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BY THE COMPTROLLER GENERAL

Report To The Congress

OF THE UNITED STATES

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Reducing Tooth Decay--More Emphasis On Fluoridation Needed

A Federal research program on tooth decay prevention was started in 1971, but public officials cannot predict when the program will achieve a decrease in tooth decay. Questionable research expenditures have been made to develop prevention techniques that do not have widespread applicability and to demonstrate a method that was already being successfully marketed.

Relatively little is being done to promote fluoridation, a proven decay prevention technique. The Public Health Service should place greater emphasis on promoting this technique.

The Congress should amend certain language in the Safe Drinking Water Act which discourages fluoridation and consider establishing a program to provide financial assistance for communities that wish to fluoridate their water supplies.

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To the President of the Senate and the
Speaker of the House of Representatives

This report describes changes needed to make Federal efforts to reduce the national incidence of tooth decay more effective. The Government has not done enough to promote water fluoridation, a proven decay prevention technique, and has made questionable research expenditures on other techniques.

We are sending copies of this report to the Secretary of Health, Education, and Welfare; the Secretary of Housing and Urban Development; the Administrator, Environmental Protection Agency; and the Director, Office of Management and Budget.

Comptroller General
of the United States

COMPTROLLER GENERAL'S REPORT TO THE CONGRESS

REDUCING TOOTH DECAY--MORE EMPHASIS ON FLUORIDATION NEEDED

D I G E S T

Bcf.

Tooth decay affects nearly every person in the United States and is a tremendous financial burden to the public and to the State and Federal governments. In fiscal year 1976, the Nation's dental health bill was nearly $9 billion, and the Federal Government, through Medicaid and other programs, spent about $500 million on dental services.

The National Caries Program was established in 1971 to research tooth decay prevention. Since that time, research progress has been made; however, there has been no measurable decrease in the national incidence of tooth decay, and program officials cannot predict when such a decrease will be achieved.

Some research expenditures have been questionable, such as about $2 million spent to demonstrate school-based mouthrinsing. When these demonstrations were begun, this technique was already known to be effective and had been commercially marketed in 40 States. (See pp. 6 to 8.)

Other questionable research expenditures involve projects to develop fluoride gels and pit and fissure sealants. These techniques were being funded and reported to the Congress as having significant potential for reducing tooth decay at a time when problems were known which would prevent their widespread use. (See pp. 9, 10, and 11 to 13.)

Greater emphasis is needed on promoting water fluoridation--a proven, cost-effective technique for reducing tooth decay. While Federal efforts to promote fluoridation have declined, expenditures for research to develop other techiques have increased.

Fluoridated water can prevent up to 65 percent of all children's tooth decay, with benefits continuing into adult life. The Public Health Service estimates that, for each dollar spent on fluoridation, $36 for tooth decay treatment could be saved. Yet over 67 million Americans continue to be served by nonfluoridated public water systems. (See pp. 18 and 19.)

The public's knowledge of fluoridation is critical to its acceptance as a public health measure. But most people do not know what it is, and many do not even know whether their water is fluoridated. (See p. 22.)

Some people cause public concern by opposing fluoridation because they believe it is a health hazard. However, extensive scientific research and use in numerous communities have shown that fluoridation is safe. (See pp. 22 and 23 and ch. 4.)

Although Public Health Service officials recognized at the inception of the National Caries Program that the program's activities were not intended as a substitute for fluoridation, the Service's role in promoting fluoridation has diminished. The Service recognizes that financial assistance to States and localities would be helpful but is not sure whether such assistance can be provided under the present legislation. (See pp. 19 and 20.)

Communities obtaining funds under title I of the Housing and Community Development Act to improve their water systems may, under some circumstances, use part of these funds for fluoridation. Officials in some communities which had received such funds but had not fluoridated told GAO that they would have included the cost of fluoridation equipment in their grant proposals had they known they could do so. (See pp. 30 and 31.)

The Safe Drinking Water Act has been misinterpreted in some communities as prohibiting fluoridation. (See pp. 31 and 32.) Environmental Protection Agency regulations implementing the act are misleading because fluoridation's dental health benefits are not prominently stated. The Agency has agreed to amend the regulations. (See pp. 32 to 34.)

The Department of Agriculture Extension Service, and possibly other federally supported organizations, could help inform the public about fluoridation and other tooth decay prevention techniques. The Public Health Service should seek out such organizations and coordinate with them in developing a public information strategy. (See p. 34.)

RECOMMENDATIONS

The Secretary of Health, Education, and Welfare should require the Director of the National Institutes of Health to:

--Develop criteria for undertaking National Caries Program demonstration projects. The criteria should require an assessment of project objectives and the need to accomplish them, the adequacy of project design to provide scientifically valid data, the selection of sites, and the cost versus anticipated benefits.

--Periodically, ~~but at~~ least annually, reassess the potential public benefit of tooth decay prevention techniques being funded by the National Caries Program. (See pp. 15 and 16.)

The Secretary should require the Assistant Secretary for Health to

--place greater emphasis on helping State and local public health agencies to promote fluoridation;

--determine whether the Public Health Service has ~~now, or will have under section 317 of the Public Health Service Act, as amended~~, the authority to provide specific financial assistance ~~to States, communities, and other authorities that want~~ to fluoridate ~~their~~ water supplies and, if such authority is lacking, request that the Congress provide it; and

--increase efforts to educate the public about the decay preventive benefits of fluoridation and seek out other organizations that can help in these efforts. (See pp. 23, 24, and 35.)

The Secretary of Housing and Urban Development ~~should instruct~~ regional officials to notify States and communities that the cost of fluoridation equipment can be included in title I water system improvement grants. (See p. 35.)

Because more widespread adoption of fluoridation could reduce the incidence of tooth decay in the population and achieve considerable savings in treatment costs, GAO recommends that the Congress consider establishing a program to provide financial assistance to communities that wish to fluoridate their water supplies. (See p. 24.) see front

The language of the Safe Drinking Water Act should be amended to more closely conform with the stated congressional intent and to reduce misinterpretation. (See p. 35.)

In October 1978, GAO furnished drafts of this report to the Department of Health, Education, and Welfare, the Department of Housing and Urban Development, and the Environmental Protection Agency and requested their comments. The Department of Housing and Urban Development and the Environmental Protection Agency provided written comments, but GAO did not receive written comments from the Department of Health, Education, and Welfare in time to include them in this report. GAO did, however, obtain comments from officials of the Public Health Service who operate programs discussed in the report.

Program officials believe that their demonstration programs for school-based fluoride mouthrinsing were carefully planned and that their decision to support research on fluoride gels and pit and fissure sealants have been justified. However, the facts presented in this report more than adequately support GAO's findings and conclusions about questionable research expenditures on these programs. (See pp. 16 and 17.)

Program officials agreed with GAO's recommendations regarding fluoridation. However, they disagreed with GAO's recommendations concerning the National Caries Program because they believed that GAO's concerns were already addressed in the program's operating policies. The Department of Housing and Urban Development and the Environmental Protection Agency agreed with GAO's recommendations involving them. (See pp. 16, 17, 24, and 36.)

Contents

ABBREVIATIONS

CDC	Center for Disease Control
EPA	Environmental Protection Agency
GAO	General Accounting Office
HEW	Department of Health, Education, and Welfare
HUD	Department of Housing and Urban Development
NCI	National Cancer Institute
NCP	National Caries Program
NIDR	National Institute of Dental Research
NIH	National Institutes of Health
PHS	Public Health Service

CHAPTER 1

INTRODUCTION

Tooth decay poses one of the country's greatest public health problems in terms of its persistence and the number of people affected. More than 95 out of 100 Americans experience some tooth decay (also known as dental caries) by the time they reach adulthood. By age 17, the average American will have nine decayed, missing, or filled teeth. The Massachusetts Department of Public Health has reported that the average 14-year-old child in the State has lost one tooth from decay, has had four filled, and has seven in need of filling. A survey of public school children in California's Marin County showed that more than 75 percent had suffered decay of their permanent teeth. Decay, if untreated, results in discomfort, pain, and eventual tooth loss. Yet according to information from the National Center for Health Statistics, only about half of the people in the United States visit a dentist in any given year.

Dental costs have risen in recent years and are expected to continue rising. The Nation's dental health bill in fiscal year 1976 was nearly $9 billion. In the same period, the Federal Government paid about $500 million for dental services, primarily for Medicaid recipients and military personnel.

At the Federal level, prevention and control of tooth decay is a responsibility of the Public Health Service (PHS), Department of Health, Education, and Welfare (HEW). Two PHS organizations--the National Institute of Dental Research (NIDR) and the Center for Disease Control (CDC)--have important dental health roles. NIDR, a part of the National Institutes of Health (NIH), administers the National Caries Program (NCP), a caries prevention research program. CDC promotes tooth decay prevention techniques that have public health application. Other HEW organizations have roles in training and placement of dental health personnel.

THE NATIONAL INSTITUTE OF DENTAL RESEARCH

In 1948, the Congress created NIDR to support dental research and research training in the United States. NIDR conducts and sponsors basic and applied research to determine the causes of dental disease. In the late 1960s, NIDR officials claimed that they were at a breakthrough point in tooth decay research and that an accelerated research effort

would eliminate tooth decay within a decade. In February 1970, caries prevention was identified as a Presidential special health initiative, and in 1971, NCP was established within NIDR with a stated goal of eliminating tooth decay as a public health problem by 1980.

Tooth decay is caused by certain mouth bacteria which produce acids that dissolve tooth enamel. Scientists believe that tooth decay is influenced by three factors: (1) bacterial agents, (2) tooth vulnerability to acid, and (3) diet, particularly sugar consumption. Although effectively modifying one or more of these factors will reduce tooth decay, it is unlikely that any one research approach will eliminate it. NCP's efforts are therefore directed at

--combating bacteria, by developing techniques to counteract decay-producing agents;

--increasing tooth resistance, by applying fluoride to the surface of the teeth, chewing and swallowing fluoride tablets, applying plastic sealants on the teeth, and conducting other research to improve tooth resistance; and

--modifying the diet, by developing sugar substitutes.

NIDR's budget for fiscal year 1978 was about $58 million, of which $11 million was for research activities under NCP, which is discussed in detail in chapter 2.

