IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

NATURAL RESOURCES DEFENSE COUNCIL, INC., Petitioner, v. ENVIRONMENTAL PROTECTION AGENCY, and LEE M. THOMAS, ADMINISTRATOR, Respondents.	Civ. No. 85-1839
consolidated with	
SOUTH CAROLINA DEPARTMENT OF HEALTH AND ENVIRONMENTAL CONTROL, Petitioner, v. ENVIRONMENTAL PROTECTION AGENCY, Respondent.	Civ. No. 85-1854

CERTIFICATE REQUIRED BY RULE 8(e) OF THE GENERAL RULES OF THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

The undersigned, counsel of record for the Petitioner, certifies that the following organizations have an interest in the outcome of this case:

Petitioners:	Natural Resources Defense Council South Carolina Department of Health and Environmental Control
Respondent:	Environmental Protection Agency and Lee M. Thomas, Administrator

There are no intervenors in either case.

These representations are made in order that the judges of this Court, inter alia, may evaluate possible disqualification or recusal.

Respectfully submitted,

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MISCELLANEOUS AUTHORITIES

JURISDICTION

The jurisdiction of this Court is based upon §1448(a) of the Safe Drinking Water Act ("SDWA"), 42 U.S.C. §300j-7.

ISSUES PRESENTED FOR REVIEW

Whether the Environmental Protection Agency's promulgation of a Recommended Maximum Contaminant Level ("RMCL") for fluoride at double the level that has been considered safe for almost 25 years violated the mandate of the Safe Drinking Water Act to set the RMCL at a level at which no known or anticipated adverse health effects occur, insofar as:

1. The RMCL for fluoride is established at a level at which exposure is known and anticipated to cause serious adverse effects on health; and

2. The basis for the RMCL excludes all adverse effects evidence that does not demonstrate impairment of bodily function in humans or otherwise conclusively prove harm to human health.

PREVIOUS CONSIDERATION BY THIS COURT

This case has not previously been before this Court or any other court although a petition for review of EPA's interim primary drinking water regulations under the Safe Drinking Water Act, including fluoride, was decided by this Court in Environmental Defense Fund, Inc. v. Costle, 188 U.S. App. D.C. 95, 578 F.2d 337 (1978). Petition for review of a separate but related drinking water regulation that is based upon the regulation being challenged in this case, is expected to be filed in this Court within 30 days.

REFERENCES TO PARTIES AND RULINGS

The parties in this case are the Natural Resources Defense Council ("NRDC"), the Environmental Protection Agency ("EPA"), Lee Thomas, the Administrator of the EPA, and the State of South Carolina Department of Public Health and Environmental Control. The regulation at issue was published at 50 Fed. Reg. 47142-47155 (Nov. 14, 1985).

STATUTE INVOLVED

The statutory provisions involved are sections 1401 and 1412 of the federal Safe Drinking Water Act, 42 U.S.C. §§300f and 300g-1. They are set forth in Attachment A of this brief.

STATEMENT OF THE CASE

I. Framework of the Safe Drinking Water Act

The Safe Drinking Water Act, enacted in 1974, is a public health protection statute intended to prevent harm from contaminants in public drinking water supplies. The legislation has an "essentially preventive purpose;"[1] it embodies Congress' "overriding intent to maximize protection of the public health."[2] To achieve this precautionary objective, the Administrator of EPA is required "to prescribe national primary drinking water regulations for contaminants which may adversely affect the public health."[3] All public water suppliers serving at least twenty-five individuals must comply with the primary regulations.[4]

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1 H.R. Rep. No. 93-1185, 93d Cong., 2d Sess. 10 (1974) [hereinafter cited as "House Report"], App.

2 House Report at 12.

3 House Report at 1, App.

[Cont. next pg.]

Congress directed that National Primary Drinking Water Regulations be promulgated in two separate stages. "Interim" Primary Regulations were required to be promulgated within 180 days after passage of the Act.[5] The interim Primary Regulations were to become effective no less than 18 months after promulgation, and were intended to remain in effect until specifically superseded by the second stage of implementation, which is promulgation of more comprehensive "revised" Primary Regulations.[6]

The interim Primary Regulations were to be promulgated expeditiously in 1975 to provide some minimum degree of protection against exposure to drinking water contamination, and were, by Congressional direction, to be "based largely on a review and updating of the [1962] USPHS [United States Public Health Service] drinking water standards."[7] By contrast, the revised National Primary Drinking Water Regulations were to be developed in a lengthier, more deliberate process. First, EPA must establish nonenforceable, health-based drinking water goals called Recommended Maximum Contaminant Levels (RMCLs). RMCLs are to be set "at a level at which...no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety."[8] Second, EPA must promulgate enforceable Maximum Contaminant Levels (MCLs), which are required

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4 §1401(4), 42 U.S.C. §300f(4).

5 §1412(a)(1), 42 U.S.C. §300g-1(a)(1).

6 §1412(b), 42 U.S.C. §300g-1(b).

7 House Report at 17, App.

8 §1412(b)(1)(B), 42 U.S.C. §300g-1(b)(1)(B).

to be set as close to the RMCL goals as is technologically feasible. The revised regulations were thus intended to provide more health protection than the temporary interim standards.[9] This case involves one of the first RMCLs established by EPA under the Safe Drinking Water Act.

II. History of Fluoride Regulation under the Safe Drinking Water Act

A. Fluoride in Drinking Water

Fluoride occurs naturally at low levels in many drinking water supplies.[10] It enters groundwater primarily from dissolved rock and minerals, and enters surface waters from soil runoff, industrial discharges, and the settling of particles containing fluoride from the atmosphere.[11] Fluoride occurs at high levels in groundwater and surface waters in many areas of the United States.[12] Drinking water fluoride levels in these areas sometimes exceed 8.0 milligrams per liter (mg/L).[13]

Although fluoride is most familiar for its cavities-reducing

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9 The Act also provides for the establishment of nonenforceable secondary drinking water regulations for contaminants "(A) which may adversely affect the odor or appearance of such water and consequently may cause a substantial number of persons served by the public water system providing such water to discontinue its use, or (B) which may otherwise adversely affect the public welfare." These secondary standards are not intended to prevent adverse health effects, whether physically debilitating or "cosmetic;" they are intended to be advisory standards for contaminants which may make water aesthetically displeasing. See 42 U.S.C. §§300g-1(c) and 300f(2), and S. Rep. No. 93-231, 93rd Cong., 2nd Sess. 7-8 (1973).

10 EPA, Criteria and Standards Division, Occurrence of Fluoride in Drinking Water, Food and Air (hereinafter cited as "EPA Occurrence Document"), at 9, App.

