

ENVIRONMENTAL PROTECTION AGENCY  
345 CONSTITUTION STREET, N.E.  
ATLANTA, GEORGIA 30303

APR 17 1979

REF: 4W-WS

Honorable Strom Thurmond  
United States Senate  
Washington, D.C. 20510

Dear Senator Thurmond:

This is in response to your March 27, 1979, letter concerning the fluoride drinking water standard for the Town of Hemingway, South Carolina.

The fluoride standard is that promulgated by the State of South Carolina in its administration of primary enforcement responsibilities under the Safe Drinking Water Act (SDWA). Under this Act, State drinking water regulations may be no less stringent than National Interim Primary Drinking Water Regulations (NIPDWR) established by EPA. The maximum contaminant level (MCL) of 1.6 mg/l fluoride is twice the optimum level for dental health protection. Many studies have shown that as the fluoride concentration in drinking water exceeds the standard level, the risk of dental fluorosis increases. Mild dental fluorosis is primarily noticeable as a slight discoloration of teeth. Moderate to severe dental fluorosis is characterized by substantial discoloration, pitting and destruction of enamel. The standard is intended to protect the public from moderate to severe fluorosis.

It is not appropriate to remove fluoride from the primary standards because, it can cause adverse health effects (moderate to severe dental fluorosis) at levels found in some drinking water. EPA is conducting epidemiological studies to further define the dental health risks and the standard level. Technology development is also being pursued to provide additional means of controlling fluoride.

Violation of a primary (health related) MCL requires that the Town of Hemingway provide periodic public notice of this fact and take prompt action to remedy the problem. The MCL violation also leaves the Town vulnerable to citizen suit and other legal proceedings. In an effort to assist the Town meet its responsibilities without fear of penalty, the South Carolina Department of Health and Environmental Control has issued a fluoride MCL exemption for Hemingway. This exemption extends the deadline for meeting the MCL and allows the Town additional time to study the problem and develop alternative methods for meeting the fluoride limit. The Hemingway fluoride exemption and more than 50 others from South Carolina communities in the same coastal region are currently under review in this office. It is too early to determine how many of these communities may need treatment facilities to reduce excessive fluorides to safe levels but the large number of communities involved indicates that correction of this problem will likely have significant financial impact on coastal South Carolina.

Although the fluoride limit and other constituents named in the NIPDWR have existed for many years as Public Health Service Drinking Water Standards, they were enforced only at State option. Under the SDWA all community water supplies were required to meet the NIPDWR limits beginning June 24, 1977. The SDWA does not provide for water system construction grants. Financial assistance for water system construction has traditionally been provided through Farmers Home Administration, Department of Housing and Urban Development, Economic Development Administration and Appalachia grants and loans. EPA has recently entered into an agreement with the Farmers Home Administration for priority consideration of small water systems which fail to meet drinking water standards. In addition to the above, the Coastal Plains Regional Commission and U.S. Geological Survey have also expressed interest in assisting these coastal South Carolina communities with their fluoride problems.

I hope the above provides the background you need concerning the problem in Hemingway. If I can be of any further assistance, please let me know.

Sincerely yours,

Original Signed By:

John C. White  
Regional Administrator

cc: Victor J. Kimm, Deputy Assistant  
Administrator for Drinking Water  
Lewis Shaw, Director - SC Department  
of Health & Environmental Control



Change III IV-1.e. 31a

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Room 1253

Rockville, MD 20857

February 14, 1983

Dr. Joseph Cotruvo, Director  
Division of Drinking Water Quality  
Environmental Protection Agency, WH-550  
401 M Street, S.W.  
Washington, D.C., 20460

Dear Dr. Cotruvo:

Thank you for providing me with a copy of the National Drinking Water Advisory Council, Minutes of Meeting, Oct. 26, 1982. I had spoken with you some time ago about my dissatisfaction with the transcript of my testimony, recognizing that I need to work on clarity. In addition, the transcript had errors of its own. None of that was particularly important as long as the spirit and intent of the message was accurate. Now I am concerned. I regret that I did not have any opportunity to review a draft for accuracy before the minutes were published. This is unfortunate since the minutes contain an important error. Please refer to page 5.

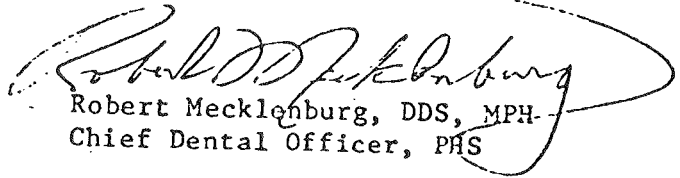
It is correct that my personal preference is for Option 2, the reclassification of fluoride to secondary standards. This preference is based on the conclusion that there is no sound scientific evidence of any adverse health effect from drinking water containing fluoride at levels found naturally in the United States.

