

REPORT OF THE
GOVERNOR'S
COMMISSION ON FLUORIDATION

WILLIAM MITCHELL
College of Law

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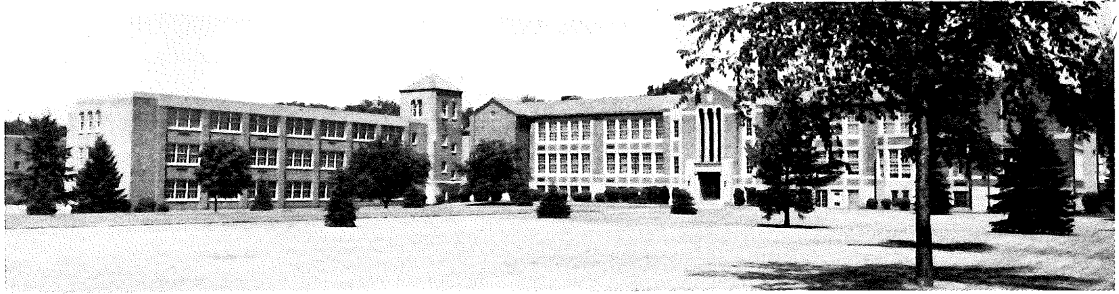
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875 SUMMIT AVENUE □ ST. PAUL, MINNESOTA 55105

TELEPHONE: (612) 227-9171

February 26, 1979

Rodney N. Searle
Speaker of the House
Minnesota State Legislature
Room 390
State Office Building
St. Paul, Minnesota 55155

Dear Mr. Speaker:

Enclosed please find the report of the Governor's Commission on Fluoridation, submitted pursuant to Chapter 453 of the 1977 Minnesota Laws.

Sincerely,

Members, Governor's Commission on Fluoridation

Michael K. Steenson

Professor Michael K. Steenson, J.D. (Chairman)

Marion W. Anders

Professor Marion W. Anders, D.V.M., Ph.D.

Peter J. Dorsen, M.D.

Peter Dorsen, M.D.

MKS/jmh

Enclosure

INTRODUCTION

The history of fluoridation in Minnesota is relatively recent. In 1967 the following law was enacted:

For the purpose of promoting public health through prevention of tooth decay, the person, firm, corporation, or municipality having jurisdiction over a municipal water supply, whether publicly or privately owned or operated, shall control the quantities of fluoride in the water so as to maintain a fluoride content prescribed by the state commissioner of health. In the manner provided by law, the state commissioner of health shall promulgate rules and regulations relating to the fluoridation of public water supplies which shall include, but not be limited to the following: (1) The means by which fluoride is controlled; (2) the methods of testing the fluoride content; and (3) the record to be kept relating to fluoridation. The state commissioner of health shall enforce the provisions of this section. In doing so he shall require the fluoridation of water in all municipal water supplies on or before January 1, 1970. The state commissioner of health shall not require the fluoridation of water in any municipal water supply where such water supply in the state of nature contains sufficient fluorides to conform with the rules and regulations of such commissioner.

In 1969 the Minnesota State Board of Health adopted regulations requiring that the fluoride content of municipal water supplies be maintained at an average concentration of 1.2 milligrams per liter. The current regulations relating to fluoridation are contained in Chapter 8 of the Minnesota State Board of Health Water Supply Regulations, Regulation 138. The regulations provide for a specific fluoride content, equipment for testing of fluoride content, and for the collection of water samples and records of fluoridation.

The fluoridation law has been the subject of two legal challenges in Minnesota. In 1972 Minnesotans Opposed to Forced Fluoridation, a private nonprofit organization, sought an injunction restraining the enforcement of the fluoridation statute in Brainerd. Defendants were the City of Brainerd and the Minnesota State Board of Health. The trial court in that case found the fluoridation law to be a valid exercise of legislative authority and that the constitutional rights of the citizens of the state were not violated, and that it did not constitute pollution in violation of the Environmental Rights Act.