11 Id. at 18, App.

12 See map of fluoride content in groundwater, Att. B.

13 EPA Occurrence Document at 43.

effects,[14] it can also harm the human body. The record in this case shows that ingestion of fluoride at low levels can result in dental fluorosis, a condition that disfigures teeth with brown to almost black stains, severe pitting, and deformation (see photographs at Att. C.);[15] in skeletal fluorosis, which in its most severe form produces crippling bone disfigurement;[16] and, possibly, in several other adverse health effects, such as cancer, mutagenicity, teratogenicity, enzyme inhibition, decreased reproductive rates, growth stunting, renal effects and cardiovascular damage.[17]

The levels at which many communities fluoridate, 0.7 to 1.2 mg/L, is the so-called "optimum" drinking water concentration, defined by EPA as "a balance between the prevention of both dental caries and objectionable fluorosis."[18] The optimum value for a particular locality varies according to the annual average maximum temperature. As temperatures and therefore drinking water consumption increase, the optimum level decreases.

The incidence of adverse effects increases substantially as the fluoride concentration is raised. EPA's tabulation of re-

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14 Many communities in the United States add small supplemental amounts of sodium fluoride to their drinking water supplies because evidence suggests that fluoride at levels between 0.7 mg/L and 1.4 mg/L reduces cavities. EPA, Drinking Water Criteria Document on Fluoride, Oct. 21, 1985, p. I-3, VI-1 (hereinafter cited as "Criteria Doc.").

15 National Primary Drinking Water Regulations; Fluoride, 50 Fed. Reg. 20164, 20169, col. 1 (May 14, 1985) (hereinafter cited as "Proposed Fluoride RMCL"), App.

16 Id. at 20170, cols. 2-3, App.

17 National Primary Drinking Water Regulations; Fluoride, 50 Fed. Reg. 47142, 47150-53 (Nov. 14, 1985) (hereinafter cited as "Final Fluoride RMCL"), App.

18 Proposed Fluoride RMCL at 20165, col. 3, App.

sults of fluoride exposure studies show staining and pitting from dental fluorosis in up to 2.4% of populations drinking water with fluoride concentrations in the optimum range; in 26.8% to 31.6% of populations drinking water with approximately 3.0 mg/L fluoride; and in 35.6% to 44.0% of populations drinking water with concentrations of 4.0 mg/L.[19]

The record also shows a risk of crippling skeletal fluorosis at low fluoride drinking water levels. Cases of crippling skeletal fluorosis have been documented in the United States at drinking water concentrations below 4 mg/L.[20] The Agency's findings predict that more than 1% of populations drinking water with fluoride concentrations of 4.0 mg/L will develop this disabling condition.[21]

B. Interim Fluoride Regulation

The federal government first acted to protect the public from the adverse health effects of fluoride in 1946 in the Public Health Service Guidelines, which set an upper limit of 1.5 ppm[22] for fluoride in drinking water to protect against dental fluorosis.[23] When the Public Health Service Drinking Water Standards were revised in 1962, they listed fluoride as an impurity "which may have deleterious physiological effects, or for which physio-

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19 Id. at 20169, cols. 2 and 3, Table 8, App.

20 Final Fluoride RMCL, at 47144, col. 3, App. ; see n. 78, infra.

21 See discussion in Section II.C.2.b., pp. 32-36, infra.

22 Parts per million (ppm) are approximately equivalent to mg/L.

23 See Ad Hoc Committee Report on Dental Fluorosis, Draft Report to the Chief Dental Officer, United States Public Health Service, July 21, 1982, p. 1, CI at I-D.82 (hereinafter cited as "Draft Medical Panel Report").

logical effects are not known."[24] These Standards stated that the "[p]resence of fluoride in average concentrations greater than two times the optimum values [0.9-1.2 mg/L]...shall constitute grounds for rejection of the supply."[25] The revised Public Health Service Standards also varied according to annual average maximum temperatures.

As noted above, the SDWA, enacted in 1974, required the Administrator of EPA to establish interim Primary Regulations for contaminants "which may adversely affect the public health" within 180 days after passage of the Act. EPA promulgated these enforceable interim standards, called Maximum Contaminant Levels (MCLs), in 1975. As Congress directed, EPA based the interim MCLs largely on the 1962 Public Health Service Drinking Water Standards.[26] The allowable level for fluoride was set according to a temperature-dependent scale ranging from 1.4 to 2.4 mg/L, or at twice the "optimum" level. (By contrast, the RMCL at issue here is four times the optimum level.)

As EPA has repeatedly explained, "[t]he Agency set this [interim] MCL based on evidence that higher levels of fluoride in drinking water could produce adverse health effects...."[27] The

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24 Public Health Service Drinking Water Standards, U.S. Dept. of Health, Education and Welfare 7 (1962), App.

25 Id. at 8, App.

26 House Report at 17, App.; see text accompanying note 4, supra.

27 Proposed Fluoride RMCL at 20165, col. 3 (emphasis added), App. ; MCLs for Fluoride, Response to Petition for Rulemaking [from South Carolina], 46 Fed. Reg. 58345 (Dec. 1, 1981); 40 Fed. Reg. 59576 (Dec. 24, 1975) (Final Interim Fluoride MCL); 40 Fed. Reg. 11991 (Mar. 14, 1975) (Proposed Interim Fluoride MCL).

interim MCL for fluoride became effective as a mandatory standard for all public water supplies in the United States in May, 1976, or 18 months after promulgation, as required by statute.

C. The South Carolina Petition

In 1981, the State of South Carolina petitioned EPA to delete fluoride from the Primary Drinking Water Regulations and to establish instead an unenforceable Secondary Drinking Water Regulation. In the petition, South Carolina argued that dental fluorosis should not be considered an adverse health effect.[28]

On October 5, 1983, EPA published an advance notice of proposed rulemaking announcing its intention to propose Revised Primary Drinking Water Regulations for many of the Interim Primary Regulations, including fluoride.[29] A proposed Revised Regulation for fluoride was not forthcoming, however, and South Carolina sued EPA in 1984 "seeking faster action in EPA's rulemakings on fluoride."[30] Subsequently, in January, 1985, EPA and South Carolina signed a Consent Decree establishing a schedule for rulemaking on EPA's decision whether to continue to include fluoride in the revised Primary Regulations. The rule that is the subject of the instant petition for review was issued pursuant to that schedule.

D. The Proposed RMCL for Fluoride

The enforceable interim MCL for the past ten years limited

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28 MCLs for Fluoride, Response to Rulemaking Petition, 46 Fed. Reg. 58345 (Dec. 1, 1981), App.