THE CENTER FOR DISEASE CONTROL

CDC, located in Atlanta, Georgia, is responsible for controlling the spread of disease in the United States. Through its Dental Disease Prevention Activity, CDC is responsible for promoting dental health prevention techniques that have public health application. 1/ PHS considers fluoridation of school and community water to have public health application. The Activity's responsibilities include providing technical assistance to State and local officials to implement fluoridation programs. Fluoride is a nutrient found in all water. Fluoridation adjusts the natural fluoride level in water to approximately one part per million, the equivalent of a drop in a bathtub full of water. Some water naturally contains this amount of fluoride or more. Research has shown that

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1/Techniques that are effective and readily deliverable to large segments of the population at a reasonable cost.

drinking optimally fluoridated water can prevent up to 65 percent of all children's tooth decay, with benefits continuing into adulthood. Presently, more than one-third of the children who could be drinking fluoridated water are without its benefits.

As of November 1978, two persons--a dentist and a public health advisor--were administering CDC's dental disease prevention program. Also, through an interagency agreement with the Environmental Protection Agency (EPA), CDC was funding an engineer in 6 of EPA's 10 regions to assist States and communities on fluoridation matters. As requested, the engineers helped make technical assessments for new fluoridation installations, periodically monitored and inspected fluoridation equipment, and provided other support. In fiscal year 1978, CDC's total budget for dental disease prevention activities was $330,000.

OBJECTIVES AND SCOPE OF REVIEW

We made our review to assess NCP's progress toward its goal of reducing or eliminating tooth decay as a public health problem. Federal efforts to promote and financially support fluoridation programs were also evaluated. The safety of water fluoridation was examined to determine the validity of claims that fluoridation is hazardous. Also, we contracted with the Gallup Organization to assess the public's knowledge and attitude toward fluoridation to determine the possible need for further education on the issue.

Our review was made at NIDR headquarters in Bethesda, Maryland. Work was also done at CDC in Atlanta, Georgia, and sites where 8 of 17 contractors were demonstrating school-based mouthrinsing in California, Connecticut, Massachusetts, Michigan, and New York. In addition, we obtained information from EPA, the Department of Housing and Urban Development (HUD), and the Department of Agriculture.

We reviewed pertinent Federal laws, regulations, agency records, and data on dental research and demonstration projects. Questionnaires were sent to public health officials in the 50 States, Washington, D.C., Puerto Rico, and 23 non-fluoridated cities. We also discussed fluoridation and related dental techniques with public interest groups, medical school officials, and officials of companies that commercially market mouthrinse solutions.

CHAPTER 2

THE NATIONAL CARIES PROGRAM

EFFORTS TO REDUCE TOOTH DECAY

Since the inception of the National Caries Program in 1971, several areas of research have been supported in an effort to reduce or eliminate tooth decay as a public health problem. Some research progress is being made; however, these efforts have not produced a measurable reduction in the national incidence of tooth decay, and program officials cannot tell when such a reduction will be achieved. NCP advanced one research effort (school-based mouthrinsing) to a demonstration phase at a time when the technique had already been proven effective and was being commercially marketed and used by several million students. Another research effort (sealants) was being advocated by NCP officials as a means of reducing tooth decay when they knew that manpower limitations and high costs would not permit its widespread application. Still another research effort (use of a mouthpiece to administer fluoride gels) was reported to the Congress to have promise when problems with the technique were known to limit its use.

In a 1967 report to the President, NIDR stated that, with an accelerated research program, the conquest of caries was anticipated within the next decade. In 1970, NIDR published a 10-year program plan suggesting approaches to develop techniques to make caries almost completely preventable by 1980. These approaches included developing (1) alternative measures for administering fluoride, (2) adhesive sealants, (3) vaccines and other techniques for combating caries-causing bacteria, and (4) sugar substitutes and other approaches for modifying the diet. NCP officials told us that research areas currently having the most promise are alternative measures for delivering fluorides, vaccines, and sugar substitutes.

NIDR recognizes that its initial goal of eliminating tooth decay by 1980 was not realistic. The goal has since been revised to that of significantly reducing the incidence of tooth decay as a public problem, without reference to a time frame or the extent of the reduction. NIDR officials explained that achieving a decrease in caries in the general population depends on many factors beyond their control, such as economic and social considerations, availability of delivery personnel, and Federal and State legislation.

From fiscal year 1972 to 1977, NCP obligated about $57.7 million. About half of this amount was to support basic research on how caries occur, to provide grants for training and career development of researchers, and to help pay administrative costs. The other half was obligated to support studies involving specific prevention techniques, as shown in the following table.

NCP studies on decay prevention techniques	FY 1972-77 obligations
	(millions)
Fluoride	$13.5
Pit and fissure sealants	3.5
Vaccines and other techniques for combating caries-causing bacteria	8.7
Sugar substitutes and other diet modification approaches	2.9
Total	$28.6

FLUORIDE STUDIES

NCP does not know why fluoride is effective against caries. An NCP official stated that answering this question might result in a more effective use of fluoride. Although NCP officials do not foresee a better use of fluoride than that provided through community water fluoridation, better alternatives might be developed for delivering fluoride to children and others who can benefit, in the population of approximately 35 million Americans not served by a community water system. In addition to funding research through school-based mouthrinsing demonstrations, NCP has studied school-based administration of fluoride gels using a custom-fitted mouthpiece.

NCP officials believe that a more effective alternative delivery technique may be one that will slowly and continuously deliver fluoride, a result achieved by routinely drinking fluoridated water. Slow-release methods being studied include using a plastic device or tablets. Studies have been discontinued on using a spray device, a method currently determined not practical.

Mouthrinsing demonstrations

The objective of the school-based mouthrinsing program, begun in 1975, is to demonstrate the effectiveness, low cost, and public acceptance of fluoride mouthrinsing to reduce the incidence of tooth decay in children. NIDR's rationale was to promote mouthrinsing into general practice through community-run models of preventive programs, as an alternative to "costly and uncertain marketing campaigns." Under the program, students mouthrinse in the classroom once a week with a fluoride solution. Mouthrinsing requires few materials, is easily learned, and can be supervised by teachers or other nondental personnel. It takes only a few minutes and can be done with little or no disruption to classroom activities.

Although mouthrinsing alone provides protection against tooth decay and may provide added protection to people living in fluoridated communities, it is not an acceptable alternative to community water fluoridation. Community water fluoridation provides a substantially higher average protection at a lower cost per person than does mouthrinsing. Research indicates that water fluoridation also provides greater assurance that all participants will receive maximum protection.

NIDR awarded 17 contracts to research and health organizations to locally administer the mouthrinsing programs. The contractors are required to conduct a 3-1/2-year mouthrinsing program for children in kindergarten through grade eight, provide NIDR with cost and program effectiveness data, and work with local officials and school authorities to develop a plan for continuing the program when Federal funding stops. About 67,000 children were participating in the program at the time of our review.

Questionable need to demonstrate mouthrinsing

Although the objectives of the mouthrinsing program have merit, they have already been achieved. In 1961, Swedish school children who rinsed with a sodium fluoride solution showed a significant reduction in tooth decay after 1 year. Numerous studies done in this country, some more than 15 years ago, including those by scientists at the University of Rochester, Forsyth Dental Center, and NIDR, have proved mouthrinsing reduces tooth decay. These studies have shown that rinsing is not only effective, but also an inexpensive, feasible method of reducing tooth decay. In 1974, the Food and Drug Administration announced that rinsing was safe and effective in reducing tooth decay.

When NIDR awarded the rinsing demonstration contracts, the technique was already being commercially marketed. One company with which we discussed mouthrinsing marketing efforts began marketing the technique at the start of the 1973-74 school year. By January 1975, when NIDR awarded the contracts, this company was supplying fluoride rinse for about 2.5 million students in 40 States. The company president said that he contacts State dental directors and local school officials and gives them background literature and brochures explaining the mouthrinsing program. The brochures outline the procedures for preparing and dispensing the mouthrinse and identify the per student cost of fluoride and supplies.

According to this official, the effectiveness and low cost of the mouthrinsing program were the principal factors considered in deciding to market this product to school systems.

NIDR officials agree that the safety and efficacy of fluoride mouthrinsing has been established, but they contend that the demonstrations have succeeded in establishing the technique's cost effectiveness and high public acceptance and in promoting its use. They stated that, while the demonstrations were being carried out, the number of children using mouthrinsing increased substantially. Although we agree that the demonstrations have likely helped to increase the number of children using mouthrinsing, no evidence suggests how much of the increase is due to the demonstration projects or NIDR's other promotion activities. We believe that because (1) the safety and effectiveness of mouthrinsing had been established, (2) mouthrinsing was being commercially marketed and used, and (3) mouthrinsing could have been publicized or promoted by NIDR without spending $2 million to demonstrate it, the decision to fund the demonstrations was questionable.

Mouthrinsing programs are costly to demonstrate

NIDR's school-based rinsing program is comparatively expensive and reaches relatively few students. NIDR spent $1 million on 17 contracts through June 30, 1977. It is estimated that, when completed, these contracts will cost about $2.3 million. Students are using a commercially available mouthrinse package that costs about $100,000. The $2.2 million difference is what NIDR will spend to examine the students' teeth to show the technique's effectiveness and to pay other costs, including costs to collect statistics on overhead, floor space required, and time required to distribute

the rinse. The average annual cost per child participating in the program is over $9, excluding NIDR's costs of administering the contracts. In contrast, at least one private company offers mouthrinsing programs for an annual cost per child of 45 cents.

NIDR officials believe that our annual cost per child figure of $9 is misleading. They cited $3.49 as the average annual cost per child in the demonstration. The difference between these figures results from NIDR's not including certain demonstration costs, such as those incurred to collect data. A total of 39 mouthrinsing programs were operating in Connecticut at the time of our fieldwork. A State official estimated that an annual expenditure of 50 cents per child would cover all costs of a school-based mouthrinsing program.

Data being collected on the technique's effectiveness are not scientifically valid because of the lack of control groups. The usefulness of cost data being collected is questionable because the cost of rinse supplies has already been determined by the marketplace. NCP officials could not tell us why they were collecting other cost information, such as the cost of classroom floor space required when administering the rinse.

The number of children rinsing under NIDR's program represents less than 0.5 percent of the 25 million school children who do not currently have access to municipally fluoridated water. In contrast, the president of a private company told us that, as of October 1977, it was marketing rinse programs to about 4.5 million students.