Following the decision in that case, the Minnesota State Board of Health attempted to persuade Brainerd to fluoridate its water. These attempts were unsuccessful. In 1974 the State Board of Health filed a petition for a writ of mandamus requiring the City of Brainerd to fluoridate.

In Minnesota State Board of Health v. City of Brainerd, 308 Minn. 24, 241 N.W.2d 624 (1976), the Minnesota Supreme Court found the fluoridation law to be constitutional. In its opinion the court noted the widespread acceptance of fluoridation:

At least in part because of this endorsement by the scientific community, the Minnesota Legislature enacted Minn. St. 144.145 requiring the fluoridation of all public water supplies. Appellants argue, though, that fluoridation presents a serious health hazard and calls to our attention certain scientific studies which indicate the dangers of fluoridation. However, it is not this court's function, at least in the absence of overwhelming evidence to the contrary, to second-guess the scientific accuracy of a legislative determination of fact. Nor is it within our province to determine the wisdom of or necessity for a legislative enactment.

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In enacting the fluoridation law, the legislature relied on the overwhelming weight of scientific opinion that fluoridation afforded a safe and effective means of reducing dental caries. We cannot say that this legislative determination is so clearly erroneous as to be arbitrary and violative of due process.

In its analysis of the constitutional question involved the court considered the following factors:

(1) The importance of the state's purpose for requiring fluoridation; (2) the nature and magnitude of the effect of forced fluoridation on the individual; (3) whether the state's purpose justifies the intrusion of forced fluoridation; and (4) whether the means adopted by the state to accomplish its purpose is proper and reasonable.

The court concluded that the statute is constitutional.

The 1977 Minnesota Legislature enacted the following law:

The governor shall appoint a three member panel to study the health effects regarding fluoridation of the municipal water supplies. Up to \$15,000 of this appropriation may be used for this purpose. Any municipal water supply not fluoridated in compliance with the rules of the state board of health as of January 1, 1977, need not comply with the rules until July 1, 1979.

Chapter 453, Law of Minnesota for 1977.

Pursuant to chapter 453 a three member commission was appointed by Governor Perpich in May of 1978 to consider the health effect of fluoridation. The members of the commission are Professor Marion Anders, Dr. Peter Dorsen, and Professor Michael Steenson. The commissions charge from the Governor is as follows:

A commission to study the 'health effects regarding fluoridation of the municipal water supplies' was created by the 1977 legislature. (chapter 453, section 6, subdivision 1). The Commission is composed of three members, selected and appointed by Governor Perpich on the basis of their competence and impartiality. They are:

Professor Marion W. Anders, D.V.M., Ph.D.

Peter Dorsen, M.D.

Professor Michael K. Steenson, J.D.

The Commission shall hold regular monthly meetings, beginning in May, 1978, to hear and consider studies on the general subject, including scientific evidence, relevant to the health effects of fluoridation.

After thorough study and evaluation, the Commission shall submit a report to the legislature containing such findings as appear to be warranted, together with a statement of formal recommendations. This report shall be filed no later than March 1, 1979.

Since the appointment of the Commission in May the members of the Commission have met on a monthly basis. The Commission received early submissions from the City of Brainerd and from the State Department of Health. On October 26th and 27th of 1978 the Commission held public hearings. Public notice of the hearings was given and, in addition, several witnesses were specially invited to attend the hearings and testify. An attachment of the witnesses testifying appears as an appendix to this report.

Because of the need for examining the epidemiological basis of the various studies concerning these health hazards the Commission determined that it would be desirable to retain a consultant to assist in the examination of the various studies submitted to the Commission. Accordingly, the Commission retained Dr. Ralph Katz, D.M.D., M.P.H., Ph.D., an Associate Professor in the Division of Health Ecology of the School of Dentistry at the University of Minnesota as its consultant.

Following the public hearings of the Commission at the end of October questions were raised by John Graham, counsel for the City of Brainerd, concerning possible bias of Dr. Katz.

In order to avoid any potential claim of prejudice the Commission agreed to retain as a second consultant Dr. John Yiamouyiannis of the National Health Federation.

The Commission requested each of the consultants to submit to it information relating to the use of Standard Mortality Ratios. The reports of the consultants are attached.