29 National Revised Primary Drinking Water Regulations; Advance Notice of Proposed Rulemaking, 48 Fed. Reg. 45502, 45514, cols. 2, 3 (Oct. 5, 1983).

30 Proposed Fluoride RMCL at 20165, col. 2, App.

fluoride in drinking water to levels ranging between 1.4 and 2.4 mg/L, depending on temperature, to prevent moderate and severe dental fluorosis and other adverse health effects. However, on May 15, 1985, EPA proposed setting the RMCL for fluoride at the elevated level of 4.0 mg/L, independent of regional temperature (and therefore consumption) variations. The Agency intended this new level to protect only against crippling skeletal fluorosis, and not against the significant levels of moderate to severe dental fluorosis that are associated with drinking water concentrations of fluoride below 4 mg/L. (See Att. D.)

To justify setting the RMCL at a level that will allow significant dental fluorosis to occur in 44 percent of the children exposed,[31] EPA redefined the category of "adverse health effects" of fluoride to exclude dental fluorosis and all other potential adverse health effects except crippling skeletal fluorosis.[32] Dental fluorosis was excluded because, according to EPA's definition, an adverse health effect of fluoride must result in functional impairment.[33]

The Agency estimated that crippling skeletal fluorosis would result from the daily consumption of 20 mg or more of fluoride for 20 years or longer.[34] Stating its belief that crippling skeletal fluorosis had not been observed in the U.S.,[35] the Agency

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31 Proposed Fluoride RMCL at 20169, Table 8, App.

32 Id. at 20172, col. 2, App.

33 Final Fluoride RMCL at 47143, col. 3, App.

34 Proposed Fluoride RMCL at 20170, col. 3, App.

35 Id. at 20170, col. 2, App.

concluded that 4 mg/L meets the statutory requirement that the RMCL be set at a level below which no known or anticipated adverse health effects occur.[36]

The record contains studies of many other potential adverse health effects of fluoride, including cancer, birth defects, allergic sensitivity and a variety of other toxic effects.[37] The Agency's proposal did not discuss these studies, however, simply concluding that they "have not been found to be scientifically supportable."[38]

NRDC submitted comments to EPA on the proposed RMCL. The comments criticized the Agency for ignoring evidence in the record showing that the proposed RMCL of 4 mg/L was not a safe level of exposure in light of the preventive health protection mandate of the Safe Drinking Water Act.[39]

E. The Final RMCL for Fluoride

On November 14, 1985, EPA established the RMCL for fluoride at 4 mg/L. Despite its earlier statement to the contrary in the RMCL proposal, the Agency acknowledged that two cases of crippling skeletal fluorosis had been observed in the U.S.[40] Nevertheless, the final RMCL notice stated, "EPA believes that an

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36 Id. at 20172, col. 2, App.

37 See Proposed Fluoride RMCL at 20174, cols. 1-3, App. See also discussion at section IV, pp. 54-75, infra.

38 Proposed Fluoride RMCL at 20169, col. 1, App.

39 Comments of the Natural Resources Defense Council, Inc. on Proposed Recommended Maximum Contaminant Level for Fluoride, July 15, 1985, CI at II-H.366, App.

40 Final Fluoride RMCL at 47144, cols. 2-3, App. See note 1 page 16, supra.

RMCL of 4 mg/L will adequately protect persons who have high water consumption."[41]

EPA estimates that crippling skeletal fluorosis results from daily fluoride consumption of 20 mg for 20 years. NRDC had argued that at a drinking water fluoride concentration of 4 mg/L, many people would consume more than 20 mg of fluoride per day from all sources, including water and diet. The Agency's water intake figures show that 1% of the population, or approximately 2.3 million people, would consume 22.08 mg of fluoride per day from water alone at a drinking water concentration of 4 mg/L.[42] In response, EPA stated that it "does not believe that the SDWA requires protection by national regulation of persons who, through unusual practices, may put themselves at risk".[43]

EPA also stated that despite recommendations to the contrary by scientific organizations and numerous commenters, it was reversing its ten year-old precedent of treating dental fluorosis as an adverse effect on health. The Agency's stated reason was that "the evidence is inadequate to conclude that dental fluorosis is an adverse health effect."[44] EPA also dismissed evidence of psychological and behavioral problems resulting from impaired self-image or loss of self-esteem due to the disfiguring

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41 Id. at 47148, col. 1, App.

42 The information is contained in a document cited in the Final Fluoride RMCL as "Price, P., EPA, Office of Drinking Water, Memo to Arthur Perler from Paul Price, October, 1985," App. For a discussion of EPA's intake figures, see discussion at Section II.C.2.b., infra.

43 Final Fluoride RMCL at 47148, col. 1, App.

44 Id. at 47143, col. 3, App.

effects of dental fluorosis. The Agency characterized such effects as not "significant enough to be termed adverse health effects within the meaning of the SDWA."[45]

EPA also determined that, in the absence of conclusive proof, the RMCL need not account for any of the other potential adverse health effects of fluoride. Thus, the Agency stated that the evidence is inadequate to conclude that exposure to fluoride in U.S. drinking water is associated with mutagenicity, carcinogenicity, teratogenicity (birth defects), enzyme inhibition, reproductive effects, thyroid effects, cardiovascular effects, stunting of growth, kidney effects, or sensitivity and allergies to fluoride.[46]

On the same day that it published the final RMCL for fluoride, EPA proposed an enforceable MCL for fluoride of 4 mg/L and an unenforceable Secondary Drinking Water Regulation for fluoride of 2 mg/L.[47] The proposed Secondary Regulation included a requirement that water suppliers notify their customers when fluoride levels in drinking water exceed 2 mg/L and advise them to seek alternative water supplies if they have children under nine years of age. The Agency also proposed to amend the Interim Primary Regulation for fluoride by raising it to 4 mg/L, effective 30 days after promulgation. On April 2, 1986, EPA promulgated the revised MCL and the amended Interim MCL, both at 4 mg/L, and

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45 Id. at 47144, Col. 1, App.

46 Id. at 47150, col. 3 to 47152, col. 3, App.

47 National Primary Drinking Water Regulations; Fluoride, 50 Fed. Reg. 47156 (Nov. 14, 1985), App.

established the secondary regulation, as proposed, at 2 mg/L.

SUMMARY OF THE ARGUMENT

Under the SDWA, EPA was required to establish the RMCL for fluoride at a level at which no adverse health effects occur for anyone. Congress intended the RMCL to be preventive. It must protect all members of the population, including especially sensitive subgroups, against all known and anticipated adverse health effects, allowing an adequate margin of safety. To accomplish this goal, Congress further directed EPA to err on the side of safety in evaluating health effects evidence.