NIDR officials advised us that this was the first time they had demonstrated a decay prevention technique and that no criteria or guidelines existed to assess what factors should be considered--such as private sector marketing efforts. NCP's associate director acknowledged that the demonstration approach is a relatively expensive way to promote mouthrinsing. He added that, when the projects have been completed and the results publicized, it is hoped that additional nonparticipating schools will initiate similar programs. If this happens, he believes the expense will have been justified. According to him, NIDR is a research organization, and outreach programs such as mouthrinsing must be done as applied research. Other methods, such as providing grant funds, partially reimbursing local governments for rinsing materials and supplies, or providing seed funds, are not permitted under NIDR's present authority. These actions would require expanding NIDR's authority or transferring the program to another PHS agency that has this authority.

Site selection guidelines need improvement

NIDR guidelines for mouthrinsing demonstration projects are not very specific about site selection. However, the guidelines for site selection address the appropriateness of school populations and specify that the location be in a nonfluoridated community. They do not specify, however, that consideration be given to such matters as whether the State had an active caries prevention program that was available to the community, whether there is a fluoridatable school or community water supply, and whether attempts are being made to fluoridate it. This has resulted in the selection of some sites where the benefits of the projects have been diminished.

For example, one project was located in Connecticut, where health officials were already actively promoting various fluoride delivery techniques, including mouthrinsing. A State health official told us that, during the first year of the NCP demonstration project, 24 other mouthrinsing projects were operating in the State. Also, at the time of our review, 167 of 169 communities in the State were participating in some type of fluoride program. Since public acceptance of mouthrinsing and other fluoride techniques was very high, the value of this project was questionable.

Five of the eight projects reviewed were located in areas with community water supplies. Two of the five projects are in a metropolitan area that recently fluoridated its water supply. Had NCP officials considered the community's plans for fluoridation, the two projects might have been located elsewhere, since mouthrinsing is most effective in nonfluoridated areas.

Fluoride gels

At a time when practical problems with fluoride gels were apparent, NIDR advised the Congress that this technique had promise for reducing dental caries but it did not mention the problems. In 1969, NIDR reported to the House Committee on Appropriations that applying a fluoride gel to the teeth for a few minutes a day several times a week, using a fitted mouthpiece, has produced a reduction of 80 percent in tooth decay in school children living in nonfluoridated areas. In that year and again in 1971, NIDR reported to the Senate Committee on Appropriations that:

"Topical application of fluoride in fitted vinyl mouthpieces, undertaken in the school environment with appropriate professional supervision, has already been shown to exert striking benefits to children of primary school age in areas where water fluoridation is not practicable. These long-term studies are being further expanded to determine whether the benefits of topical application in mouthpieces augment those already extant in areas where community water supplies are fluoridated. Another program of considerable promise is related to an assessment of the long-term benefits which the topical mouthpiece method may provide to preschool children who have not yet developed their adult dentition."

Administration of flouride gels by this technique requires that each child be fitted with a new mouthpiece as often as every 6 months. The mouthpiece is saturated with a fluoride solution before each use and is kept in the mouth for 5 minutes. A dental official involved in research on this technique reported that the procedure requires close supervision; that children tend to salivate excessively, with the saliva sometimes running down their chins; and that children brought together for the procedure frequently become loud and hard to control. He also considered the total annual cost per child for this technique to be relatively high.

An NCP official stated that the impracticality of almost daily classroom use of this technique became evident in the 1960s, during studies funded by NIDR. He explained that objectives of the NCP-funded studies have been to (1) determine if infrequent application of gels helps to reduce caries and (2) study fluoride uptake in tooth enamel. If NCP finds that infrequent use of this technique is sufficiently effective, it is hoped that the technique will be more acceptable for use in schools and that some alternative to the mouthpiece will prove practical as a delivery vehicle. In addition, the NCP official pointed out that NIDR-supported studies have shown that frequent use of fluoride gels can prevent the unique caries problems of certain cancer patients whose salivary function is destroyed by cancer therapy.

Slow-release methods

Fluoride-filled plastic device

In 1977, an NIDR official reported that results of animal studies have confirmed the feasibility of gluing to the teeth

a tiny wafer that slowly releases fluoride in the mouth for up to 6 months, at which time a new wafer is applied. An NCP official stated that, since trained personnel would be required to apply the device, it might not have public health applicability. He did not know how much the wafer would cost or what other factors might limit its widespread use. NCP plans to apply to the Food and Drug Administration for approval to use the wafer in clinical studies.

Fluoride tablets

Fluoride tablets have been available to the public for about 25 years. An NCP official has reported that public health programs in which tablets have been distributed for home use have generally been unsuccessful because children and their parents find it difficult to comply with the strict regimen required. Clinical studies have shown, however, that administering fluoride tablets in schools can be successful.

A disadvantage of traditional tablets is that the fluoride is rapidly cleared from the body. NCP has recently completed animal studies on a new tablet that slowly releases fluoride throughout the day. An NCP official stated that, like traditional fluoride tablets, the new tablets must be consumed daily for maximum effectiveness. At the end of our review, NCP was having the new tablet manufactured for use in clinical studies. According to NCP officials, any further action they take will depend on results of the clinical studies.

Fluoride spray

NCP has developed a device for spraying spheres of fluoride in a sticky gum base onto the teeth. There are no current plans to study this method further because, among other problems (1) one spraying is effective for no more than 8 hours and (2) the spheres taste gritty and unpleasant. Also, considerable toxicity testing would be required to get Food and Drug Administration approval for using this technique in humans.

PIT AND FISSURE SEALANT STUDIES

Protecting the pits and fissures of the teeth's chewing surfaces is difficult. Several techniques, including restoring pits and fissures, have been used to prevent dental caries, but none have been widely accepted by the dental profession. In the late 1950s, NIDR-supported researchers reported progress in developing a technique to seal pits and fissures of the teeth with a plastic material.

In its 10-year program plans, NIDR officials reported that the technique was highly promising, that it was under clinical study, and that it would undergo larger scale field trials. By fiscal year 1978, NCP had funded 27 pit and fissure sealant clinical studies costing $4.2 million, including studies of the sealant's effectiveness when used with various fluoride delivery techniques.

Sealants developed through NIDR funding must be applied by trained personnel, and application takes about 30 minutes. NIDR recognized as early as January 1969 that this requirement represented a barrier to widespread use of sealants. At that time, the chairman of the NIDR Caries Task Force, reporting on this technique, stated that "application of this measure on a public health scale would of course have to overcome an enormous manpower problem."

Nevertheless, on several occasions, NIDR reported to congressional appropriations committees the strong potential for use of this technique. For example:

--In May 1971, during House appropriations hearings, NIDR reported on the results of a pit and fissure sealant research project stating that "It is fully expected that expanded use of the preventive measures developed in this project will have a strong impact on reducing the number of teeth lost from decay throughout the world."

--During House appropriations hearings in February 1972, NIDR reported progress in several caries prevention areas and added that "the most conspicuous research progress made recently, however, involves an adhesive sealant."

--During House appropriations hearings in February 1976, NIDR reported in its prepared text that "Our extensive field trials of an adhesive sealant to protect occlusal surfaces of teeth were completed, with safety and efficacy of the technique demonstrated. Community demonstrations of the technique are being planned."

In addition to the previously discussed manpower problem reported in January 1969, a report in the February 1973 Journal of the Michigan Dental Association indicated that there was a practical barrier to widespread application of pit and fissure sealants. Based on studies of three types of sealant materials, including the type being studied by NCP, officials at the University of Southern California

School of Dentistry, authors of the report, stated that excessive time and cost would be required to provide lifetime protection using pit and fissure sealants, compared with a tooth restoration technique available since the 1920s. The authors stated that further clinical trials must be completed before the public can be assured of the role of such sealants in preventing caries.

During questioning about pit and fissure sealants at the February 1976 House appropriations hearings, the Director of NIDR reported that "for usage in public programs, there might be some problems with cost." In the next month, during a meeting of NIDR's Dental Caries Program Advisory Committee, an NCP official reported that the cost over a 10-year period could exceed $20 per cavity prevented, primarily because of the need for trained personnel and for repeated contact with each child to seal newly erupting teeth and to replace lost material.

An objective of many studies was to determine the length of time sealants stay on the teeth. An NCP official explained that sealant retention rate results reported in the late 1960s appeared promising, and NCP believed sealant costs could be reduced if later studies showed increases in retention rates. The February 1973 report of University of Southern California dental officials indicated that more recent studies showed retention rates to be lower than previously reported. An NCP official stated that in the fall of 1975, NCP concluded that there was a cost problem with sealants, regardless of retention rates. Another NCP official indicated that pit and fissure sealant studies could have been curtailed earlier, had more serious consideration been given to manpower costs.

Several NCP-funded studies sought to determine whether dental auxiliary personnel with adequate training could apply sealants as well as dentists. Results of these studies indicated that they could. However, regarding public health applicability, this was a moot question since the technique was too expensive even if auxiliary personnel were used.

NCP officials believe they have shown that use of pit and fissure sealants is practical for children over 10 years old and that the technique should be endorsed as an effective preventive method for general use in dental office and clinic situations. However, few people currently benefit from the technique. These officials have no plans to stop funding ongoing sealant research, but they have not started any new studies since making their cost-effectiveness analysis which was presented to the Dental Caries Program Advisory Committee in 1976.

VACCINE STUDIES

The NIDR 10-year program plan discussed the need to determine if vaccines can be used to prevent caries. Research efforts in the early 1970s continued to indicate the vaccine approach to be a promising one. In 1974, NCP began to increase funding for research in this area. Currently, it is funding animal studies, involving four groups of vaccines, with the hope that the vaccine approach will result in widespread reduction in tooth decay.

NIDR recently estimated that vaccines may be ready for use on humans by the end of the 1980s. However, NCP officials told us that it is still too early to determine when, or if, a vaccine against caries will become a reality, or how effective any vaccine developed for humans will be. An NCP official pointed out that the vaccine approach has resulted in a 50- to 90-percent reduction in caries in animals, but that its effectiveness in humans is unknown. He added that vaccines must be purified, which requires extensive laboratory testing, before they can be considered for use in humans. They must then be tested for safety--a time-consuming, complex procedure. Other variables affecting possible success of the vaccine approach include

--frequency of administration (every month or once in a lifetime),

--route of administration (oral or injection),

--benefits weighed against costs and risks of a vaccine program,

--additional research costs to develop the vaccines, and

--public acceptance of vaccines as a caries preventive.