It is clear that the question of mandatory fluoridation has raised a variety of questions, legal, ethical, and moral, as well as scientific. (Submissions file) The Minnesota Fluoridation Law has been challenged as unconstitutional. A number of private citizens have expressed concern to the Commission over fluoridation. Charges have been made that fluoridation is part of a conspiracy.

The emotion surrounding the issue is high and the charges against fluoridation many. However, the Commission determined that some limitations had to be placed on the scope of its study because of the shortness of time and the large amount of data existing.

Because the constitutional review standards have been established by the Minnesota Supreme Court, the legal framework is clear. Unless it is established that substantial health hazards exist, the deference accorded to the legislature by the supreme court is conclusive. The Commission was of the opinion that the legal standards did not lend themselves to review.

Likewise, the moral or ethical aspects of fluoridation were determined to be an improper area of inquiry, given the subjective nature of such an inquiry. The charges of conspiracy were not documented and were impossible to examine.

The Commission's inquiry thus narrowed to an examination of the potential health hazard created by fluoridation. The primary potential health hazards which received the attention of the Commission related to carcinogenesis, Down's Syndrome, and the allergic effects of fluoridation.

A. Carcinogenesis

After many years of fluoridation of public drinking water supplies, statements distributed on 6 January 1975 and 25 March 1975 by Dr. J.A. Yiamouyiannis of the National Health Federation alleged a link between fluoridation and cancer death rates. A similar statement appeared in the Congressional Record - House on 21 July 1975 (pp. H7173-7176). Finally, after some adjustments of the data base, a paper was published by Yiamouyiannis and Burk (1977) purporting to show that fluoridation was associated with an increase in cancer death rates in man. Although this allegation was based largely on crude cancer death rates, the authors claimed that age, racial, or sex compositions of the populations studied did not serve to explain the observed increases in cancer death rates. Finally, the authors argued, on the basis of computations involving "hypothetical populations", that Standardized Mortality Ratios (SMR), which are widely used and accepted in cancer epidemiology, are unreliable.

The statements by the National Health Federation and the report by Yiamouyiannis and Burk [1977] have prompted a number of investigations of the possible relationship between fluoridation and cancer mortality. These reports have consistently failed to establish a causal relationship between fluoridation and cancer

mortality (Hoover et al., 1976; Oldham and Newell, 1977; Doll and Kinlen, 1977; Royal College of Physicians, 1976; Taves, 1977; Taves, in press; Erickson, 1978; Environmental Health Directorate, 1977; Rogot et al., 1978; National Academy of Sciences, 1977). The common finding appears to be that the differences observed in crude cancer death rates between fluoridated and non-fluoridated cities are attributable to demographic factors, and, when these are corrected for using widely accepted epidemiological procedures, the differences become non-significant.

There are several points which should be mentioned. First, it is a well-established axiom in science that one cannot prove a negative hypothesis; thus, one cannot prove that fluoridation does not cause cancer. While the preponderance of evidence does not support the view that fluoridation alters cancer mortality rates, it is helpful to estimate the uncertainty of the data. The paper by Taves (1977) is particularly informative in this respect; he indicates that the available data cannot rule out the possibility that fluoridation may cause a 1.5% change in total cancer death rates or a 15% change in site (organ) specific cancer death rates. In other words, current epidemiological methodology is capable of detecting an increase or decrease of 1.5% in total cancer death rates, or 15% in site (organ) specific cancer rates associated with fluoridation. In this sense, it is of interest to note that, in the recent Canadian study (Environmental Health Directorate, 1977), only changes in total cancer death rates in the range of 7.6 to 40.7 % could have been detected; by comparison, the uncertainty in the U.S. data is substantially smaller. This degree of uncertainty, while unavoidable, is scientifically

acceptable.