EPA's decision to set the RMCL for fluoride at 4 mg/L was designed to provide protection only against crippling skeletal fluorosis, the sole adverse health effect of fluoride that the Agency is willing to recognize as included within the meaning of the SDWA. This level significantly increases, in fact doubles, the maximum concentration of fluoride in drinking water that EPA has considered to be a safe exposure for the past ten years.

The record shows that an RMCL of 4 mg/L of fluoride will not protect the whole population against crippling skeletal fluorosis. Instead, a substantial number of people (over 1% of the population) will develop this disease after 20 years of exposure at the level of the RMCL. In addition, approximately 40% of children exposed to 4 mg/L will suffer the permanent disfiguring effects of dental fluorosis. Finally, the record contains extensive evidence that fluoride may cause or contribute to many other serious adverse health effects, including osteosclerosis (a milder form of skeletal fluorosis), growth

stunting, adverse cardiovascular effects, cancer, mutagenicity, adverse reproductive effects, kidney effects, enzyme inhibition, allergic sensitivity, and a number of other chronic effects. The EPA did not design the RMCL to provide protection against any of these effects except crippling skeletal fluorosis, and the RMCL will not even do that.

By setting the RMCL at a level at which both crippling skeletal fluorosis and dental fluorosis are known to occur with no margin of safety, and which entirely disregards several other potential adverse effects, EPA has clearly violated its duty under the SDWA. The RMCL should therefore be set aside.

Crippling Skeletal Fluorosis

EPA does not dispute that crippling skeletal fluorosis can occur at and below drinking water fluoride concentrations of 4 mg/L. The Agency specifically conceded that cases of crippling skeletal fluorosis have been identified in the United States in association with drinking water concentrations of fluoride at and below 4 mg/L. EPA's own drinking water consumption figures show that after 20 years of consuming water at a fluoride level of 4 mg/L, more than 1% of the population will be afflicted with crippling skeletal fluorosis as a result of drinking water consumption alone. When dietary fluoride intake is accounted for, the Agency's figures additionally show that, at the level of the RMCL, over 2% of the population is at significant risk for crippling skeletal fluorosis. Further, the Agency acknowledges that certain segments of the general population may be at increased risk from waterborne fluoride, and that the RMCL will not prevent crippling skeletal fluorosis in sensitive individuals,

such as kidney patients and diabetics, who must consume large amounts of water.

To defend its action in setting the RMCL at a level at which it acknowledges adverse health effects will occur, the Agency discounts the risk of crippling skeletal fluorosis as extremely low. Even allowing an "extremely low" incidence of crippling skeletal fluorosis, however, violates the Agency's statutory duty to protect against any known or anticipated adverse effects on health, and to allow an adequate margin of safety for the most sensitive subgroups of the population.

Further, the evidence contradicts EPA's judgment that the incidence of crippling skeletal fluorosis in the United States must be "extremely low." Because the Agency belatedly discovered only two cases of crippling skeletal fluorosis in the United States, it reasoned that risk of the disease must be small. The record suggests, however, that the number of identified cases of crippling skeletal fluorosis in the United States is probably greater than EPA believes. The Agency itself admits that it does not have sufficient information to estimate the rate of occurrence of skeletal fluorosis in the United States.

The Supreme Court has held that an agency's action is arbitrary and capricious when it runs contrary to clear congressional intent. This Court need not go further than EPA's own findings in this case to conclude that the Agency has violated the clear intent of the SDWA by setting the RMCL at a level which will allow crippling skeletal fluorosis to occur.

Dental Fluorosis

EPA does not dispute that drinking water fluoride con-

centrations of 4 mg/L and below will result in moderate to severe dental fluorosis in significant portions of the population. EPA's tabulation of results of fluoride exposure show extensive staining and pitting of teeth caused by moderate to severe dental fluorosis in as many as 44 percent of children drinking water with approximately 4 mg/L of fluoride. From 1975 through 1985, EPA considered dental fluorosis an adverse health effect and regulated to prevent it. To justify raising the permissible exposure to fluoride in drinking water to a level at which the teeth of four out of every ten children will be stained, pitted, and deformed, the Agency now simply states that it no longer regards dental fluorosis as an adverse health effect under the Safe Drinking Water Act.

The arbitrary and capricious nature of this radical departure from the Agency's long-standing prior conclusion is underscored by the absence of <u>any</u> stated factual basis for its reversal of position. The Supreme Court has held that a regulatory agency changing its course is obligated to supply a reasoned analysis beyond that which may be required when an agency chooses not to act in the first instance. Here, the Agency examined no relevant data and provided no explanation for its sudden conclusion that this permanently disfiguring condition is no longer included within the SDWA's broad protection against any known or anticipated adverse health effects. Instead, EPA merely stated that adverse health effects, at least for fluoride, should be measured by functional impairment.

EPA also refused to take into account any possibility that dental fluorosis might be an indicator of systemic harm, despite

strong indications in the record to the contrary. The Agency acknowledges that fluoride accumulates readily in bones and teeth, and that dental fluorosis and crippling skeletal fluorosis are related in that both are determined by the bone levels of fluoride. Further, the transcript and draft report of a panel of medical experts convened by the Surgeon General in 1983 clearly indicates the members' opinion that dental fluorosis has medical ramifications and could represent as yet unknown skeletal effects in children, and thus should be prevented. Nevertheless, the Agency stated that it received no relevant information on whether dental fluorosis progresses beyond cosmetic effects to adverse health effects, and refused, absent conclusive proof, to set the RMCL at a level that would prevent such potential effects.

EPA's reversal on dental fluorosis rejects the advice of a majority of the scientific and medical bodies that have evaluated evidence about the medical significance and psychological impacts of dental fluorosis. To buttress its conclusion that dental fluorosis is no longer an adverse health effect, the Agency noted that its judgment "agrees with" the opinions of the current Surgeon General and a number of professional medical and dental groups. It is understandable that EPA would want to cite support when setting a standard at a level that will produce such significant adverse health effects. However, EPA cannot satisfy its duty to provide a reasoned explanation for its abrupt change in course merely by noting with whom it agrees and disagrees. The groups on whose support EPA relies offered the Agency no factual basis to support their position that dental fluorosis should no longer be considered an adverse health effect.