The second half of the published statement, "and admitted that there are obvious adverse health effects above 8 ppm, and would alter his preference to option 5 (primarily and secondary regulations)" is inaccurate and misleading. I was not "admitting" anything since I know of no creditable evidence that demonstrates adverse health effects at 8 ppm. Since there are some indications of beneficial effects in some populations at levels higher than 8 ppm, it would be premature to draw such a conclusion. I am not aware of any studies which shows impairment of function, promotion of disease or impairment of either the quality or length of life at 8 ppm, or at concentrations anywhere near that. 8 ppm was noted only in reference to the safety levels which just had been discussed at great length by the advisory council.

My comments in regard to Option 5 were meant only to favor a contingency which would provide a means for managing an adverse health effect in the unlikely event new studies should show adverse health effect that are unknown at this time. Clearly, adverse health effects begin at some concentration, but this is well beyond levels found in U.S. drinking water supplies. Nevertheless, it is appropriate to encourage additional studies since relatively few have been conducted at the higher ranges of natural concentration of fluoride in drinking water. In principle, all that is known to man deserves periodic review.

I am pleased that your office is so diligent in trying to locate studies that might support the regulatory position previously taken by the Environmental Protection Agency. It certainly keeps alert everyone who has an interest in the regulation.

Please delete the inaccurate and misleading clause from my statement and so advise those who have been provided copies of the report. Thank you.

  
Robert Mecklenburg, DDS, MPH  
Chief Dental Officer, PHS

cc: Surgeon General



# Memorandum

Date June 1, 1983

From Office of Scientific and Health Reports, NIDR

Subject Comments on draft of fluoride health effects committee report

To Jay R. Shapiro  
Deputy Director, The Clinical Center

On page 4, changes are marked in paragraph #1 to better define locations of high-fluoride public water supplies.

I discussed soft tissue fluoride concentrations with Dr. Frank Smith at Rochester. He is submitting a rewritten sentence as a replacement for the last sentence in paragraph #3 on page 5. I concur with his suggestions.

On page 8, in paragraph d., I have suggested a change simply for clarity in line 10: "protect against the risk of femoral fracture, and perhaps even increase that risk".

On page 11, in paragraph 7-c., it might be useful to point out that the intensity of the effects of the accumulation of fluoride in hard tissue is affected by the level of exposure and the consequent rate of accumulation, which partially explains the differences that may be found in the pathologies of bones having equal fluoride concentrations.

On page 14, in the discussion of cardiotoxic effects, "potential" seems a strong word for effects for which there is so little evidence. In this same paragraph, we state that severe dental fluorosis is a health effect to be avoided. I think we as a committee need to recognize that this is a departure from the conclusions reached through fifty years of PHS-sponsored epidemiological and clinical investigations. I too feel that moderate and severe dental fluorosis are to be avoided, but am less certain that we should invert history to accomplish that end.

The impending Federal regulatory action on fluoride in water that may draw its chief support from our findings will be subject to intense political opposition and probably will be the subject of court hearings. Where is our supporting evidence for the health effect of dental fluorosis? Which member will give our testimony?

For complete clarity, the last line on page 14 could be changed to read "intake from water with a fluoride concentration in excess of 5 ppm" etc.

John S. Small  
Information Specialist  
NIDR 496-4261

OCT 7 1983

ODW:EHellack;lh:X27575;FM-1111;MSHE:9/28/83;Due Date 9/28/83  
AX-07521  
cc: Administrator (PYI)  
Deputy Administrator (PYI)  
OPRM (PYI)  
OLEC (PYI)  
OKD (PYI)  
OIL (PYI)

Robert S. Jackson, M.D.  
Commissioner, South Carolina Department  
of Health and Environmental Control  
2100 Bull Street  
Columbia, South Carolina 29201

Dear Dr. Jackson:

Mr. William D. Buckelshaus, RPA Administrator has asked me to reply to your letter of August 31, 1983, in regard to the status of drinking water regulations for fluoride.

I realize that the delay in completing the review of the Maximum Contaminant Level for fluoride must seem interminable to the State of South Carolina, but I assure you that we are moving as rapidly as we can. The further review of the fluoride issue by the Surgeon General was necessitated by the recommendations of the National Drinking Water Advisory Council. (Attached) The Council concluded that, in addition to esthetic effects on teeth, fluoride could cause adverse health effects. Since these conclusions appeared to be at odds with the Surgeon General's statement that "no sound evidence exists which shows that drinking water with the various concentrations of fluoride found naturally in public water supplies in the U.S. has any adverse effect on general health," it was necessary to request clarification from the Office of the Surgeon General.