SUGAR SUBSTITUTE STUDIES

Sucrose, ordinary table sugar, is the principal dietary cause of dental caries. During its 10-year program plans, NIDR expressed the need to find noncariogenic alternatives to sucrose. Other sugars, such as glucose and fructose, were viewed as possible alternatives, but later studies indicated they were not. More recently, NCP has been trying to find alternative sweeteners to sugar.

NCP support for studies involving sugar substitutes totaled about $800,000 by the end of fiscal year 1977. An NCP official stated that funding has been limited because of intense commercial involvement in this field, concern about whether a commercial firm would market any sugar substitute NCP may develop, and the need to satisfy extensive Food and Drug Administration requirements before a new sweetener can be available to the public. According to this official, a recent surge in demand for nonfattening sugar substitutes has been encouraging, and NCP is considering an expansion of research in this area.

CONCLUSIONS

Since the start of NCP, there has been no measurable decrease in the national incidence of tooth decay, and program officials cannot predict when such a decrease will be achieved. Several areas of research are being supported, and some research progress is being made. However, some expenditures have been questionable, such as the $2 million spent to demonstrate school-based mouthrinsing--a technique that was already known to be effective in reducing tooth decay and that had been commercially marketed in 40 States.

Other questionable expenditures involved projects undertaken to develop techniques having widespread applicability, but which were continued after it beame clear that such applicability was limited. NIDR advocated a technique for sealing pits and fissures of the teeth based on the technique's widespread applicability, although NIDR officials knew manpower limitations precluded such use. NIDR has also supported studies on school-based administration of fluoride gels, using a custom fitted mouthpiece, as a means of reducing the national incidence of tooth decay when this technique was known to be impractical for widespread use.

RECOMMENDATIONS TO THE SECRETARY OF HEW

To better ensure that caries prevention techniques are economically and effectively introduced to the public and to prevent unnecessary use of research funds, we recommend that the Secretary of HEW require the Director of NIH to:

--Develop criteria for undertaking National Caries Program demonstration projects. The criteria should require an assessment of project objectives and the

need to accomplish them, the adequacy of project design to provide scientifically valid data, the selection of sites, and the cost versus anticipated benefits.

--Periodically, but at least annually, reassess the potential public benefit of caries prevention techniques being funded by the National Caries Program.

COMMENTS OF NIDR OFFICIALS

NIDR officials believed that NCP's mouthrinsing demonstration program was carefully planned and that NIDR did not give misleading testimony to congressional subcommittees, as they stated that our report implies. Also, they believed that their decisions to support research on adhesive pit and fissure sealants and on fluoride gels had been justified. However, we believe the facts in this report more than adequately support our findings and conclusions about the questionable need for NCP to demonstrate mouthrinsing and to support research on sealants and gels after it had become clear that the potential for widespread use of these techniques was limited. We have included in our report a discussion of NIDR's comments, where appropriate.

NIDR officials disagreed with our recommendations, stating that further criteria for undertaking NCP demonstration projects are not needed and that the potential public benefits of caries prevention techniques funded by NCP are already being frequently reassessed. The officials stated that the general philosophy and broad criteria for its demonstration projects were developed in 1974. They also stated that (1) the Dental Caries Program Advisory Committee reviews NCP operations at meetings held three times each year and (2) NCP convenes workshops for non-Government scientists about three times yearly. These workshops focus on and reassess the potential public benefits of specific segments of NCP research activities.

The documentation NIDR officials refer to as philosophy and criteria pertains to guidelines for implementing the mouthrinsing demonstration projects after the decision had been made to conduct such demonstrations. What we are recommending is that NIH develop criteria for NCP to follow in deciding if demonstration projects of any type are needed.

While we agree that existing groups can be used to review NCP's research activities, none of these groups is specifically required to periodically reassess the potential

public benefit of NCP-funded caries prevention techniques. We did not find that such reassessments were routinely made. We either attended or reviewed the minutes of several meetings of the Dental Caries Program Advisory Committee. Although technical aspects of NCP's operations and a theoretical model for measuring the net social value of caries prevention techniques were discussed, we noted only one instance in which the potential public benefit of an NCP-funded technique was seriously questioned. This instance, involving pit and fissure sealants, is mentioned on page 13. Since this committee reviews NCP activities, it may be an appropriate group to be specifically charged with the task of taking the initiative for ensuring that the potential public benefits of all NCP programs are regularly reassessed.

CHAPTER 3

DECLINING FEDERAL FLUORIDATION EFFORTS

Despite the health and economic benefits associated with fluoridating drinking water, this recognized dental prevention technique is not being fully used. Today, about 105 million people are drinking adjusted or naturally fluoridated water, but over 67 million others who could be are not. In 27 States, less than half of the population used fluoridated water as of December 1975. (See app. I.) Some progress has been made in fluoridating water supplies in larger cities. Seventy percent of all cities with populations of 100,000 or more have fluoridated water--Chicago and Washington, D.C., for example, have been fluoridating for more than 20 years.

Fluoridation is being underused because:

--PHS is not actively promoting fluoridation.

--Federal funds are not available to assist communities that want to fluoridate, except in certain instances where other water system improvements are involved.

--Many people don't know what fluoridation is or what its decay preventive benefits are.

--People opposed to fluoridation cause public concern.

PHS officials have unsuccessfully attempted to place more emphasis on fluoridation. HEW's long-range health plans for the past several years have included such initiatives as making fluoridation a national health priority, but these plans have not been adequately acted on. If it is a national goal to substantially reduce tooth decay, PHS should place more emphasis on fluoridation--the most effective known way of doing so.

The costs of dental care are substantial--the Federal Government alone, through various programs, spent about $500 million on dental health services in fiscal year 1976. If a program were developed to provide financial assistance for communities that wish to fluoridate their water supplies, the incidence of caries in the population could decrease and considerable savings in treatment costs could be achieved.

PHS estimates that, for each dollar spent on fluoridation, $36 in the cost of caries treatment could be saved. Once fluoridation is attained throughout almost all of the

Nation, PHS estimates $3.5 billion can be saved in the cost of caries treatment during the first 16 years of life for each future generation of children born in fluoridated communities. This estimate includes a savings of $2.1 billion among children in communities already fluoridated and another $1.4 billion that would accrue if the remaining 5,860 communities PHS has targeted for fluoridation were to fluoridate.

FLUORIDATION PROMOTIONAL EFFORTS

PHS recognized at the inception of NCP that it was not intended as a substitute for fluoridation. In 1970, the Surgeon General acknowledged that, unless fluoridation were also emphasized, little progress would be made in controlling tooth decay.

Despite this, PHS' role in promoting fluoridation has diminished in recent years. Since 1971, PHS has spent less than $200,000 a year to promote fluoridation. In contrast, for the same period, PHS has spent an average of about $9 million annually to support various research strategies to reduce dental caries.

There have been several major reorganizations within PHS, and the division responsible for promoting fluoridation has been transferred several times. In 1976, the job of promoting fluoridation, and all other proven and effective dental disease prevention methods, was transferred from that division to CDC in Atlanta. The transfer was made to reverse PHS' decreasing emphasis in promoting fluoridation. PHS officials believed that placing fluoridation promotion within CDC would give it the organizational identity it lacked (disease prevention) as part of another HEW bureau.

Although the responsibility for promoting fluoridation was transferred to CDC, funding was not, and CDC had to absorb the cost of this activity within its existing budget. As of November 1978, only two professional staff--a public health advisor and a dentist--were administering CDC's dental disease prevention program for the entire country. In the mid-1960s, when fluoridation was being actively promoted, there were more than 20 Federal officials responding to State and local governments that wanted assistance in fluoridating their school and community water supplies. This deemphasis is difficult to understand when PHS acknowledges that achieving community acceptance of fluoridation requires a sustained educational and promotional effort.

State and local public health officials do not believe that PHS is committed to promoting fluoridation. We sent a questionnaire to the dental director in each State, and over 85 percent of those responding indicated that PHS' promotional efforts were inadequate. Responses to a questionnaire sent to 23 nonfluoridated cities showed that officials from several cities believe PHS is not adequately assisting public health officials in promoting fluoridation.

FINANCIAL ASSISTANCE

Section 317 of the Public Health Service Act authorizes the Secretary of HEW to award grants for disease control programs. That section has been amended by section 202 of the Health Services and Centers Amendments of 1978, and effective October 1, 1979, authorizes the Secretary to make grants for preventive health service programs. Because appropriations were authorized for a period prior to October 1, 1979, it is not clear which version of section 317 presently applies. While fluoridation is almost certainly included in preventive health service programs, it is not clear whether it may be part of a disease control program. Consequently, PHS officials are not sure whether they can provide specific financial assistance to local governments for fluoridation projects. PHS dental officials have requested HEW counsel for an opinion on this question. By the end of our review, HEW counsel had not responded. If HEW counsel determines that PHS has the authority to award such community fluoridation grants, PHS plans to make about $500,000 from its operating funds available for this purpose.

In the past, as discussed below, two types of financial assistance were available: contract funds that encouraged schools to fluoridate and dental health grant funds to local governments. Neither type of funds is currently available.

School water fluoridation

Although not as effective as community water fluoridation, fluoridating a school's water system is well suited for localities that do not have a central water supply. In 1972, PHS contracted with eight States to fluoridate 85 school water systems. About $185,000 in contract funds was used as seed money to encourage the States to fluoridate additional school water systems on their own. PHS acknowledges that, although school water fluoridation is an effective technique with widespread public health applicability, as of January 1978 only 385 schools in 13 States were fluoridating. PHS' long-range plans discuss school fluoridation initiatives, but these plans have never been implemented.

According to one local public health official, the main reason that many schools are not fluoridating is that local officials are not familiar with the technique and PHS is not adequately promoting it.

Dental health grant program

During fiscal years 1965 through 1967, grant funds were made available to State and local governments to establish and maintain public health services. During these 3 years, about $2.5 million in grant funds were spent on dental health. At least 13 States used these funds to strengthen and extend their fluoridation programs. For example, Tennessee used its funds to reimburse small communities for the cost of fluoridating their water supplies, and as a result, 31 communities fluoridated. The State continued the program with its own funds after Federal funding terminated. Presently, more than 2.8 million of the 3 million Tennesseans served by central water systems are drinking fluoridated water.

In the late 1960s, this grant program was replaced by block grants that allowed States to spend funds on general public health measures, including dental health. The amount spent on dental health is not known. However, PHS officials believe that very few States have spent these funds for dental health because of its relatively low priority in relation to other public health problems. The dental health grant fund program for the mid-1960s provided needed financial assistance to communities that wanted to fluoridate. PHS officials told us that many communities, particularly small ones, cannot afford to purchase fluoridation equipment. Although the cost of equipment is not prohibitive, it can be a significant item in a small community's budget.