According to EPA, the position of many of these groups was developed to advance their efforts to promote fluoridation of community water supplies in the face of organized efforts by opponents of fluoridation. These medical and dental groups have opposed EPA's 1976 finding that dental fluorosis is an "adverse health effect" because in the past this finding has been used to support the view that fluoridation is undesirable. EPA's heavy reliance on the opinions of these groups, whose objectivity about the health effects of fluoride has been compromised by their involvement in the fluoridation controversy, further underscores the arbitrary and capricious nature of the Agency's otherwise unexplained reversal of a ten year-old health protection precedent.

Other Adverse Health Effects

In 1980, the National Academy of Sciences cautioned that until more precise measures of the margin of safety for the use of fluoride are available regarding crippling skeletal fluorosis and other aspects of fluoride toxicity, the levels of fluoride in drinking water should not exceed the optimal levels for preventing cavities (0.7 to 1.4 mg/L). The record contains a very large body of evidence which documents or suggests various chronic adverse effects associated with exposure to low levels of fluoride. Numerous published articles from peer-reviewed medical and dental journals show a wide range of actual or potential adverse health effects of the contaminant. However, EPA discarded the evidence of every one of these effects as not conclusive, not demonstrated in humans, not widespread in the U.S. population, or not causative of clinically significant

impairment of function.

To justify setting the fluoride RMCL at a level which is twice the interim MCL, EPA narrowly defined "adverse health effect" to include only crippling skeletal fluorosis and a very small number of other drastic effects, such as death and gastrointestinal hemorrhage. The Agency then found that none of the many other chronic toxicity studies on fluoride raised even a possibility of such an adverse health effect. NRDC submits that it was arbitrary and capricious for the Agency to exclude all evidence about all of the adverse health effects of fluoride except crippling skeletal fluorosis.

The Safe Drinking Water Act directs EPA to set the RMCL for fluoride to protect against all known and potential adverse health effects, and to provide an adequate margin of safety for all sensitive subgroups of the population. When Congress established such a preventive standard, it did not intend the Agency to refuse to protect against adverse health effects until they were both conclusively proven to occur and shown to fit within an unduly narrow definition of "adverse health effect."

ARGUMENT

I. Establishment of Maximum Contaminant Levels Under the Safe Drinking Water Act

A. The Standard-Setting Procedure

The statute requires EPA to establish both nonenforceable RMCLs and enforceable MCLs for contaminants "which may have an adverse effect on the health of persons."[48] In establishing these

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48 §1412(b), 42 U.S.C. §300g-1(b).

standards, the law specifically directs that "[e]ach such [RMCL] shall be set at a level at which...no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety."[49] Thereafter, the enforceable MCL is to be set as close to the RMCL as is feasible with the use of the best available technology, treatment techniques, and other means, taking costs into consideration.[50]

EPA is further required to base the RMCLs on a National Academy of Sciences (NAS) study and report, completed pursuant to section 300g-1(e), which "shall evaluate and explain (separately and in composite) the impact of the following considerations:

> (A) The existence of groups or individuals in the population which are more susceptible to adverse effects than the normal healthy adult.
>
> (B) The exposure to contaminants in other media than drinking water (including exposures in food, in the ambient air, and in occupational settings) and the resulting body burden of contaminants.
>
> (C) Synergistic effects resulting from exposure to or interaction by two or more contaminants.
>
> (D) The contaminant exposure and body burden levels which alter physiological function or structure in a manner reasonably suspected of increasing the risk of illness."[51]

B. The Legislative History Shows Congress' Intent that RMCLs Prevent Any Adverse Effects Upon Human Health

The House Report makes clear that an RMCL must be set at a level which will prevent any possible adverse effect on health by allowing an adequate margin of safety from both known and antic-

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49 §1412(b)(1)(B), 42 U.S.C. §300g-1(b)(1)(B).

50 §1412(b)(3), 42 U.S.C. §300g-1(b)(3).

51 §1412(e)(3), 42 U.S.C. 300g-1(e)(3).

ipated adverse health effects:

> The incorporation of an adequate margin of safety is not to be confused with the anticipation of adverse health effects. Recommended maximum contaminant levels are to be established by a three-step process. First, the known adverse health effects of contaminants are to be compiled. Second, the Administrator must decide whether any adverse effects can be reasonably anticipated, even though not proved to exist. It is at this point that the Administrator must consider the possible impact of synergistic effects, long-term and multi-media exposures, and the existence of more susceptible groups in the population. Finally, the recommended maximum level must be set to prevent the occurrence of any known or anticipated adverse effect. It must include an adequate margin of safety, unless there is no safe threshold for a contaminant. In such a case, the recommended maximum contaminant level should be set at the zero level.[52]

These considerations reflect Congress' intent that RMCLs are to be preventive. RMCLs are not enforceable limits; rather, they are goals which EPA must consider when setting the enforceable MCLs.

The legislative history also unambiguously demonstrates that Congress intended EPA to apply preventive evidentiary standards in establishing RMCLs. The House Report emphasizes that

> [t]he Committee did not intend to require conclusive proof that a contaminant will cause adverse health effects as a condition for regulation of a suspect contaminant. Rather, all that is required is that the Administrator make a reasoned and plausible judgment that a contaminant may have such an effect. Moreover, the contaminant need not have the adverse effect directly in order for the Administrator to regulate it as a primary contaminant. If...it may contribute to such effect, the contaminant should be controlled under primary regulations.[53]

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52 House Report at 20 (emphasis added), App.

53 House Report at 10 (emphasis in original), App.; The Chairman of the House Subcommittee on Health and Environment and floor manager of the bill which became the Safe Drinking Water Act, Rep. Paul Rogers, similarly stressed during the House debate on final passage, "Section 1412 of the Safe Drinking Water Act does not require preponderant proof of a demonstrable health hazard as a precondition for standard-setting. All it requires is a reasoned judgment by the Administrator that a contaminant may pose a

[Cont. next pg.]

Finally, and of major significance for all of EPA's health-based standard-setting under the Safe Drinking Water Act, the Administrator must resolve uncertainties in favor of protecting public health. In 1974, Rep. Rogers summarized the intent of Congress as follows:[54]

> We cannot afford to wait 20 years for health effects research to be completed to begin controlling contaminants which there is some basis to believe endanger public health. If there are uncertainties, they must be resolved on the side of protection of health.

Congress reiterated this clear policy in the recent Report on the House version of the Safe Drinking Water Act Amendments of 1985, which states unequivocally that "[i]f the scientific evidence is unclear, the Administrator must err on the side of protecting public health."[55]

Given such unambiguous statements of legislative intent, this Court has observed with respect to the Safe Drinking Water Act: "It seems particularly clear from the legislative history that Congress contemplated prompt regulation, whenever feasible, of every contaminant identified as possibly injurious to health."[56] EPA does not dispute that these directions from Congress must guide the Administrator in establishing RMCLs and revised Primary Drinking Water Regulations under the Safe Drinking Water Act.[57]

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threat to human health." 120 Cong. Rec. H10793 (daily ed. Nov. 19, 1974) (remarks of Rep. Rogers).

