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'83 Transcripts Show Fluoride Disagreements

BY JOEL GRIFFITHS

●*"I realize that we have few facts and many unknowns . . ."*—Stanley Wallach, M.D., Veterans Administration Medical Center, Albany, N.Y.

●*"We could cut it that close. I just don't know where the truth is. That is what I don't know."*—Jay R. Shapiro, M.D., Clinical Center, National Institutes of Health.

●*"If you are talking about potential toxicity, we have no idea whether it is 18 or puberty. We have no idea"*—Michael Kleerekoper, M.D., Henry Ford Hospital, Detroit.

The question these scientists are struggling to resolve in the face of such dizzying uncertainties is, of all things: What constitutes a safe level of fluoride in U.S. drinking water? Moreover, they are world-class experts working with the best data available. They are members of an ad-hoc committee convened by U.S. Surgeon General C. Everett Koop, M.D., at the request of the Environmental Protection Agency to review the literature on the health effects of fluoride in drinking water

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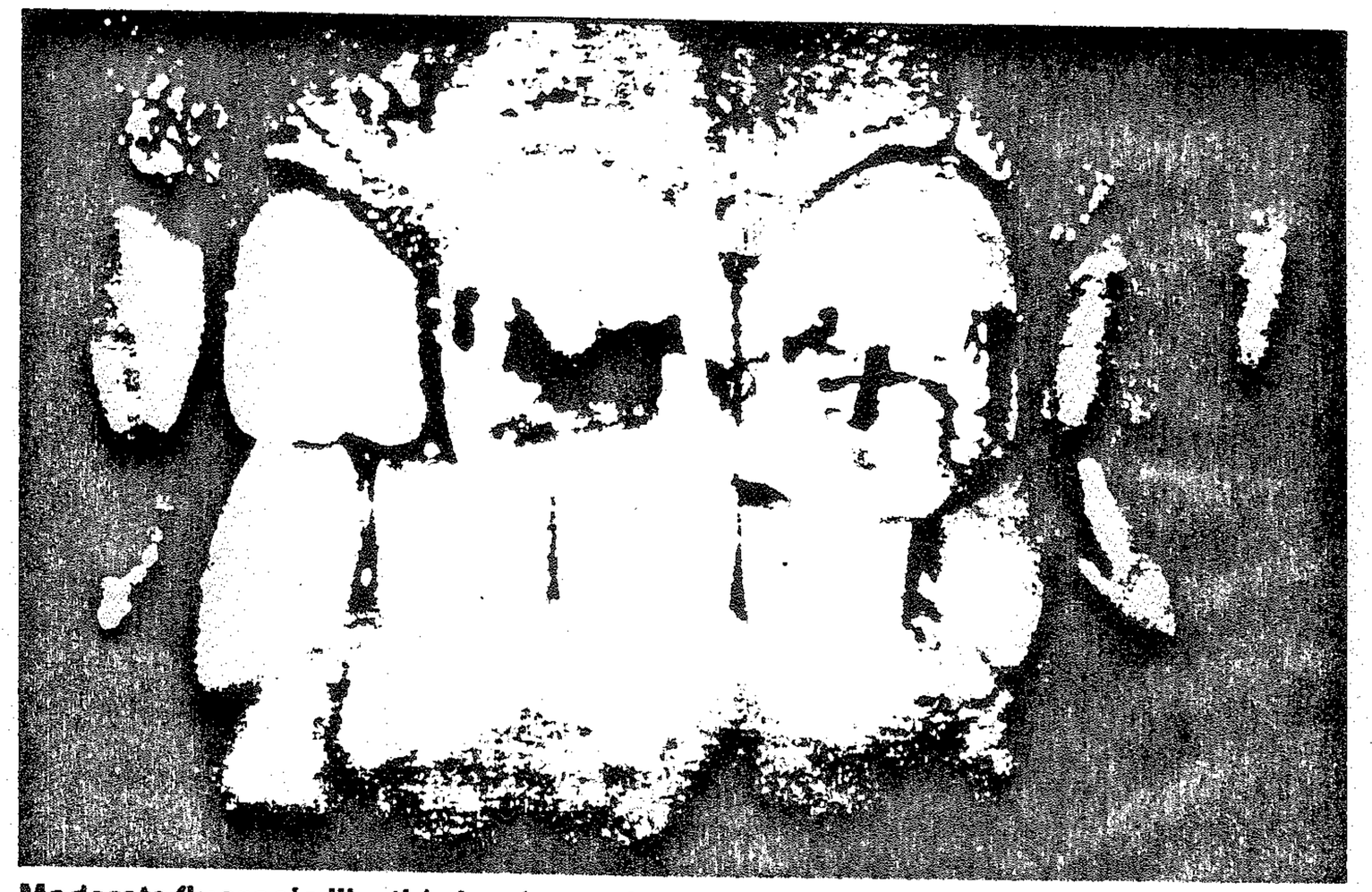

Moderate fluorosis like this has been observed at 2-3 ppm, less than the law allows.

