DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date July 22, 1982

From Chief Dental Officer
Public Health Service

Subject FOR THE RECORD: Background for the PHS Response to EPA on Fluoride in Drinking Water

To

The subject statement was prepared for the Surgeon General to send to the Environmental Protection Agency in response to a request for advice and counsel on the scientific aspects of fluoride in drinking water.

An ad hoc committee appointed by the Chief Dental Officer to consider the issue represented a variety of PHS agencies. All members were highly qualified and respected professionals of the Service. They are:

Dr. Tullio Albertini, Division of Dentistry, HRA
Dr. William Bock, Dental Disease Prevention Activity, CDC
Mr. John Cofrancesco, Office of Environmental Health, IHS, HSA
Dr. William Driscoll, National Caries Program, NIDR, NIH
Mr. John Scott Small, Water Fluoridation Specialist, NIDR, NIH
Dr. Norman Clark, Office of the Chief Dental Officer, PHS; Chairman

Wide professional review was solicited. A series of draft statements were prepared which were intended to draw out information which might not have been otherwise considered. Responses were requested from the American Dental Association, American Association of Public Health Dentists, American Public Health Association, Association of State and Territorial Dental Directors and dental representatives of PHS programs. Draft statements were also offered for discussion before the ADA and STTDD. This open approach served to highlight several issues of concern.

There were four issues of concern that were set aside as not appropriate for inclusion in the response requested. These were:

1. A major if not primary concern to state health representatives is the cost of water defluoridation. An argument has often been made that fluoride should not be in the primary drinking water standards because the cost of defluoridation is more than communities can afford. This issue was set aside for two reasons: 1) The PHS does not have jurisdiction in the placement of substances ("contaminants" by legal definition) in the primary and/or secondary standards, 2) It is a responsibility of health professionals to advise individuals and communities about the consequences and associated costs of choices that may affect their health and general welfare. However, it is considered presumptuous for the profession to attempt to decide for individuals and communities what they can or cannot afford.

2. There is a concern that recognition of fluorosis as a health problem could leave the practice of community water fluoridation open to attack by antifluoridationists. Any statement which limits fluoride concentrations in drinking water could be misquoted to the public and could potentially weaken the case for fluoridating water at optimum levels. This concern was set aside because the scientific evidence and professional judgement relevant to attributes and consequences of fluoride concentrations above optimum must stand on their own merits and not be altered for political expediency. Although often difficult to achieve, the only defense against the distortion of truth and behavior which may not be in the public interest is a well informed public.

3. There is a concern for the application of stringent requirements of law and the EPA regulations in relation to the magnitude of the fluorosis condition. The primary-secondary construction of the Safe Drinking Water Act is a legal classification that, while administratively manageable, may be less than perfect and occasionally ambiguous for describing how various substances may specifically affect health and public welfare. Legal processes may be required to more clearly define Congressional intent as to EPA's assignment of fluoride in the regulations or to change the regulations to provide for a well proportioned relationship between the significance of a substance in water and the legal remedies required. Scientific review and professional guidance should form the foundation for regulatory considerations but cannot replace them.

4. A fourth issue is the argument that fluoride in the concentrations found naturally in drinking water does not constitute a "health hazard." Certainly, scientific evidence firmly supports that assertion. However, the Safe Drinking Water Act does not mention "health hazards." It refers to "any adverse health effect" and maximum contaminant levels at which "no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety." Therefore, the issue that is addressed by the PHS is not the possibility of mortality and morbidity implied in the term "health hazard," but the much broader area of concern for determining if there is any scientific evidence that fluoride in public drinking water causes an adverse general or dental <u>health</u> effect. It is this broader issue that became the focus of the scientific review.

Accepted definitions of health were used in the evaluation. Webster states that it is "a state of being sound in body or mind". The WHO definition asserts that "Health is a state of complete physical, mental and social well being, and not merely the absence of disease or infirmity." Oral health can be defined within the context of either general definition. It is more than the absence of dental caries, periodontal disease and other active oral disease processes. It also means that teeth are not missing, nor oral structures malfunctioning due to malocclusion or other pathologic conditions, or painful, or in other ways inhibiting to the normal processes of life. Fluoride, in the concentrations found in natural drinking water supplies in the U.S. was evaluated in this context.

The scientific evaluation and considerations of the merit of various studies lead to the following conclusions:

1. Mineralized tissue, including teeth, retain fluoride at levels far greater than non mineralized tissues. Since fluoride is not easily retained by other tissues, it is extremely safe in the concentrations found naturally in drinking water. There is evidence that dental caries prevalence is significantly lower among people drinking water at concentrations where there is some risk of developing objectional dental fluorosis compared with persons drinking optimally or less than optimally fluoridated water. However, since protection against dental caries does not significantly increase beyond fluoride concentrations of two times optimum, and the risk of objectionable fluorosis increases above this concentration, twice optimum is a conservative PHS standard for a maximum recommended concentration in natural drinking water supplies.

2. At natural fluoride concentrations in U.S. drinking water supplies which are over twice the optimum concentrations, no sound scientific evidence was found that associates fluoride with any adverse general health effects, either physical, mental or social.

3. At natural fluoride concentrations in drinking water which are over twice the optimum concentration, no sound scientific evidence was found that associates fluoride with adverse dental health effects, such as increased tooth loss or impaired function. Therefore, it is concluded that dental fluorosis is primarily a problem of esthetics.

4. The PHS guidance to the EPA does not provide any scientifically supportable evidence that could justify the continued placement of fluoride, in the concentrations found naturally in U.S. drinking water supplies, in any list of chemicals that produce adverse health effects.

5. Additional studies should be conducted which examine dental health effects relative to varying concentrations of fluoride in drinking water.

Moderate and severe dental fluorosis as an important and preventable dental problem. It is an anatomical, morphological condition that is cosmetically undesirable to many people. The prevalence of moderate and severe dental fluorosis can be remedied through professional corrective and community preventive efforts wherever the condition exists. The dental profession has a clear responsibility to recognize the condition, advise the public and to assist communities in preventing objectional fluorosis.

The PHS has long supported water fluoridation and has published a table of the optimum concentrations for caries prevention which produces minimal risk of producing objectional fluorosis in a community. This table was specifically constructed for guidance to communities for <u>adding</u> fluoride to the drinking water. It was not intended to be a guide for fluoride <u>removal</u>. It is recommended that two times the optimum concentration be used as a guide as to which communities should consider fluoride <u>removal</u> since there is evidence that dental health benefits do not significantly improve above that point.

It is recommended that criteria and standards be developed by the PHS which can be used by the profession to directly monitor the level of fluoride and non-fluoride opacities and enamel defects in population groups so that point prevalence and trends can be determined.

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