A second point that should be mentioned is that no independent analysis and reaffirmation of the Yiamouyiannis and Burk (1977) study has come to the attention of the Commission. Although Dr. Yiamouyiannis indicated at least three corroborating studies (Transcript, Vol, II, 97-98), the Commission has been unable to locate a copy of the "Austin study" and that by Okamura and Matsuhisa (1963) is of questionable impact because of the variance in demographic factors between Japan and the United States. The statement by Cecilioni (1977) cannot be considered as confirmatory in that no consideration was given to demographic variables affecting cancer mortality. In summary, the three studies cited by Dr. Yiamouyiannis do not appear to provide independent confirming authority of the Yiamouyiannis and Burk (1977) study.

A third point is that a claim for the carcinogenicity of fluoride should be scientifically consistent with other knowledge. Thus, the possible linkage between fluoride exposure and stomach cancer (Hoover et al., 1976) would be reasonable because of the irritant properties of hydrofluoric acid in the stomach; however, other studies (Royal College of Physicians, 1976) have not supported such an association. By the same token, because of the high affinity of fluoride for bone, bone is a potential target for fluoride-induced harm; again, no association between fluoride exposure and bone cancer has been detected (Royal College of Physicians, 1976). In addition, because most mutagens are thought to be carcinogens, data suggesting that fluoride is mutagenic has been reported by several authors, and if persuasive, may suggest a reasonable basis for a linkage between fluoride exposure in

drinking water and cancer. This body of information has been reviewed (National Academy of Sciences, 1977; Taves, in press) and the contention that fluoride is a mammalian mutagen has not been supported or confirmed. Furthermore, the evidence presented in the testimony of Dr. George Martin (Transcript, Vol. I, 92-108) does not suggest that fluoride is mutagenic. If fluoride were a mutagen for man, an increase in the incidence of Down's Syndrome might be seen but this does not appear to be the case (see below). In view of this, the mutagenicity data does not support the claim of a possible association between fluoride and cancer as has been suggested by Yaimouyiannis and Burk (1977).

The Commission is aware of the recent decision of Judge Flaherty in the case of Aitkenhead v. Borough of West View Water Authority, in the Court of Common Pleas of Allegheny County, Pennsylvania, Civil Division. Substantially the same body of scientific literature was available to the Commission as to the trial court in Pennsylvania; in addition, the plaintiff's summary of evidence, the defendant's summary of evidence, Judge Flaherty's opinion, and the transcript of the proceedings were available to the Commission. In ruling in favor of the plaintiff, Judge Flaherty appeared to place primary reliance on the study of Drs. Yiamouyiannis and Burk (1977). Although the Commission has examined the same body of evidence as did Judge Flaherty, the Commission has come to the opposite conclusion; an association between fluoridation and cancer has not been shown.

The basic question concerning the Yiamouyiannis and Burk (1977) study is whether the crude cancer death rates utilized by Drs.

Yiamouyiannis and Burk to establish the link between fluoridation and cancer should be adjusted by known demographic factors affecting cancer mortality rates. The basic position taken by Drs. Burk and Yiamouyiannis is that the best evidence of the fluoridation-cancer link is crude cancer death rates, without any adjustment.

However, the Commission is of the opinion that if accepted methods of adjustment, including the use of Standardized Mortality Ratios, are used, the fluoridation-cancer link is not supported. (Report of Dr. Ralph Katz). This opinion is supported by recent studies (see above) utilizing Standardized Mortality Ratios have failed to confirm a link between fluoridation of public drinking water supplies and cancer.

It is the view of the Commission that the available evidence does not suggest that fluoride (1 mg/liter) is a causal factor in human cancer.

B. Down's Syndrome and Fluoridation

The assertion that Down's Syndrome (mongolism) is increased by fluoride in drinking water stems from a study by Rapaport (1956) in which he reported a nearly three-fold increase in the incidence of Down's Syndrome in towns whose drinking water contained 0.1 ppm fluoride as compared to towns with water containing 2.6 ppm of fluoride. A major criticism of this report is that cases were not assigned by place of residence of the mother but rather by the place of birth (Russell, 1965). A later study by Rapaport also suggesting a role for fluoride in Down's Syndrome (1959) has been discredited because his assertion that younger

mothers were more affected by fluoride was based on data that did not utilize age-specific rates. Another study by Rapaport (1963), again claiming an association between fluoride and Down's Syndrome, has been discredited because of the inadequacy of his method of obtaining the level of ascertainment (i.e. the method of obtaining information concerning the incidence of Down's Syndrome) (Royal College of Physicians, 1976).