Disagreement Marked Fluoride Review That Led to New Standard

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and to recommend safe levels. The year is 1983, nearly 40 years after fluoridation of U.S. water supplies began. the quotes are from a hitherto unpublicized transcript of the committee's meeting obtained by Martha Bevis of Houston with the aid of her Congressman.

"Let me go ahead on what we don't know. First of all, any problem with a low latency isn't going to show up by anything available to us at the present time"—Dr. Wallach.

"I am saying that I accept that we do not have the numbers from what it is in the literature"—Dr. Shapiro.

Such statements typify the commmittee's deliberations, which are being cited by fluoridation opponents as revealing an astonishing lack of safety data about a chemical currently being added to more than half of U.S. public water supplies. Indeed, as the following excerpts show, the degree of uncertainty on several crucial issues appears near-Heisenbergian.

The proposed permissible levels under discussion were 4 ppm for adults and 2 ppm for children and adolescents. (By comparison, the recommended level of fluoride in drinking water for caries prevention averages 1 ppm, although some proponents have advocated higher levels, and a 1979 study by the CDC found more than half of water companies adding either too much or too little.)

The committee apparently felt restrained from setting permissible levels that would interfere with fluoridation for dental purposes. Noted Stephen J. Marx, M.D., with the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases: "I think we have a problem with the lower age range because there we can't say that we want to have the margin of safety of, say, two- to fourfold, because then we get into the range in which you have therapeutic effects of fluoride for prophylaxis and dental care. If we were just handling this as an environmental contaminant, we could say we begin to see fluorosis at 2 ppm. So we want a safety factor of 4. We recommend that it be kept below half a part per million [0.5 ppm].

"We have to make an allowance there. We can't just talk about safety."

Since 99% of ingested fluoride is assimilated into bone, the major adverse health effects under review were those summarized by Dr. Marx: "Just as dental fluorosis is a manifestation of moderately low levels of fluoride excess, osteosclerosis is

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+Actually, the Surgeon General's panel was commissioned by the EPA to determine a safe level of fluoride at whatever ppm (part per million) — even 0.

Fluoride Uncertainty Revealed in Transcripts

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the next stage and crippling fluorosis is a much more severe stage."

Opening the discussion of crippling fluorosis, Dr. Kleerekoper asked: "Jay [Shapiro], what is the level of fluoride in the drinking water in those communities that get . . . crippling endemic bone fluorosis?" Responded Dr. Shapiro, who chaired the committee: "You don't know what the level is, but certainly you are talking 8-10 ppm and above."

However, Frank A. Smith, Ph.D., interjected: "The problem with that literature is that they tell you the . . . waters contain 1.6-15 or 18 or 23 ppm, and you never know what well the guy is using that shows this."

"Let me quote you a study," continued Dr. Smith, who was then a toxicologist at the University of Rochester (N.Y.) Medical Center. "There is only one subject, of course, but he appears to have been drinking for 43 years water with fluoride concentrations of from 2.4 to 3.5 ppm. Now he had polydipsia of unknown origin, but he did have fluorotic radical myelopathy."

Dr. Kleerekoper pointed out that "the reports outside of the United States, taking everything into consideration, do get clinically observable adverse effects certainly at 4 ppm or above. There are plenty of papers." To this Herta Spencer, M.D., Hines (Ill.) VA Hospital, objected: "I don't believe we can compare a report in India, which is a tropical country where you don't know how much water you take in, where the nutritional status is very poor, . . . to the high-fluoride areas in this country." Dr. Smith: "I think you are going to find some populations of that sort in this country, too." Dr. Spencer: "Then we should see more pathological indications of myelopathy and fluorosis in this country. Why don't we see it in the areas of 4 ppm?"

"I think that you have to conclude that we haven't looked for it and we really don't know," summarized Dr. Shapiro. It is estimated that 184,000 Americans are drinking water that contains more than 4 ppm fluoride.

Moving on to osteosclerosis and its pathologic significance, Dr. Kleerekoper announced: "I don't know whether there is a component of the crippling fluorosis that is related to osteosclerosis." Dr. Wallach: "If you don't know, that makes it potential." Dr. Shapiro: "That is the point. You don't really know what is happening. I think it is reasonable to leave it as a potential adverse effect."