Forty of the forty-two States 1/ responding to our questionnaire indicated that providing financial assistance to communities that want to fluoridate would give them an incentive to do so. Similarly, 18 of the 21 cities 2/ responding to our question on financial assistance indicated that providing funds for fluoridation equipment would help local efforts.

1/Only 42 States were asked to respond to certain questions. The other eight States had passed mandatory fluoridation laws, and these questions were not applicable to them.

2/We sent questionnaires to 23 cities. One city did not respond to the questionnaire, and another did not answer the question on financial assistance.

NEED TO EDUCATE THE PUBLIC ABOUT THE BENEFITS OF FLUORIDATION

The public's knowledge of fluoridation is critical to its acceptance as a public health measure. Although fluoridation has been used to prevent tooth decay for almost 35 years and was officially sanctioned as being safe and effective by PHS in 1950, most people do not know what it is.

To determine what people knew about fluoridation, we contracted with a private polling firm (Gallup Organization) to interview a national sample of adults, 18 years of age or older. (See app. II.) The poll, taken from October 20 through 24, 1977, showed that 76 million adults--or about 51 percent of U.S. adults--do not know what fluoridation is. As many as 43 million adults believe that the purpose of fluoridation is to purify drinking water or reduce pollution. About 45 million adults served by public water systems do not even know whether the water they are drinking is fluoridated.

PHS officials acknowledged that efforts to educate the public about the benefits of fluoridation have substantially diminished in recent years.

PEOPLE OPPOSED TO FLUORIDATION CAUSE PUBLIC CONCERN

Some people oppose fluoridation because they believe it is a health hazard. (See ch. 4 for a discussion of the safety of fluoridation.) These people are in the minority, but they can influence others who are undecided about fluoridation. The Gallup Poll showed that, once people became aware of the purpose of fluoridation, most (51 percent) favored it, only a small group (10 percent) opposed it, but many (39 percent) were undecided. In contrast, a poll commissioned by PHS in 1965, when fluoridation was being actively promoted, indicated that almost 75 percent of the people favored fluoridation and only about 15 percent were undecided. The two polls indicate a shift from favoring to being undecided about fluoridation.

Convincing the undecided voter that fluoridation is a safe and effective way to reduce tooth decay is critical to its acceptance as a public health measure because in many localities the decision to fluoridate is based on a referendum vote. The undecided voter may become confused and vote against fluoridation, especially if there is strong opposition to it. Some may not even vote on the referendum question.

For example, in Los Angeles--the Nation's largest unfluoridated city--fluoridation was defeated in a 1975 referendum. The referendum was forced by a local organization that continued to strongly oppose fluoridation even after the Los Angeles City Council voted to fluoridate the city's water supplies. State and local officials said that this organization caused the referendum to be defeated by telling voters that fluoridation was not safe.

Organized opposition to fluoridation was cited as a problem by 35 of 42 State public health officials that responded to our questionnaire. Twenty-six of these officials thought it was a serious problem that hampered local fluoridation efforts. Similarly, 15 of the 20 municipal public health officials responding to our question viewed organized opposition to fluoridation as a serious problem.

CONCLUSIONS

To reduce dental caries, PHS should place greater emphasis on promoting fluoridation of community water supplies. Fluoridation has been shown to be a cost-effective way to reduce tooth decay. Yet many people do not know what fluoridation is and cannot make an informed choice. As a result, local fluoridation efforts suffer.

PHS is not sure whether present legislation allows it to provide specific financial assistance to local governments for fluoridation projects. Even if HEW counsel decides that such assistance can be provided under section 317 of the Public Health Service Act, funds would be limited because fluoridation would have to compete with many other health-related programs also eligible for funding. We believe that, because of the potential financial and health benefits that can be achieved through fluoridation projects, the Congress should consider establishing a program expressly for providing financial assistance for fluoridation projects.

RECOMMENDATIONS TO THE SECRETARY OF HEW

To promote more widespread use of fluoridation, we recommend that the Secretary of HEW require the Assistant Secretary for Health to:

--Place greater emphasis on helping State and local public health agencies to promote fluoridation.

--Determine whether PHS has now, or will have under section 317 of the Public Health Service Act, as amended, the authority to provide specific assistance to States, communities, and other authorities that want to fluoridate their water supplies and, if such authority is lacking, request that the Congress provide it.

--Increase efforts to educate the public about the decay preventive benefits of fluoridation.

RECOMMENDATION TO THE CONGRESS

Because more widespread adoption of fluoridation could reduce the incidence of caries in the population and achieve considerable savings in treatment costs, we recommend that the Congress consider establishing a program to provide financial assistance for communities that wish to fluoridate their water supplies.

COMMENTS OF NIDR AND CDC OFFICIALS

NIDR and CDC officials agreed with our recommendations to the Secretary of HEW. CDC officials are exploring legal questions about providing grants to States, communities, and other authorities that want to fluoridate their water supplies.

These officials also concurred in our recommendation to the Congress regarding financial assistance to communities that wish to fluoridate their water supplies.

CHAPTER 4

FLUORIDATION SAFETY

Fluoridation was introduced in the United States in 1945. Its effectiveness and safety have been the subject of considerable national and international scientific research. Fluoride research has been performed by a broad range of scientists, including physicians, dentists, chemists, biologists, toxicologists, epidemiologists, and pharmacologists. Scientists at NIH and other organizations have concluded that fluoridation may be the most thoroughly studied public health measure in modern history.

Numerous prestigious organizations have endorsed community water fluoridation as a safe, effective method of reducing tooth decay. These endorsements are based on scientific research and extensive experience in U.S. cities and towns and in other countries. This research and experience have shown that there is no known scientific reason for people in any community with a central water supply to be without the health and economic benefits of fluoridation. It has been endorsed by the Surgeon General and every President of the United States since 1952 as a safe and effective public health measure.

CURRENT SAFETY CONCERNS

Despite the endorsements and the extensive research that has shown fluoridation to be safe, concerns about its safety are still voiced today, principally by a few organized groups that have traditionally opposed this technique. These concerns involve natural versus artificial fluoridation and the alleged relationship between fluoridation and cancer, allergies, birth defects, toxicity, kidney disease, and bone development.

Natural versus artificial fluoridation

All U.S. water supplies contain some natural fluoride, usually at very low concentrations that will not prevent tooth decay. Some people opposed to fluoridation contend that fluoride occurring naturally in water is safe, but that artificially fluoridated water is harmful and causes various health problems. This contention is not supported by any facts.

The fluoride ion found in water is the same whether it occurs naturally or is added. Various substances are used

to fluoridate water supplies. When added to water, these substances release a fluoride ion identical to that found in naturally fluoridated water.

No evidence that fluoridation causes cancer

Many studies have been done to determine whether drinking fluoridated water may cause cancer. Although a few studies alleged that a relationship exists between drinking fluoridated water and cancer in animals, these studies have not withstood scientific analysis. For example, two of the studies, done by the same researcher, suggested that fluoride may cause cancer in rodents. These studies were independently repeated, and the findings were refuted because there was a lack of adequate control and possibly even bias.

Recently, the National Cancer Institute (NCI) reviewed selected studies dealing with the alleged relationship between fluoridation and cancer. NCI's review

--compared mortality in geographic areas with various levels of naturally fluoridated water,

--analyzed mortality trends in artifically fluoridated areas, and

--analyzed cancer occurrence statistics in artificially fluoridated areas.

NCI found no difference in cancer rates between fluoridated and nonfluoridated areas when proper adjustments were made for age, sex, and race factors. NCI concluded that "no trends in cancer rates can be ascribed to the consumption of water that is artificially or naturally fluoridated." An NCI official stated that, because of its widespread consumption, fluoride will continue to be monitored, even though NCI recognizes that low-level consumption of fluoride is necessary to human health.

In 1977, the National Academy of Sciences' National Research Council--an organization of distinguished scientists and engineers--made an independent study of the relationship between fluoride and cancer. It concluded that "the available evidence does not even suggest that fluoridation has increased the overall cancer mortality rates."

Fluoridation does not cause allergic reactions

Some opponents of fluoridation have stated that people who drink fluoridated water can have allergic reactions. Despite repeated statements by PHS that there has never been a clinically substantiated case of allergy caused by drinking fluoridated water, fluoridation opponents continue to make this claim.

To settle the issue, PHS asked the American Academy of Allergy, a professional association of physicians who treat allergies, to determine whether drinking fluoridated water causes allergic reactions. The Academy concluded that "There is no evidence of allergy or intolerance to fluorides as used in the fluoridation of community water supplies."

Fluoridation and birth defects

Some opponents of fluoridation have stated that drinking fluoridated water causes birth defects. However, research done by NIH in collaboration with scientists from the University of Minnesota concluded that there was no relationship between fluoride and birth defects.

As a result of studies published by a psychiatrist, some persons also claim that drinking fluoridated water can cause Down's Syndrome (mongolism). However, qualified epidemiologists and other researchers from NIH have charged that the studies' design and statistical procedures were so faulty that the conclusions were invalid. Also, in a followup study PHS found no association between mongolism and drinking fluoridated water. This same conclusion was reached by a British researcher in an independent study.

Some opponents contend that infant mortality increased in the United States after fluoridation was introduced. This contention is not supported by facts. The infant mortality rate (infant deaths per 1,000 live births) has continued to decline since the introduction of fluoridation in 1945. The National Institute of Child Health and Human Development compared the trend of the infant mortality rate and the trend of the population drinking fluoridated water over a 26-year period. In 1945, when controlled fluoridation began, the infant mortality rate was 38.3 per 1,000. In 1971, when nearly half the people of the United States were drinking fluoridated water, the rate was 19.2. The sharpest recent fall in the infant mortality rate occurred from 1965 to 1971, which was also a period of especially rapid growth in the adoption of fluoridation.

Fluoridation is not toxic

Like iron and several other elements in drinking water, fluoride is beneficial at low levels but undesirable at high levels. Some opponents argue that fluoride is an ingredient used in various poisons and insecticides, and that drinking fluoridated water can cause such maladies as vomiting, abdominal pain, migraine headaches, convulsions, and mental deterioration.

