



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 26 1984

OFFICE OF
WATER

NOTE:

SUBJECT: The adverse health effects of fluorosis

TO: William D. Ruckelshaus
Administrator

FROM: Victor J. Kimm, Director *VJK*
Office of Drinking Water (WH550)

After our meeting with Dr. Koop you asked for further information on three issues. These are discussed below, as is a fourth, a recent move in South Carolina District Court, to force revision of the Fluoride regulation on an accelerated schedule.

1. OGC memo on definition of adverse health effects.

Your first question was on the legal interpretation of what constitutes an adverse health effect, and the extent of your discretion in this matter. OGC has developed a memorandum (Attachment 1) in response.

The basic findings of OGC are that there is no case law which provides a standard by which to operate nor had Congress made specific reference to a definition in any legislation or legislative history. There is case law which suggests that you have relatively broad discretion in these matters.

Specifically with regard to Fluorides, the last sentence of the OGC memo states:

"On balance, I believe that a Primary regulation to control the dental effects of fluoride would be upheld because of the substantial deference accorded the Administrator in defining adverse health effects."

2. Evaluating the psychological effects of fluorosis.

At your suggestion we have contacted former Surgeon General Richmond, and have forwarded a letter asking him to comment on the practicality of convening a panel of behavioral scientists to review the fluorosis issue.

One drawback of such a panel, were it formed, is the amount of time it will take to receive the report which would

ensue. As the next point will show, there may be sufficient data now to demonstrate a clear functional effect from fluorosis, obviating the need for review of psychological effects.

3. A review of data on functional tooth deficits associated with fluorosis.

The Surgeon General suggested verbally that high fluoride exposures led to better (i.e., stronger) teeth, discoloration and pitting notwithstanding. He also suggested that he would consider chips, fractures and related cavities to be functional deficits which are adverse health effects.

It is difficult to conclude a priori that teeth which spontaneously pit are stronger teeth. Further, data suggest that the effects of fluorosis are not merely discoloration and pitting, but fracturing, caries and tooth loss as well. The data which support this statement are presented in attachments 2, 3 and 4.

These include peer reviewed case controlled studies which document increases in caries associated with higher degrees of fluorosis, as well as increased rates of caries in some populations exposed to higher levels of fluoride (for levels above the optimal). As the second attachment indicates, five of eight studies found higher caries among those with the more extreme levels of mottling. But, as there are three studies which suggest the obverse, there will be those who wish to continue to argue the point.

The Drinking Water Research Division (ORD) plotted the caries dose-effect relationship, based on their studies and those of other peer reviewed case controlled studies. (Attachment 5) The curve slopes downward (fewer cavities) until the optimal level is reached, then begins to slope back upward (more cavities) as the fluoride level increases. (The current MCL is set at twice optimal.) The statistical validity range of these points has not yet been determined.

A third piece of data is from a study of the costs of dental repair due to fluorosis. A panel of six dental practitioners were assembled to serve as a referee panel. These dentists were highly experienced. They each had practices in or adjacent to a community with fluoride levels in the critical to high range (> 2 times optimal), had experience in providing care for mild to severe mottled enamel, had a minimum of five years experience in general practice, and represented a geographic distribution in the nation.

This panel was asked to evaluate the dental needs of 55 teenagers selected from a population exposed to 4.8 ppm or less fluoride. They were to indicate what procedures would be used to repair cosmetic defects (mottling) and functional effects (pits, chips and fractures). The results of the evaluation indicate that both functional damage and cosmetic damage occurred, and that it would cost much more to fix the functional than the cosmetic damage.

We have some color photos of fluorotic teeth which shows the kind of chipping, pitting and fracturing individuals exposed to high fluoride levels must endure. It is difficult to examine such photos and conclude that such effects are not adverse.

4. Court ordered accelerated regulation.

The speed with which the fluoride issue is resolved may have to increase, as the State of South Carolina has taken steps to seek a court ordered regulatory schedule. It remains to be seen if and when this will occur.

Next Steps

You should know that this issue is being reviewed by the National Drinking Water Advisory Council next week. They will provide you their recommendations at that time.

We would like to discuss the options which are available to resolve this issue during your briefing, scheduled for July 27th.

cc: Jack E. Ravan