It should please you to know that we have received word from the Office of the Surgeon General indicating that the medical panel's review has been completed and it has been transmitted to the Surgeon General. Thus we would expect his decision shortly. As soon as that response has been received, you will be notified of the Surgeon General's recommendations and of this Agency's intentions in response to the South Carolina petition.

Sincerely yours,

William A. Whittington

Rebecca W. Fanwer  
Acting Assistant Administrator  
Office of Water (WR-556)

AX

structural change in human body - brittle + chip

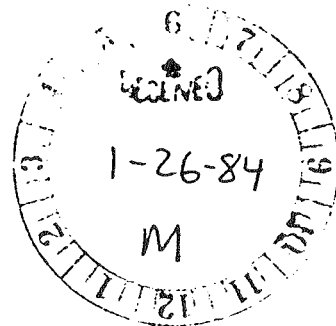
(notes by someone in EPA)

structural change in human body - brittle + chip

JAN 23 1984

S.B. Koop Letter/Report to EPA

The Surgeon General of the Public Health Service Washington DC 20201



Mr. William D. Ruckelshaus Administrator Environmental Protection Agency 401 M Street, S.W. Washington, D.C. 20460

Dear Mr. Ruckelshaus:

On July 30, 1982, I responded to a request from the Environmental Protection Agency (EPA) to review the scientific aspects of epidemiological studies relating to the effects of fluoride ingested through drinking water and to provide advice on the validity and significance of the findings relative to dental fluorosis. My summary conclusion, based on the lack of sufficient scientific evidence to the contrary, was that dental fluorosis, while not a desirable condition, was nevertheless not an adverse health effect. Thus, from an oral health standpoint, fluoride as currently found in U.S. drinking water supplies, does not constitute a hazard. A copy of that response is enclosed (Tab A).

This letter is in response to a January 19, 1983 EPA request that "the Public Health Service (PHS) review medical and epidemiologic literature on fluoride and non-dental (underlining added) health effects." Specifically, the PHS was requested "to make recommendations on the significance of that data relative to drinking water fluoride concentrations."

I convened an expert committee to review the scientific literature and to assess the continued validity of past findings in terms of ongoing research. A copy of the committee report is enclosed (Tab B). My conclusions and recommendations are made in consideration of the ad hoc committee's report and subsequent considerations by the committee chairman, other consultants and PHS authorities.

Adverse health effects were defined by the committee as death (poisoning), gastrointestinal hemorrhage, gastrointestinal irritation, arthralgias, and crippling fluorosis. No record exists of poisoning death from fluorides consumed in drinking water. There are no scientifically credible reports of gastrointestinal effects at levels found in drinking water. Clinical experience suggests that arthralgias are not likely to occur in patients who are on therapeutic regimens of less than 20 milligrams (mg) per day. Crippling fluorosis has been detected in some people who have consumed 20 mg or more of fluoride per day from all sources for twenty or more years. Such a situation does not exist in the U.S. today.

\* All documents cite the April 18-19, 1983 meeting. The Surgeon General's panel did not learn until 1990 that their conclusions had been altered. (Daniel Grossman, "The Progressive," Dec. 1990, pg. 21)

Fluoride can produce medically detectable changes in tissue, particularly bone, in individuals who have consumed less than 20 mg of fluoride per day. There has been radiological evidence of mild osteosclerosis (increased bone density) in a few individuals who have regularly used drinking water containing fluoride at levels as low as 5 milligrams per liter (one milligram per liter = one part per million [ppm]). Factors such as total intake, age, and the presence of other medical conditions or other environmental factors could influence the occurrence of these early radiological changes. It must be emphasized that these changes are not considered adverse health effects.

My letter of July 30, 1982 addressed the dental effects of fluoride in drinking water. My recommendations about the advisability of limiting fluoride concentrations to twice the optimum in order to avoid unsightly dental fluorosis still pertain. At the same time, based on current scientific evidence, there is essentially no likelihood of even non-adverse medical effects where drinking water supplies contain up to four times the optimum concentration of fluoride.

Because of the very limited number of studies which address the medical effects of regularly using drinking water containing fluoride at levels over four times optimum, I strongly reaffirm my previous recommendation that additional studies be conducted so that this recommendation can stand or be adjusted on the basis of more complete scientific evidence.

Thank you for the opportunity to provide this additional information for your consideration and guidance for future policy.

Sincerely yours,



C. Everett Koop, M.D.  
Surgeon General

Enclosures