54 120 Cong. Rec. H10794 (daily ed. Nov. 19, 1974) (emphasis added).

55 H.R. Rep. No. 98-1034, 99th Cong., 1st Sess. 22 (1985).

56 Environmental Defense Fund, Inc. v. Costle, 188 U.S. App. D.C. at ___, 578 F.2d at 344 (1978) (emphasis added).

57 For EPA's repeated acknowledgment of its statutory responsibilities under the SDWA, see infra, pages 25-26.

Thus, Congress has set the boundaries within which the Administrator's judgment may properly be exercised: precautionary health-based RMCLs must protect public health against any known or anticipated adverse health effects with an adequate margin of safety. Reviewing almost identical language under the Clean Air Act, this Court has observed that directions to the Administrator to allow an adequate margin of safety are "to protect against effects which have not yet been uncovered by research and effects whose medical significance is a matter of disagreement."[58] Rejecting arguments that such language is intended to protect against only clearly harmful effects, this Court added that waiting until EPA "can conclusively demonstrate that a particular effect is adverse to health before it acts is inconsistent with both the Act's precautionary and preventive orientation and the nature of the Administrator's statutory responsibilities."[59]

II. EPA's Establishment of a Recommended Maximum Contaminant Level for Fluoride at 4 mg/l Violates the Express Requirements of the Safe Drinking Water Act

A. The Standard of Review

Under §706 of the Administrative Procedure Act,[60] an agency's decision may be set aside if found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." An agency's decision is arbitrary and capricious when any

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58 Lead Industries Ass'n, Inc. v. Environmental Protection Agency, 208 U.S. App. D.C. 1, 647 F.2d 1130, 1154 (1980).

59 Id. at 1155.

60 5 U.S.C. §706(2)(A).

one of the following conditions is found:

1. The agency has acted in contravention of the express legislative intent of Congress.[61] A reviewing court "must reject administrative constructions which are contrary to clear congressional intent" because "[a] court, as well as the agency, must give effect to the unambiguously expressed intent of Congress."[62]

2. The agency has failed to supply a reasoned explanation or reliable foundation for its decision.[63] "[T]he orderly functioning of the process of [judicial] review requires that the grounds upon which the administrative agency acted be clearly disclosed and adequately sustained."[64] In addition, where "the facts are uncertain, the Administrator 'should so state and go on to identify the considerations he found persuasive.'"[65] The court must therefore take a hard look at both the facts and the agency's reasoning.[66]

3. The agency has made a clear error of judgment.[67] Evidence

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61 Chevron, U.S.A., Inc. v. Natural Resources Defense Council, ___ U.S. ___, 104 S.Ct. 2778, 2781-82, 81 L.Ed.2d 694 (1984).

62 Chevron, 104 S.Ct. at 2781-82; see also General Motors Corp. v. Ruckelshaus, ___ U.S. App. D.C. ___, 742 F.2d 1561, 1567 (1984).

63 SEC v. Chenery Corp., 332 U.S. 194, 196 (1946); South Terminal Corp. v. EPA, 504 F.2d 646, 655 (1st Cir. 1974).

64 SEC v. Chenery Corp., 318 U.S. 80, 94 (1943).

65 Small Refiner Lead Phase-Down Task Force v. EPA, 227 U.S. App. D.C. 201, 705 F.2d 506, 520 (1983) (quoting Industrial Union Dep't. AFL-CIO v. Hodgson, 162 U.S. App. D.C. 331, 499 F.2d 467, 476 (1974).

66 Nat'l Lime Ass'n. v. EPA, 200 U.S. App. D.C. 363, 627 F.2d 416, 451 (1980).

67 Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 416 (1971).

of arbitrary and capricious errors of judgment include situations in which the agency has "offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise."[68]

4. The presumption of the court is against an agency's deviating from a long-standing course of action.[69] The court should be "satisfied both that the agency was aware it was changing its view and has articulated permissible reasons for that change, and also that the new position is consistent with the law."[70]

B. The Statute Requires that the RMCL be Set at a Level which Protects Against Any Adverse Health Effect with an Adequate Margin of Safety

Section 1412(b) of the Safe Drinking Water Act requires the Administrator of EPA to establish an RMCL for each contaminant which in his judgment "may have any adverse effect" on human health.[71] Consistent with this requirement, each RMCL must be set at a level at which "no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety."[72]

EPA has repeatedly acknowledged that its statutory responsi-

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68 Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Ins. Co., 463 U.S. 29, 43 (1983).

69 State Farm, 463 U.S. at 42.

70 NAACP v. FCC, 221 U.S. App. D.C. 44, 682 F.2d 993, 998 (1983).

71 §1412(b)(1)(B), 42 U.S.C. §300g-1(b)(1)(B)(emphasis added).

72 Id.

bilities under the Safe Drinking Water Act include the following requirements and considerations:

1. "Under the SDWA, EPA is charged with setting standards to protect the most sensitive subgroup of a population."[73]

2. "The Safe Drinking Water Act does not require that there be any adverse health effect occurring in the U.S. population as a prerequisite to regulation. Rather, the intent of the Act is to be preventive."[74]

3. "[C]onsistent with the legislative history of the SDWA...conclusive proof is not needed in order to regulate a substance; all that is required is that a judgment be made that a contaminant may have an adverse effect."[75]

4. "[A] contaminant need not have the adverse effect directly in order for the Administrator to regulate it as a primary contaminant....[I]f it may contribute to such effect, the contaminant should be controlled under the primary regulations."[76]

5. "EPA regulates compounds where there is a possibility of an adverse health effect."[77]

6. "Requiring widespread occurrence and a significant risk of

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73 Final Fluoride RMCL at 47151, col. 3, App.; Summary of Comments and Responses from the May 14, 1985 RMCL Proposal 10, 116 [hereinafter cited as "Response to Comments"]; National Primary Drinking Water Regulations: Volatile Synthetic Organic Chemicals, 50 Fed. Reg. 46880, 46895, col. 1 (Nov. 13, 1985) [hereinafter cited as "Final RMCLs for Volatile Organics"]; App.

74 Response to Comments at 2.

75 Final RMCLs for Volatile Organics at 46893, col. 1 (emphasis in original), App._____; see also, Id. at 46899, col. 3, App.