The Society of Toxicology, a professional association of physicians and scientists that study toxic substances, made a comprehensive review of the voluminous and steadily growing literature on the biological effects of fluoride. The review concluded that drinking optimally fluoridated water is not harmful.

Drinking fluoridated water does not damage internal organs

Some opponents of fluoridation have stated that drinking fluoridated water damages internal organs, especially the kidneys. Medical research has shown that this is not so. Studies by PHS and others, done on people who had been drinking water that is naturally high in fluoride for as long as 70 years, have shown no harm to internal organs.

Research has shown that the kidneys are not damaged, even after heavy continued high doses of fluoride. A study of two groups of children--one living in a fluoridated community, the other in a nonfluoridated community--showed that drinking fluoridated water did not harm the kidneys. A similar study done in a Texas community with a very high fluoride level (about eight times the optimum level) reached the same conclusion. Similarly, other studies have shown no differences in the incidence of kidney disease in fluoridated versus nonfluoridated cities.

The lives of people with chronic kidney failure depend on hemodialysis (treatment with an artificial kidney machine). The process requires a large amount of water (50 to 100 times more fluid than used by normal kidneys), and some fluoridation opponents have claimed that this high exposure may be harmful. But, there is no scientific evidence that optimally fluoridated water harms the kidneys or any other internal organs. In 1973, the National Kidney Foundation concluded that "* * * based on medical evidence fluoride does not harm the kidney, nor does it have any harmful effect on the patient undergoing dialysis."

Fluoridation does not harm bone development

Some fluoridation opponents have stated that drinking fluoridated water harms bone development and will cause crippling fluorosis. The relationship between the fluoride content of water and human bone structure has been studied. At optimally fluoridated levels, no harmful effects have been found. On the contrary, there is evidence that, at higher concentrations, fluoride helps prevent osteoporosis (weakening of the bone structure) and arteriosclerosis (hardening of the arteries). This evidence has stimulated further research into the possibility that fluoride may be useful in treating these two common diseases of aging. In one study, the residents of a community whose water has a naturally high fluoride level were examined for possible skeletal disease. No evidence associating fluoride with arthritis or other problems was noted, and less osteoporosis was seen than in a comparable low fluoride community.

ORGANIZATIONS ENDORSING FLUORIDATION

Fluoridation has been endorsed as a safe, effective method of reducing tooth decay by numerous health organizations, including the American Medical Association, the U.N. World Health Organization, and PHS. The National Academy of Sciences also endorsed fluoridation as being safe and effective. The Academy's National Research Council recently completed a study which concluded that fluoridation is safe and that no one has ever been harmed by drinking optimally fluoridated water. The Council's study did recommend that additional studies be done to clarify and follow up on the observations of earlier studies. For example, the Council suggested updating a few epidemiological studies of fluoridated cities and periodically monitoring total fluoride intake. (For a more complete list of organizations endorsing fluoridation, see app. III.)

CONCLUSIONS

Numerous prestigious scientific organizations have endorsed fluoridation as a safe, effective method for preventing tooth decay. These endorsements are based on extensive community experience and worldwide research. Nevertheless, opponents of fluoridation continue to raise questions about its safety. The questions raised cause public concern, which in turn hinders local fluoridation efforts.

CHAPTER 5

IMPROVED FEDERAL COORDINATION COULD ADVANCE FLUORIDATION

PHS is the principal Federal agency involved in promoting fluoridation, but other agencies can play an important role as well. HUD and EPA administer programs that can encourage local communities to fluoridate. HUD provides grant funds to help cities and towns develop decent housing and a suitable living environment. Under certain circumstances, some of these funds can be used to help communities fluoridate as part of a plan for improving water system facilities. EPA's responsibilities include administering the Safe Drinking Water Act (Public Law 93-523). The Department of Agriculture Extension Service supplies health education information through its various programs and could disseminate information on fluoridation. Improved coordination between PHS, HUD, EPA, and the Department of Agriculture could advance fluoridation.

HUD CAN DO MORE TO ADVANCE FLUORIDATION

Title I of the Housing and Community Development Act of 1974 provides Community Development Block Grants to local communities to help them develop decent housing and a suitable living environment. Funds for water system improvements can be included in the grants.

Communities normally do not include fluoridation equipment costs in proposals submitted to HUD, possibly because they are not aware that these costs are eligible. Several local and regional HUD officials were not sure that fluoridation equipment costs could be covered under the act.

Many communities cannot afford to fluoridate. In Massachusetts, for example, 17 cities and towns that had met local requirements to fluoridate their water supplies had not done so because of funding problems. Seven of these communities had received HUD grants for water-related projects. Local officials from these seven communities said they were not aware that HUD funds were available to purchase fluoridation equipment, and had they known, they would have included the equipment cost in their proposals. Several indicated that the availability of Community Development Block Grant funding for this purpose provided an incentive to fluoridate. According to one official, for the past 5 years he had tried unsuccessfully to obtain funds through his community for

fluoridation equipment. Had he known HUD funds were available, he would have included fluoridation equipment costs in a grant application recently submitted by the town.

Officials at HUD's central office confirmed that, if a community meets certain criteria, it can obtain Community Development Block Grants for improving its water system, which may allow some funds to be used for fluoridation. However, a community must include in its application a request for funds for fluoridation, and the request must be part of an application for a water system or water treatment facility.

EPA CAN DO MORE TO ADVANCE FLUORIDATION

EPA could help PHS fluoridation efforts by contributing toward removal of unintended barriers that discourage communities that may want to fluoridate. The language of the Safe Drinking Water Act has been misinterpreted by some to prohibit fluoridation, and the regulations implementing the act are misleading because fluoridation's dental health benefits are not prominently stated.

The Safe Drinking Water Act appears to prohibit fluoridation

The Safe Drinking Water Act includes specific language designed to make it clear that local communities are not required by Federal law to fluoridate their water supplies. Section 1412b(6) of the act states that:

> "No national primary drinking water regulation may require the addition of any substance for preventive health care purposes unrelated to contamination of drinking water." (Underscoring supplied.)

According to EPA, this section means that EPA cannot require local authorities to add substances to water supplies for preventive health purposes only (e.g., fluoride to prevent tooth decay). EPA has stated that the Congress intended section 1412b(6) to neither require nor prohibit the addition of preventive health substances to drinking water. House Report Number 93-1185, which is a legislative history of the Safe Drinking Water Act, specifically states that EPA cannot prohibit the addition of fluoride to drinking water up to the amount allowed under a maximum contaminant level. But because the act does not specifically state that there

is no prohibition against adding fluoride to the drinking water, some people are misinterpreting section 1412b(6) and it is having serious effects.

For example, people opposed to fluoridation have placed advertisements in newspapers claiming that, under the act, fluoride cannot legally be added to a water supply. Such an advertisement in a Boston paper contributed to the delay in fluoridating 32 greater Boston communities. The group placing the ad also retained an attorney, who formally requested EPA to stop the fluoridation project because it violated section 1412 of the act. In addition, opponents of fluoridation have distributed national newsletters and initiated letter writing campaigns to EPA and Members of Congress claiming a violation of the act.

In 1977, Florida passed a law based on the Federal law which states, in part, that "no State primary drinking water regulation may require the addition of any substance for preventive health care purposes unrelated to contamination of drinking water." Florida officials we contacted have been trying to get legislation passed that will encourage fluoridation statewide. They believe the recently passed law reduces their chances of getting such legislation passed.

In December 1977, an official of the Institute of Dental Research in Prague, Czechoslovakia, wrote to the PHS Chief Dental Officer, explaining that anti-fluoridationists, whom he identified as scientists of some standing, declared that fluoridation was banned by U.S. law. This official asked for an explanation of the act and the American Government's official policy on fluoridation. PHS responded that the act is not to be used to require or prohibit the addition of fluoride to drinking water for prevention of tooth decay. The response noted that PHS continues to place a high priority on disease prevention, including use of water fluoridation.

EPA regulations discourage fluoridation

PHS officials are concerned that regulations implementing the Safe Drinking Water Act can be misinterpreted and discourage fluoridation. The regulations could also encourage waterworks officials to add less than the recommended amount of fluoride to the water just to be sure they do not add too much. Thus, they believe the regulations could cause a public health problem--increased tooth decay.

Section 141 of the regulations lists specific contamination levels for chemicals found in water. Fluoride is

included as a contaminant, which implies that it is harmful at any level. This section of the regulation is not annotated to delineate the fluoride level in water which is considered optimal and which will reduce tooth decay by 65 percent when consumed from early childhood. Moreover, the regulations do not acknowledge that EPA has publicly endorsed fluoridation.

Although optimal fluoridation and its benefits are discussed in the appendix to the regulations, HEW officials do not believe this is adequate. In commenting on this regulation, the Surgeon General stated that:

> "It is, indeed, unfortunate that fluoride-along with other substances found in water-is listed as a 'contaminant' in the National Interim Primary Drinking Water Regulations. Those opposed to the fluoridation of community water supplies and others who do not have a clear understanding of it may assume incorrectly that the inclusion of fluoride at excessive levels in a list of possible drinking water contaminants means that all fluoride is undesirable. Such certainly is not the case. Research and practical experience over several decades have provided convincing evidence of the safety and effectiveness of water fluoridation as a measure for preventing dental caries.
>
> "The Public Health Service has endorsed this measure for more than a quarter of a century and will continue to place high priority on its wide application."

One local official reported to us that he had recently spoken as an expert witness at a town meeting after the community had defeated an appropriation request for fluoridation equipment. He noted that persons attending were confused and misinformed about fluoridation. Questions he was asked included:

--If fluoridation is so good, why does EPA define fluoride as a contaminant?

--Didn't EPA set a maximum level for fluoridation because water personnel add too much fluoride to the water?

--Aren't we taking a risk with fluoridation at the recommended level for reducing tooth decay when only twice that level can be dangerous like arsenic as defined by EPA?

According to EPA officials, they traditionally have not stated in their regulations that a contaminant is beneficial at low levels. However, in carrying out their responsibilities under the Safe Drinking Water Act, they do not want to harm the fluoridation promotion efforts of others. The officials agreed to clarify section 141 of the regulations by including a statement that, at optimum levels, fluoride will substantially reduce tooth decay without harming human health and that EPA has publicly endorsed fluoridation.

THE DEPARTMENT OF AGRICULTURE EXTENSION SERVICE COULD HELP EDUCATE THE PUBLIC ABOUT FLUORIDATION

As discussed in chapter 3, the public needs to be educated about the benefits of fluoridation. The Department of Agriculture Extension Service could help. Other organizations receiving Federal support may also be available to help provide information on the benefits and safety of caries preventive techniques such as fluoridation.