In contrast, Berry (1958, 1962) studied nine English towns and found no relationship between the incidence of Down's Syndrome and the fluoride content of the drinking water. Also, data from Birmingham, England, for the years of 1960-1971, which used complete ascertainment and was adjusted for age at parturition, showed no increase in the incidence of Down's Syndrome since 1964, the year fluoridation was initiated (Record, 1974).

In addition, a study of individuals in Hartlepool, County Durham, showed the expected incidence of Down's Syndrome although the drinking water always contained high fluoride levels (1.5-2.0 mg. fluoride/liter) (Milligan, 1975).

Needleman et al. (1974) also examined the incidence of Down's Syndrome as it relates to the ingestion of fluoridated water. They concluded that an increase of up to 25% in the incidence of Down's Syndrome from short-term exposure to fluoride could be eliminated.

Erickson et al. (1976), reporting on the results of two separate studies, found there was no evidence supporting an association between fluoride ingestion and Down's Syndrome. In one population studied by Erickson he found the crude incidence of selected common congenital malformations appeared to vary randomly between those areas with and without fluoridated water.

Consideration of the maternal age specific incidence of Down's Syndrome between fluoridated and nonfluoridated areas showed a statistical significance only in the 35-39 year age group, in which the rate was much higher in nonfluoridated areas. However, this difference is reversed for ages over 40 but the difference is not statistically significant. It should also be noted that Burgstahler (1977) claimed that Erickson's findings actually confirmed those of Rapaport in that younger mothers were most affected. However, it has been argued that this contention is based on selective use of data (Taves, in press).

It should be noted that most of the studies dealing with an association between Down's Syndrome and fluoridation have been based on relatively short-term (less than life-time) exposure to fluoride. Taves (in press) recommends that further studies of larger populations with life-time exposure to fluoride are necessary.

In summary, the available data does not incriminate fluoride as a causative factor in increasing the incidence of Down's Syndrome.

C. Allergic Effects of Fluoride

It has been alleged that ingestion of water containing low levels of fluoride (1 ppm) has been associated with a variety of allergic-type responses. Included are gastrointestinal symptoms, arthralgia, stomatitis, headache, backache, weakness or lethargy, paresthesias, muscle tenderness, swelling and edema, dysuria, limitation of motion, loss of memory, muscle fibrillation, conjunctivitis, rhinitis, tinnitus, vertigo, bleeding gums, urticaria and blurred vision. In addition, Waldbott has claimed an

association between Chizzola maculae (dime-sized, bruise-like lesions of the skin) and the ingestion of water containing fluoride (Waldbott and Steinegger, 1973).

At the hearings, Dr. Waldbott presented his experiences with patients from Bay City and Saginaw, Michigan, as well as from Windsor, Ontario, claiming untoward reactions to fluoride (Transcript, Volume I, 157-166). Dr. Petraborg presented three patients to the Commission who claimed that their health was adversely affected by drinking fluoridated water in the community of Aitkin, Minnesota (Transcript, Volume II, 104-118). Their complaints were clinically non-specific and are not well-substantiated medically; furthermore, they were not properly challenged to reproduce their symptoms. In an article describing seven cases of fluoride intoxication, Petraborg (1974) states: "During their illness they had not been aware that their water supply had been fluoridated." However, the possibility of suggestibility after-the-fact that fluoride had caused their illness could not be eliminated. Since there is no laboratory data available and their complaints are vague, it is difficult to conclude that fluoride made these patients ill.