76 Id. at 46891, col. 1, App.

77 Id. at 46900, col. 1, App.

harm to the public before regulating would not be consistent with the preventive purpose of the statute."[78]

7. "EPA should err on the side of safety in setting [RMCLs]...."[79]

These criteria accurately define the scope within which the Administrator's discretion may be exercised in establishing RMCLs under the SDWA. Unfortunately, they were not applied in setting the RMCL for fluoride. Instead, EPA applied separate, far less protective criteria, which the Agency made applicable only to the adverse health effects evidence on fluoride.

C. EPA's Rationale for the Fluoride RMCL Ignores the Statutory Requirements and Criteria for Establishing an RMCL

As the following discussion shows, EPA's establishment of 4 mg/L as the RMCL for fluoride violates the SDWA on several grounds. Although the statute directs that the RMCL be set at a level at which no known or anticipated adverse health effects occur, the RMCL for fluoride has been set at a level at which EPA acknowledges crippling skeletal fluorosis is known and anticipated to occur. The fluoride RMCL thus allows no margin of safety for large population subgroups who consume higher than average amounts of drinking water or are especially sensitive to the effects of waterborne fluoride. Finally, the RMCL for fluoride is not intended to protect against the permanent disfiguring effects of dental fluorosis, or the potential cardiotoxic and other adverse health effects of the contaminant.

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78 Final RMCLs for Volatile Organics at 46899, col. 3, App.

79 Id. at 46891, col. 1 and 46893, col. 1, App.

1. The Stated Basis for the Fluoride RMCL

On November 14, 1985, EPA established the RMCL for fluoride in drinking water at 4 mg per liter to protect against crippling skeletal fluorosis. The Agency defined crippling skeletal fluorosis as "the deposition of irregular bone deposits which, in the case of the joints, results in arthralgia and crippling."[80] EPA further concluded that "crippling skeletal fluorosis is an adverse health effect which results from intakes of 20 mg/day [of fluoride] over periods of 20 years or more...."[81] The Agency determined that "an RMCL of 4 mg fluoride per liter will protect against crippling skeletal fluorosis with an adequate margin of safety."[82]

To make the foregoing findings, EPA defined "adverse health effect" as follows:[83]

> In the case of regulating fluoride under the SDWA,...adverse health effects are considered to be death, gastrointestinal hemorrhage or irritation, arthralgias, and crippling fluorosis or any other effect which results in functional impairment.

Accordingly, the Agency concluded that[84]

> dental fluorosis is not an adverse health effect in the context of the Safe Drinking Water Act; EPA believes that adverse health effects, at least for fluoride, should be measured by functional impairment.

Applying this narrow definition, which excludes numerous

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80 Proposed Fluoride RMCL at 20170, col. 2, App.

81 Final Fluoride RMCL at 47144, col. 2, App.

82 Id. at 47142, col. 1, App.

83 Id. at 47143, col. 3 (emphasis added) (citation omitted), App.

84 Id. at 47146, col. 3 (emphasis added), App.

other actual and potential adverse health effects as well as animal studies and laboratory studies, the Agency determined that "crippling skeletal fluorosis is the only adverse human health effect [of fluoride] within the meaning of the SDWA...."[85] Dental fluorosis, "which was formerly regarded as an adverse health effect and which was the basis for the interim drinking water standard, is not an adverse health effect under the Safe Drinking Water Act, but rather a cosmetic effect...."[86]

In addition, all other actual or potential adverse health effects of fluoride which did not meet EPA's narrow definition, such as osteosclerosis (a less severe stage of skeletal fluorosis), skeletal retardation, kidney impairment, adverse reproductive effects, cardiotoxic effects, enzyme inhibition, oncogenicity, mutagenicity, allergic sensitivity and liver toxicity, were similarly disregarded as not adverse health effects "within the meaning of the Safe Drinking Water Act."[87]

To reach the conclusion that crippling skeletal fluorosis is the only adverse health effect of fluoride cognizable under the SDWA, the Agency crafted a completely new set of evaluation criteria by which to judge the health effects evidence on fluoride. In general, these criteria required that evidence sufficient to characterize an effect associated with fluoride exposure as an "adverse health effect" under the SDWA had to be conclusive, significant, detected in humans, occur widely in the

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85 Response to Comments at 10.

86 Final Fluoride RMCL at 47142, col. 1 (emphasis in original), App.

87 Response to Comments at 10.

population, and result in functional impairment. Finally, the new criteria were arbitrarily made applicable only to the evidence on fluoride; they stand in stark contrast to the properly preventive standards applied in establishing RMCLs for eight other drinking water contaminants, which were promulgated by EPA one day before the RMCL for fluoride was published.[88]

Instead of the precautionary, preventive approach Congress directed EPA to utilize in developing RMCLs, the Agency's action in setting the RMCL for fluoride directly contravenes the unambiguous legislative intent that RMCLs must protect against all "known and anticipated adverse effects on health," and must allow an "adequate margin of safety."[89] The Supreme Court has held that "the judiciary...must reject administrative constructions which are contrary to clear congressional intent."[90] Where, as here, the Agency's definition creates "so formidable an obstacle" to inclusion in the category of adverse health effects that it is inconsistent "with the express terms and underlying Congressional intention,"[91] this Court has held that the Agency has made "a fundamental mistake."[92] This case presents a glaring example of such an instance.

EPA set the RMCL for fluoride at 4 mg/L based on the

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88 Cf. Final RMCLs for Volatile Organics at 46890-46900, App.

89 §1412(b)(1)(B), 42 U.S.C. §300g-1(b)(1)(B).

90 Chevron, U.S.A. v. NRDC, ___ U.S. ___, 104 S.Ct. 2778, 2782 n.9 (1984).

91 Natural Resources Defense Council v. Herrington, ___ U.S. App. D.C. ___, 768 F.2d 1355, 1372-73 (1985).

92 Id.

erroneous view that under the SDWA, RMCLs are to protect only against effects that have been demonstrated to impair function or otherwise clearly harm human health. As a result of this interpretation, all other evidence which EPA deemed "not conclusive", or which was merely suggestive of adverse health effects, or the medical significance of which was a matter of disagreement, was rejected outright by the Agency. Thus, a very large body of published studies and reports were effectively ignored in setting the MCL and in providing the statutorily required margin of safety. Yet, this Court has found that

> Congress' directive to the Administrator to allow an "adequate margin of safety" alone plainly refutes any suggestion that the Administrator is only authorized to set primary...standards which are designed to protect against health effects that are known to be clearly harmful.[93]

2. The RMCL is Set at a Level at and Below Which Crippling Skeletal Fluorosis is Known to Occur

EPA states in the Final Fluoride RMCL that the RMCL "will protect against crippling skeletal fluorosis with an adequate margin of safety."[94] Accepting, arguendo, that crippling skeletal fluorosis is the only known or anticipated health risk posed by fluoride concentrations in drinking water, the Agency cannot show support in the record for the conclusion that 4 mg/L provides the requisite "adequate margin of safety" against even this disease.

a. Crippling skeletal fluorosis has been documented in the U.S. at drinking water levels below 4 mg/L

The Agency specifically concedes that cases of crippling

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93 Lead Industries, supra note 58, 208 U.S. App. D.C. at ___, 647 F.2d at 1154-55 (interpreting virtually identical standard-setting language in the Clean Air Act).