The Department of Agriculture Extension Service, funded jointly by the Federal Government and the States, serves as a focal point for distribution of information through its various programs. It sponsors health education workshops, including promotion of dental health. It also provides advisory support to State and local education organizations, such as the National Extension Homemakers clubs, a voluntary community education organization.

The Extension Service supported fluoridation in the past, issuing publications providing facts on fluoride programs. However, there has not been an active liaison or continuing exchange between the Extension Service and PHS. At our suggestion, PHS officials contacted the president of the National Extension Homemakers Association during 1977 and early 1978. PHS provided them with information to be disseminated to their members. However, PHS officials informed us that staff limitations have precluded effective continued coordination with this organization.

CONCLUSIONS

Community Development Block Grant funds available under title I of the Housing and Community Development Act can be used for water system improvements. Some of the funds from such grants may be used to purchase fluoridation equipment. Regional HUD officials and community officials applying for water system improvement grants should be informed that fluoridation equipment costs can be paid from Community Development Block Grant proceeds and should be advised of the circumstances under which this is allowed.

EPA officials have agreed to clarify the language of the regulations implementing the Safe Drinking Water Act to help remove barriers that discourage fluoridation.

PHS should seek out other organizations that can help educate the public about the benefits of fluoridation and continue its coordination with the Department of Agriculture Extension Service to develop a public information strategy.

RECOMMENDATIONS TO AGENCY OFFICIALS

To eliminate existing confusion about whether HUD's grants for development may include purchase of fluoridation equipment, we recommend that the Secretary of HUD instruct regional officials to notify States and communities that the cost of fluoridation equipment may be included in title I water system improvement grants.

To improve public awareness of tooth decay prevention techniques, we recommend that the Secretary of HEW require the Assistant Secretary for Health to seek out organizations that can help educate the public about the benefits of fluoridation.

RECOMMENDATION TO THE CONGRESS

To bring the language of the Safe Drinking Water Act into closer conformance with the stated congressional intent and to minimize the misinterpretation, we recommend that section 1412b(6) be amended to read:

> "No national primary drinking water regulation may require <u>or prohibit</u> the addition of any substance for preventive health purposes unrelated to contamination of drinking water." (Underscoring designates new language.)

AGENCY COMMENTS AND OUR EVALUATION

In its comments on a draft of this report (see app. IV), HUD agreed with our recommendation to the Secretary and said that it will advise its field staff that fluoridation is an eligible activity under the Community Development Block Grant program. However, HUD noted that informing applicants that fluoridation of community water systems is eligible for funding under this program must be done with caution, because it might be misinterpreted as an attempt by HUD to urge communities to fluoridate their water systems, and because funds will be approved for fluoridation only under certain circumstances. Although we agree with HUD that attempts should be made to avoid misinterpretations, we believe that communities should be made aware that fluoridation is an eligible activity under the Community Development Block Grant Program so they can make informed decisions when applying for grant funds.

NIDR and CDC officials agreed with our recommendation to the Secretary of HEW. They said they have initiated a program which includes coordination with HUD, EPA, the Department of Agriculture, and other Federal agencies to insure that States and communities are aware of the various funds available to them.

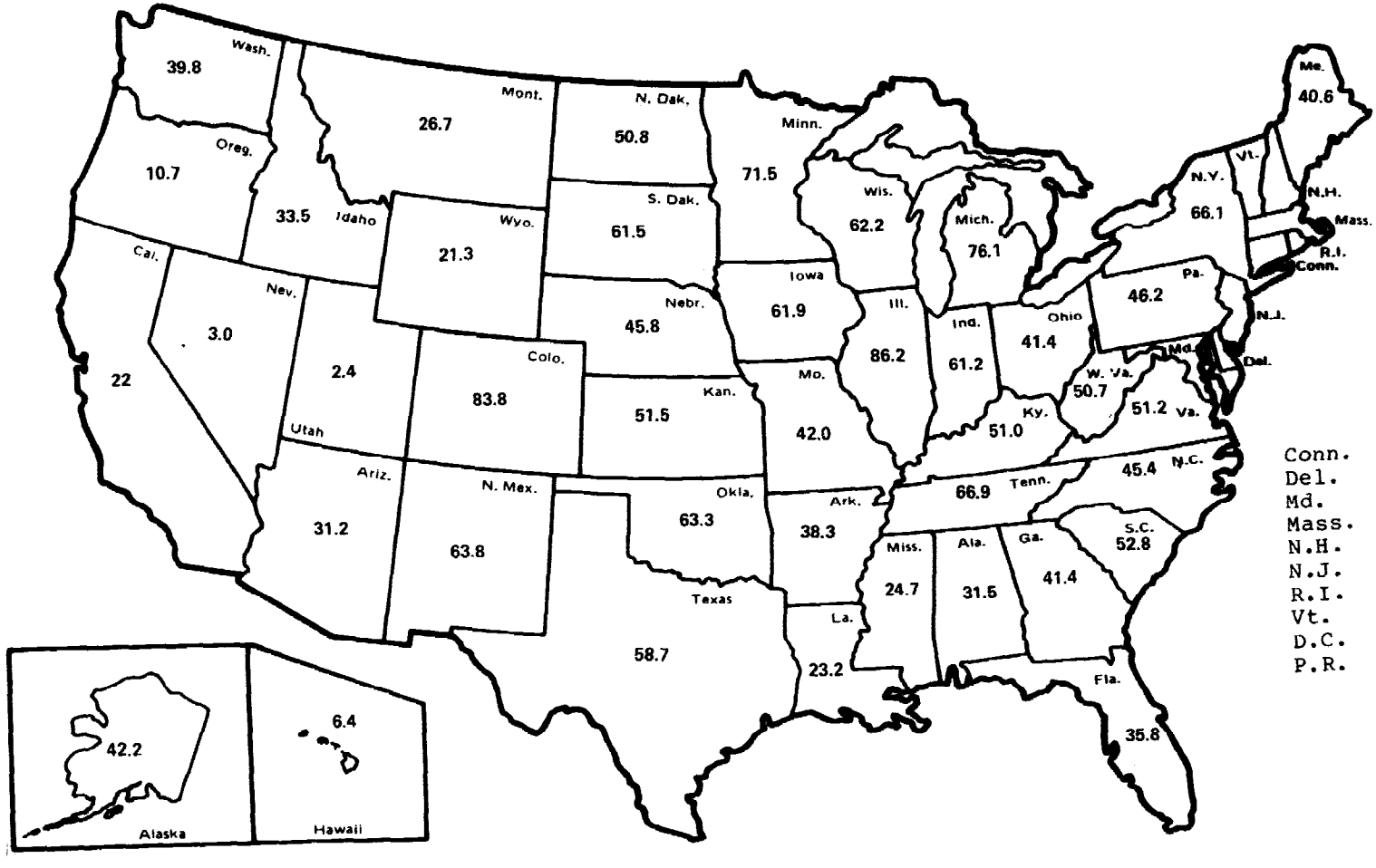
According to CDC officials, section 1412b(6) of the Safe Drinking Water Act was added specifically because of the efforts of those opposed to fluoridation. The officials believed the provision has been misused by fluoridation opponents and misinterpreted by some in EPA as a prohibition against fluoridation. They therefore believed that section 1412b(6) should be deleted.

EPA (see app. V) agreed with our recommendation to the Congress, stating that it is also going to incorporate an amplifying statement on the benefits of fluoride in its National Interim Primary Drinking Water Regulations.

PERCENTAGE OF POPULATION USING

NATURAL OR ADJUSTED FLUORIDATED

WATER BY STATE AS OF DECEMBER 31, 1975



Conn.	79.4
Del.	39.5
Md.	68.1
Mass.	a/51.3
N.H.	13.3
N.J.	21.4
R.I.	66.3
Vt.	37.0
D.C.	98.4
P.R.	81.4

a/Adjusted to reflect the fluoridation of the city of Boston in 1978.

APPENDIX I

APPENDIX II

A SURVEY CONCERNING

WATER FLUORIDATION

Conducted For:

U.S. GENERAL ACCOUNTING OFFICE

THE GALLUP OMNIBUS

A Service of:

THE GALLUP ORGANIZATION, INC.

53 Bank Street

Princeton, New Jersey 08540

November 1977

GO 77139

APPENDIX II

INTRODUCTION

Objectives of the Study

This is a report on a study undertaken to assess the public's knowledge of and attitudes toward water fluoridation. More specifically the objectives included:

1. *A measurement of the public's perception of the purpose for public water fluoridation;*
2. *Finding out how many of those interviewed are served by a public water system which is fluoridated and among those not served by such a system whether the nearest public water system is fluoridated or not;*
3. *Measuring the public's attitudes toward the desirability of public water fluoridation.*

Design of the Research

The findings are based on personal interviews conducted with a national sample of 1517 adults, 18 years of age and older during the period of October 20 - 24, 1977. The following questions were asked:

1. *As you understand it, which one of the items on this card best describes the purpose of public water fluoridation?*

   The card shown read:

   To reduce pollution
   To improve the taste of water
   To reduce tooth decay
   To purify water
   Don't know

Those who did not answer "To Reduce Tooth Decay" to Question 1 were read the following statement:

Fluoridation is the adjustment of the fluoride level of water for the purpose of reducing tooth decay.

APPENDIX II

All persons were asked:

2. *Which of the answers on this card best describes the water supply situation where you live?*

The card shown read:

I'm served by a public water system and:

It is fluoridated
It is not fluoridated
I don't know if it is fluoridated

I'm not served by a public water system but the nearest such system to my residence:

Is fluoridated
Is not fluoridated
I don't know if it is fluoridated

3. *Which one of the answers on this card describes how you feel about public water fluoridation?*

The card shown read:

Very desirable
Desirable
Don't care one way or the other
Undesirable
Very undesirable
I need more information to make a decision.

Interviews were made in advance of the survey with a small sample in order to test the questions.*

Information about the design and composition of the sample and tables of sampling tolerances to have in mind when reading the report will be found in the Technical Appendices at the end of the report.

*The questions pre-tested will be found in the appendices.