Exposure to alternative sources of fluoride has not resulted in allergic reactions. For example, investigators have not found symptoms of fluoride allergy among the thousands of patients who have undergone anesthesia with methoxyflurane which is converted to fluoride in the body (NAS-NRC, 1971), nor have allergic reactions been evident among children consuming fluoride tablets (O'Meara, 1968) or among populations consuming high natural fluoride in their water (Jolly et al., 1969; Singh et al., 1962). The Royal College of Physicians (1976) refutes the connection between the

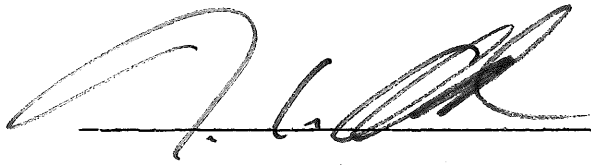
reaction of patients ingesting high doses of sodium fluoride in the treatment of osteoporosis with the symptoms of those individuals who consume water containing 1 mg fluoride/liter. Furthermore, allergic-like symptoms have not been observed, despite the presence of skeletal fluorosis, among residents of Oklahoma and Texas consuming water containing 4-8 mg fluoride/liter (Stevenson and Watson, 1960).

The American Academy of Allergy (Austen et al., 1971), after reviewing the available literature concerning fluoride allergy, concluded that these cases did not represent immunologically mediated reactions of Type I to IV. They also discounted the contention that allergy or intolerance to fluoride might occur as one of the poorly understood types of drug reactions that may or may not be immunologically mediated. Indeed, they found insufficient clinical and laboratory evidence to state that true syndromes of fluoride allergy or intolerance do, in fact, exist.

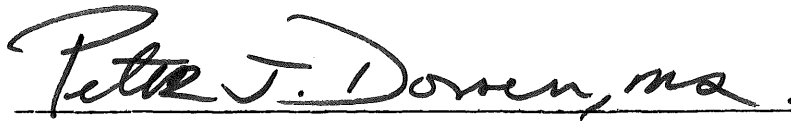
In conclusion, no persuasive evidence supporting an association between the ingestion of drinking water containing (1 mg/liter) fluoride and allergic symptoms or intolerance was presented to the Commission and, at best, the evidence appears anecdotal or uncontrolled. The Commission does not accept the view that an allergic reaction is produced among populations consuming drinking water containing 1 mg fluoride/liter.

CONCLUSION

With regard to potential adverse health effects of fluoridation, the Commission finds that the claims that fluoride is allergenic, mutagenic, or carcinogenic are not supported by the preponderance of available scientific data.



Professor Marion W. Anders, D.V.M., Ph.D.



Peter Dorsen, M.D.



Professor Michael K. Steenson, J.D. (Chairman)

Dated: 2-26-79

APPENDIX

Since the appointment of the Commission in May of 1978, the members of the Commission have met on a monthly basis. The Commission received early submissions from the City of Brainerd and the State Department of Health. On October 26th and 27th of 1978, the Commission held public hearings at the William Mitchell College of Law. Public notice of the hearings was given and, in addition, several witnesses with special expertise were invited to attend the hearings and to testify. The witnesses who appeared at the hearings are as follows:

Professor Wallace D. Armstrong
Department of Biochemistry
Medical School
University of Minnesota

Dr. Dean Burk
Dean Burk Foundation

Mrs. Lorraine Erickson
Aitkin, Minnesota

Dr. Bernard Flavhan
Minnesota Department of Health

Arthur Gillen, Esquire
Minnesota Dental Association

Dr. Vernon N. Houk
Director, Environmental Health Services Division
United States Public Health Service

Mrs. Pearl Kelsey
Aitkin, Minnesota

Dr. George R. Martin
Laboratory of Developmental Biology and Anomalies
National Institute of Dental Research
National Institutes of Health

Dr. H. T. Petraborg
Aitkin, Minnesota

Herman Pittman
Aitkin, Minnesota

Dr. Marvin A. Schneiderman
Associate Director
Field Studies and Statistics Program
Division of Cancer Cause and Prevention

APPENDIX

Professor Leon Singer
Department of Biochemistry
University of Minnesota

Dr. Donald Taves
Department of Pharmacology and Toxicology
University of Rochester
School of Medicine and Dentistry

Dr. Robert Uppgaard
Pequot Lakes, Minnesota

Dr. Waldbott
Detroit, Michigan

Dr. John Yiamouyiannis
Science Director
National Health Federation

A transcript of the hearings is attached.

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