on a five-year average of the maximum daily air temperature for the supplier's service area. CDC recommends the concentration be controlled within a range no less than 0.1 ppm below and no more than 0.5 ppm above a supplier's target concentration. For example, if the target concentration is determined to be 0.9 ppm, the control range would be between 0.8 ppm and 1.4 ppm. The Board's standard of 0.8–1.3 ppm in WAC 246-290-460 was set based on different target concentrations across the state, which fall between 0.9 ppm and 1.1 ppm. The allowable range permits a variation of no more than 0.4 above the target concentration for the warmest part of the state. Therefore, the Board's rule is more stringent than the CDC recommendation.

The National Research Council (NRC) Committee on Fluoride in Drinking Water issued a report in 2006 titled *FLUORIDE IN DRINKING WATER: A Scientific Review of EPA's Standards.* It

recommended the MCL for fluoride be lowered from 4 ppm, but did not recommend a new level. It concluded that 2 ppm seemed safe, but might be high enough to cause moderate tooth discoloration (less that 15% of children). It did not specifically address the issue of the CDC-recommended 0.7 - 1.2 ppm concentration range for adding fluoride to a water supply. On March 29, 2010, EPA published in the *Federal Register* an announcement of a six-year review of the MCLs for 71 chemicals, one of which was fluoride. It requested public comments on the reviews by May 28, 2010. EPA's conclusion is that it does not have information at this time that warrants it making a change to the MCL for fluoride, but studies are continuing.

CDC considers drinking water fluoridation one of the top ten great public health achievements of the 20th century. A series of surgeon general statements, the last issued in 2004, have strongly supported fluoridation of community water systems. CDC states that the 2006 National Research Council report supports CDC's recommended "optimal" fluoridation levels as being safe. CDC further states that the most common chemical used for fluoridation, fluorosilicic acid, and related compounds are derived in high purity from the gypsum and phosphate fertilizer manufacturing process. CDC cautions against the overuse of fluoride-containing products to control total intake. In a telephone call between Ned Therien and William Bailey, DDS, MPH, U.S. Public Health Service, on May 21 of this year, Captain Bailey stated that CDC is continually reviewing data regarding the "optimal" level and safety of tap water fluoridation. He also stated that EPA is currently doing risk assessment reviews of dose-response, source contribution, and the potential for carcinogenicity of fluoride.

In 1979, EPA and FDA finalized a memorandum of understanding regarding regulating fluoride levels in drinking water. They concluded the 1974 Safe Drinking Water Act gives EPA authority for regulating chemicals in tap water, while FDA has authority for chemicals in bottled water. Under CFR Title 21, Section 165.110, FDA has set a limit for fluoride added to bottled water in the U.S. of between 0.7 and 1.7 ppm, depending on annual average maximum air temperature for the location where bottled. In a May 21 e-mail exchange between Ned Therien and John V. Kelsey, DDS, MBA, Dental Team Leader, Division of Dermatology and Dental Products, FDA, Dr. Kelsey confirmed that FDA does not have regulatory responsibility for public water supplies, but rather that is the responsibility of EPA. He said if the Board accepted the language proposed in the petition, it effectively would ban public water fluoridation in Washington.

The Washington State Department of Health encourages community water fluoridation as a public health measure. State Health Officer Maxine Hayes, MD, MPH, issued a statement in support of community water fluoridation in 2006. The department's Oral Health Program echoes the recommendations of CDC on community water fluoridation and provides warnings about the overuse of fluoridated products. Many health professional associations support CDC's recommendations on community water fluoridation, including the American Dental Association, American Medical Association, American Academy of Family Physicians, and American Public Health Association.

The EH Committee concludes:

- EPA is the lead federal agency for regulating the maximum levels of contaminants and additives in tap water under the Safe Drinking Water Act.
- FDA has relinquished any authority it might have for regulating fluoride levels in tap water under the memorandum of understanding with EPA.
- The Board cannot direct a federal agency to take action.
- The State Board of Pharmacy has stated it cannot regulate tap water fluoridation under its authority.
- An NRC committee evaluated the scientific evidence of the health effects of fluoride in drinking water and published a report in 2006 that concluded fluoride levels in drinking water below 2 ppm are safe for health.
- EPA announced completion of a review of MCLs in the Federal Register in March 2010 that concluded it did not have evidence to revise the MCL for fluoride.
- EPA will be conducting additional reviews regarding fluoride levels in drinking water.
- EPA recognizes NSF/ANSI Standard 60 as appropriate for the approval of drinking water additives.
- The range of 0.8 ppm to 1.3 ppm fluoride in WAC 246-290-460 is within the control range (0.1 ppm below to 0.5 ppm above) recommended by CDC for target "optimal" concentrations based on average maximum temperatures in various regions of Washington.

The EH Committee recommends the Board deny Dr. Osmunson's petition for rule making on the grounds that FDA has stated it has no intention to regulate fluoride levels or approve additives for tap water. Therefore, adopting the proposed rule changes would, essentially, prohibit all tap water fluoridation in Washington and make Board rules conflict with RCW 57.08.012.

The EH Committee considers much of the discussion in the petition to make points that go beyond the requested rule changes and are not pertinent to its decision. However, the Committee recommends the Department of Health monitor EPA evaluations of safe drinking water levels for fluoride and recommendations from CDC for "optimal" fluoride levels, and that the Department propose rule amendments based on any changes. The Committee further recommends the next time the Department undertakes a major review of chapter 246-290 WAC, it consider proposing the word "optimal" in section 460(3) be changed to a phrase such as "generally regarded as safe." The Committee further recommends the Board continue to review legal points raised in the petition concerning state law and Attorney General opinions.