APPENDIX II

THE FINDINGS

Awareness of Purpose of Water Fluoridation

The question: *"As you understand it, which one of the items on this card best describes the purpose of public water fluoridation?"*

The card shown read:

To reduce pollution
To improve the taste of water
To reduce tooth decay
To purify water
I really don't know

About half (49%) of all persons interviewed chose the answer "To reduce tooth decay". The proportions of the entire sample selecting each answer were as follows:

	Per Cent
To reduce tooth decay	49
To purify water	23
To reduce pollution	6
To improve the taste of water	4
I really don't know	18
	100
Number of Interviews	1517

The results were tabulated by demographic groups which revealed the following:

1. There was no significant difference between the proportion of men and women who answered "To reduce tooth decay".

2. There were large differences by annual family income -- the proportions answering "To reduce tooth decay" were:

	Per Cent
$20,000 or more	67
$15,000 - $19,999	55
$10,000 - $14,999	48
$5,000 - $9,999	36
Under $5,000	28

APPENDIX II

3. There were major differences according to educational attainment. Among those who had attended college, 70 percent chose "To reduce tooth decay"; among those with a high school education 46 percent selected this answer, and only 19 percent of those with a grammar school education gave the correct answer.

4. Differences by age groups showed that more of those in the middle years, 30 - 49 years, than of either younger or older people know the purpose of water fluoridation. The percentages were:

	Per Cent
18 - 29 years	46
30 - 49 years	59
50 years and older	43

5. Differences by size of community in the proportions answering "To reduce tooth decay" were not large.

6. More (66%) of those in the Western region of the country than of those in other regions said that water fluoridation is to reduce tooth decay. The proportions in other regions were: 46 percent in the East, 47 percent in the Midwest, and 44 percent in the South.

7. In households where there were children, 53 percent answered "To reduce tooth decay" while in households without children 45 percent gave this answer.

APPENDIX II

Knowledge About Fluoridation of Public Water Supply

In order to find out to what extent the public knows that the public water system is fluoridated in the area where they live, the following question was asked:

"Which of the answers on this card best describes the water supply situation where you live? Just read off the letter of the statement which applies to you."

The card shown read:

I'm served by a public water system and:

A It is fluoridated.
B It is not fluoridated.
C I don't know if it is fluoridated.

I'm not served by a public water system but the nearest such system to my residence:

D Is fluoridated.
E Is not fluoridated.
F I don't know if it is fluoridated.

Before being asked the above question all persons who did not answer "To reduce tooth decay" in the previous question were told:

"Fluoridation is the adjustment of the fluoride level of water for the purpose of reducing tooth decay."

Replies to the question divided as follows revealing that approximately one-third of those interviewed do not know whether or not the water supply in their area is fluoridated.

	Per Cent
I'm served by a public water system and:	
A It is fluoridated.	34
B It is not fluoridated.	14
C I don't know if it is fluoridated.	30
Total served by a public water system	78
I'm not served by a public water system but the nearest such system to my residence:	
D Is fluoridated.	3
E Is not fluoridated.	11
F I don't know if it is fluoridated.	5
Total not served by a public water system	19
Do not know water supply situation	2
Total	99*
Number of Interviews	1517

*Total is 99% due to rounding of percentages. Actual total is 100%.

APPENDIX II

Combining the results for both areas served and not served by a public water supply the results are as follows:

	Per Cent
A plus D Water is fluoridated	37
B plus E Water is not fluoridated	25
C plus F Don't know if water is fluoridated	35
Do not know water supply situation	2
Total	99

Analyses of the results by population groups show that people living in the large cities, those of 100,000 or more, are less well informed about whether their water is fluoridated than those in smaller communities. Differences by sex were small. Knowledge about fluoridation of the water supply was greater among those who had attended college than among those who had not. In areas served by a public water supply system younger people (under 30 years) were somewhat less well informed about fluoridation of the water supply than older people. There was little difference between those with and without children in the home. The proportion of those interviewed who said their public water system is not fluoridated was greater in the West than in other regions of the country.

The results of this question were cross-tabulated against answers to the first question (knowledge of the purpose of fluoridation). This shows more of those who know that the purpose of water fluoridation is to reduce tooth decay, than of other people, know about the water fluoridation situation where they live.

APPENDIX II

Attitudes Toward Public Water Fluoridation

Among those with opinions about public water fluoridation, fluoridation of the public water supply system is thought to be desirable by about five times as many people as think it is undesirable. The question and national results are as follows:

"Which one of the answers on this card describes how you feel about public water fluoridation?"

The card shown read:

Very desirable
Desirable
Don't care one way or the other
Undesirable
Very undesirable
I need more information to make a decision.

The national results were:

	Per Cent
Very desirable plus desirable	51
Very desirable	18
Desirable	33
Don't care one way or the other	12
Undesirable plus very undesirable	10
Undesirable	6
Very undesirable	4
I need more information to make a decision.	24
Can't Say	4
Total	101*

*Adds to 101% due to rounding of percentages. Actual total is 100%.

APPENDIX II

Tabulations of the results by population groups show that people with the largest family incomes and those with the most formal education favor fluoridation more than those with smaller incomes and less formal education. Opposition to fluoridation is somewhat greater in rural areas than in the nation's cities. More of those in households with children than of those in households where no children are present think fluoridation is desirable. Differences by sex were small. Attitudes of older people (over 50 years) were somewhat less favorable than those of younger adults.

In areas served by a public water system, more of those who had reported that their system is fluoridated than of those who said their water system is not fluoridated think that fluoridation is desirable.

APPENDIX III

NATIONAL AND INTERNATIONAL ORGANIZATIONS

THAT HAVE ENDORSED FLUORIDATION

American Academy of Dental Medicine
American Academy of Pediatrics
American Association for the Advancement of Science
American Association of Dental Schools
American Association of Industrial Dentists
American Association of Public Health Dentists
American College of Dentists
American Commission on Community Health Services
American Dental Association
American Dental Hygienists Association
American Federation of Labor and Congress of Industrial Organizations
American Heart Association
American Hospital Association
American Institute of Nutrition
American Legion
American Medical Association
American Nurses Association
American Osteopathic Association
American Pharmaceutical Association
American Public Health Association
American Public Welfare Association
American School Health Association
American Society of Dentistry for Children
American Veterinary Medical Association
American Water Works Association
Association of Public Health Veterinarians
Association of State and Territorial Dental Directors
Association of State and Territorial Health Officers
Canadian Dental Association
Canadian Medical Association
Canadian Public Health Association
College of American Pathologists
Commission on Chronic Illness
Environmental Protection Agency
Federation Dentaire Internationale
Federation of American Societies for Experimental Biology
Great Britain Ministry of Health
Health Insurance Association of America
Health League of Canada
Inter-Association Committee on Health
International Dental Federation
Mayo Clinic

National Congress of Parents and Teachers
National Education Association
National Institute of Municipal Law Officers
National Nutrition Consortium
National Research Council
Office of Civil Defense
Pan American Health Organization
Royal College of Physicians (London)
Society of Toxicology
U.S. Department of Agriculture
U.S. Department of Defense
U.S. Department of Health, Education, and Welfare
U.S. Jaycees
World Health Organization

APPENDIX IV

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT
WASHINGTON, D.C. 20410

December 6, 1978

OFFICE OF THE ASSISTANT SECRETARY
FOR COMMUNITY PLANNING AND DEVELOPMENT

IN REPLY REFER TO:

Mr. Henry Eschwege
Director, Community and Economic
Development Division
United States General Accounting Office
Washington, D. C. 20548

Dear Mr. Eschwege:

We have completed our review of the draft GAO report (GAO)CPD-486: "Research Efforts to Prevent Tooth Decay Should be Balanced with More Emphasis on a Proven Technique - Fluoridation," and wish to offer the following comments about the issues raised regarding the use of Community Development Block Grant Funds to undertake fluoridation of community water systems.

Generally, we are in agreement with the comments made in this report regarding the need to make communities aware that fluoridation installations may be eligible to receive Community Development Block Grant (CDBG) funds. However, it should be noted that certain limitations apply to the receipt of funds for this purpose.

First, cities desiring to make application for CDBG funds for fluoridation equipment must include this as part of an application for a water system or water treatment facility. Applications which request funds solely for fluoridation of water systems would not likely be able to meet the program requirements and would thus be ineligible.

Secondly, consistent with the requirements of the Housing and Community Development Act of 1974, all activities funded with CDBG funds, including water treatment facilities, must either principally benefit low- and moderate-income persons, eliminate slums or blight or meet a community need having a particular urgency.

Moreover, it should be kept in mind that while HUD can provide information on the availability of CDBG funds for fluoridating community water supplies, the final decision regarding the submission of requests for projects to receive Block Grant funds is left up to the citizens and local officials of a community.

APPENDIX IV

Finally, with respect to the suggestion that we inform our applicants that fluoridation of community water systems is eligible for CDBG funding, we feel that such a notification procedure could prove inappropriate if caution is not exercized, since it might very easily be interpreted as an attempt by HUD to urge communities to fluoridate their water systems, and also because while fluoridation may be an eligible activity, it will not be considered an approvable activity unless it meets all applicable CDBG program requirements. However, we will advise our field staff that fluoridation is an approvable activity under the CDBG program as long as other applicable program requirements are met.

We appreciate the opportunity to comment upon this report.

Sincerely,

Robert C. Embry, Jr.
Assistant Secretary

APPENDIX V

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

JAN 8 1979

OFFICE OF
PLANNING AND MANAGEMENT

Honorable Henry Eschwege
Director, Community & Economic
Development Division
United States General Accounting Office
Washington, D.C. 20548

Dear Mr. Eschwege:

The Environmental Protection Agency (EPA) has reviewed the General Accounting Office (GAO) draft report entitled "Research Efforts To Prevent Tooth Decay Should Be Balanced With More Emphasis On A Proven Technique - Fluoridation," and have the following comments on GAO's recommendation to Congress.

Recommendation to the Congress

In order to bring the language of section 1412b(6) of the Safe Drinking Water Act into closer conformance with the stated congressional intent, and to reduce the misinterpretation that has been occurring, we recommend that section 1412b(6) be amended to read:

> "No national primary drinking water regulation may require or prohibit the addition of any substance for preventive health purposes unrelated to contamination of drinking water." (underscoring designates new language)

We agree with this recommendation. EPA is also going to incorporate an amplifying statement on the benefits of flouride in the National Interim Primary Drinking Water Regulations.

APPENDIX V

We appreciate the opportunity to comment on the report prior to its submission to Congress.

Sincerely yours,

for William Drayton, Jr.
Assistant Administrator for
Planning and Management

(10385)

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