At another point, however, David W. Rowe, M.D., then a pediatrician at the University of Connecticut Health Center, Farmington, remarked: "If it were my daughter, I would be concerned. We can say all of those things, but when you see a change occurring in the bones that we don't know what its implications are, but it is clearly recognized as two standard deviations from the norm . . . "

Suggested Dr. Shapiro: "Let's just say, because we really don't have the information to come off of this, that osteosclerosis occurs and we really don't know whether it is potentially adverse or not. We don't have the data."

Skeletal Effects?

Dr. Marx: "But we can still vote on it. That is what we are here for." By restricting the definition of osteosclerosis to a radio-dense skeleton, the committee was able to agree that osteosclerosis was not an adverse health effect.

The members were, however, concerned about the possible effects of osteosclerosis on skeletal development in children and young adults. Important,

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then, was the question: At what levels of fluoride in drinking water did osteosclerosis begin to occur? Referring to levels of 2-3 ppm, Dr. Kleerekoper, a bone specialist, acknowledged: "There is just no information as to what the bone looks like at that point."

Moderate dental fluorosis, however, has been observed to occur in a small percentage of individuals drinking water with 2-3 ppm fluoride. Was the presence of dental fluorosis therefore an indicator that bone changes were also present? The discussion was summarized by Robert Marcus, M.D., then with the Palo Alto (Calif.) VA Medical Center: "I think it is fairly close to unanimous that we all agree that dental fluorosis, in fact, has medical ramifications. Almost everybody agreed on that. Not knowing where bone disease begins at any age, what you are saying is that if there is something going on in the teeth, then the likelihood is that there is something going on in the bones. You don't know that it is there; you don't know that it is *not* there." The fluoride levels of possible health significance, then, were quite low. At one point Dr. Shapiro asked, "You have some data on a town in Texas where there were some children with rather severe fluorosis with a level of something like 1.2 ppm in the drinking water. Is that true?" Dr. Smith: "I think that is correct."

'Rocks in Your Head'

The panel therefore debated whether the permissible level for children should be lower than the one it had already set for adults—4 ppm. A proposed level of 2 ppm would be indicated, moderated Dr. Shapiro, "if one seriously believes going above that and allowing children to take in 4 ppm would be compromising their health. Unfortunately, we don't have the answer one way or another." Dr. Kleerekoper was able to magnify the uncertainty:

> ***'I would make it very very clear that we know nothing about this issue'***

"From all the available data, we can't state that there is no apparent adverse health effect on a water fluoride level of 2 ppm or below." Finally, Dr. Wallach clarified the committee's thinking with this observation: "You would have to have rocks in your head, in my opinion, to allow your child much more than 2 ppm." Dr. Rowe: "I think we all agree on that."

The committee thereupon plunged back into the unknown with a debate over what the cutoff age for the 2-ppm limit should be. Dr. Kleerekoper strove to delimit the magnitude of the mystery: "If you are talking about potential toxicity, we have no idea whether it is 18 or puberty. We have no idea." Dr. Marcus offered: "My own feeling would be that I would go to nine, since this is the best information you have, at least as far as teeth are concerned, but I would make it very, very clear that we know nothing about this issue and maybe it should be 14, maybe it should be 18." Later, Dr. Kleerekoper attempted to forge a consensus: "I think everybody is in agreement, including the dental aspects, that, after age nine, 4 ppm is without harm, both observed or even potential." But Bess Dawson Hughes, M.D., USDA Human Nutrition Research Center, Boston, countered: "No, I am not in agreement with that. I am not sure a 10-year-old is going to have no harm from 4 ppm. I am not sure what it is going to do to their bone turnover rate and to the concerns that have been expressed here."

Vote time was announced by Dr. Shapiro: "All right. How many people feel that 18—picking that one out of the air—is a more appropriate age to run the 12 ppm up to than nine?" The first vote was Dr. Wallach's: "I know I mentioned every age under the sun. I guess I will settle with a recommendation for 18." Split down the middle, the committee voted 5-4 for age nine.

Following the meeting, the committee apparently became uncertain even about its own uncertainty: it eviscerated its recommendations and conclusions and vouched unequivocally for the safety of fluoride levels of 4 ppm.

Voluntary Regulation Urged

On April 27, 1985, Douglas H. Ginsburg, then Office of Management and Budget administrator for the Office of Information and Regulatory Affairs, sent an internal memo to EPA administrator Lee Thomas. The memo (MT, Aug 7, 1985) not only supported increasing the standard but also urged EPA to consider a voluntary, rather than mandatory, regulation. The memo cited estimates that a mandatory regulation could cost the federal government $5 million a year to administer, yet would affect a minority of the populace. The memo questioned why EPA would "impose burdens or costs on everyone in order to deal with a few."

Next issue: more on the safety of the EPA's 4-ppm regulation.

error and should be "4 ppm." The "12 ppm" is a typographical