94 Final Fluoride RMCL at 47142, col. 1, App.

skeletal fluorosis have been identified in the United States in association with drinking water concentrations of fluoride at and below 4 mg/L.[95] Although the Preamble to the Final Fluoride RMCL states that only two such cases in the United States have been identified,[96] the record suggests that the number is probably greater.[97] In this connection, the Agency admitted in its November 13, 1985 proposal of an enforceable fluoride MCL, which is based on the RMCL at issue here, that:

> EPA does not have sufficient information to estimate the rate of occurrence of skeletal fluorosis, despite reference in the literature to cases of this disease in the United States and in other countries. Therefore, EPA is unable to estimate the cases of skeletal fluorosis avoided for different levels of fluoride in drinking water.[98]

This revealing admission sharply underscores the arbitrary and capricious nature of EPA's repeated but unsubstantiated claims about the likely incidence of crippling skeletal fluorosis made throughout the RMCL rulemaking. In the proposal, the

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95 Final Fluoride RMCL at 47147, cols. 1-2, App.

96 Id. at 47144, col. 3, App.

97 Ten separate studies describing cases of severe skeletal fluorosis in the U.S. are described in the Response to Comments at 120-122; several foreign studies also document crippling skeletal fluorosis associated with drinking water fluoride concentrations below 4 mg/l. See, e.g., Krishnamachari, KAVR, et al. 1976. Endemic Genu valgum -- A new dimension to the fluorosis problem in India. Fluoride 9:195-200, cited in CI at III-F.2; Siddiqui, A.H. 1955. Fluorosis in Nalgonda District, Hyderabad-Deccan. Brit. Med. J. :1408-1413, cited in CI at III-F.2); Singh, A., et al. 1961. Skeletal Fluorosis and its neurological complications. Lancet. Jan. 28, 1961:197-200, CI at III-F.2); Jolly, et al. 1968. An Epidemiological, Clinical and Biochemical Study of Endemic Dental and Skeletal Fluorosis in Punjab. Fluoride Quarterly Reports 1:65-75, cited in CI at II-H.366.

98 National Primary Drinking Water Regulations; Fluoride. 50 Fed. Reg. 47156, 47168, col. 3, (emphasis added) [hereinafter "Proposed Fluoride MCL"], App.

Agency asserted that the incidence of skeletal fluorosis in the U.S. was non-existent.[99] When evidence to the contrary was brought to EPA's attention, the Agency insisted that the incidence and population at risk at 4 mg/L are "extremely small"[100] or "very negligible."[101] The EPA's own drinking water consumption figures, however, decisively rebut this conclusion.

b. EPA's Drinking Water Consumption Figures Demonstrate that at a Drinking Water Concentration of 4 mg/L, a Significant Number of Persons are at Risk of Developing Crippling Skeletal Fluorosis

On December 10, 1985, the President-elect of the EPA Local of the National Federation of Federal Employees (NFFE) wrote EPA Administrator Lee Thomas requesting that the effective date of the final RMCL (December 16, 1985) be suspended because "new information that completely negates any claim that the RMCL of 4 mg/L is safe was overlooked."[102] Referencing the Agency's finding that crippling skeletal fluorosis results from intakes of 20 mg/day of fluoride for 20 years or more, the NFFE letter continued:[103]

> The new information documents that the drinking water consumption of the American public is much greater than anticipated, and that 1% of the population -- if they drink water containing fluoride at the RMCL -- will ingest 20 mg/day or more from drinking water alone. This means that the Agency

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99 Proposed Fluoride RMCL at 20170, col. 2, App.

100 Final Fluoride RMCL at 47144, col. 3, App. ; see also, Response to Comments, Appendix A, Reference: Marier, J.R., 1977, Some current aspects of environmental fluoride. Sci. Tot. Env. 8:252-265.

101 Id. at 47151, col. 3, App. ; see also Id. at 47144, col. 3, App. and 47147, col. 3, App.

102 Letter from Robert J. Carton, Ph.D., President-elect of NFFE Local 2050 to Lee M. Thomas, Administrator of EPA, Dec. 10, 1985, (emphasis in original), Att. E.

103 Id.

proposes to set a standard which it knows in advance will cause crippling skeletal fluorosis to some people in the U.S.

The "new information" consists of drinking water consumption data gathered by the Department of Agriculture in 1977 and 1978, and analyzed by EPA's Office of Pesticide Programs as part of its Tolerance Assessment Program in 1984.[104] (See Att. F.)

Despite EPA's insistence that "an RMCL of 4 mg/L will adequately protect persons who have high water consumption"[105] against crippling skeletal fluorosis, the Agency's own tap-water consumption data conclusively refute this contention. Indeed, these data show beyond question that, as the NFFE letter warned, EPA has set the final RMCL at a level which will result in crippling skeletal fluorosis in some people in the U.S.

As EPA's figures clearly indicate, an adult male weighing 78.8 kg (or 173 lbs.), with a fluid consumption of 70 ml/kg of body weight, will consume 5.52 liters of drinking water per day.[106] A simple calculation shows that at a fluoride concentration of 4 mg/L, such a consumer will ingest 22.08 mg/day of fluoride [5.52 liters/day x 4 mg/L]. The fluoride intake for such an individual from drinking water alone exceeds the 20 mg/day level at which crippling skeletal fluorosis is known to occur. Not

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104 These data were not made available by EPA during the public comment period on the RMCL. They were subject to public review, however, as part of the November 14 - December 30, 1985 rulemaking on the proposed enforceable MCL for fluoride, and were included in the record of the RMCL rulemaking as an addendum to an EPA staff memorandum dated November 12, 1985 on the issue of variations in tap water consumption. The document is referenced in the Final Fluoride RMCL as "Price, P., EPA, Office of Drinking Water, Memo to Arthur Perler from Paul Price, October, 1985", App.

105 Final Fluoride RMCL at 47148, col. 1, App.

106 See Att. F.

only is such an individual at risk of developing crippling skeletal fluorosis with no margin of safety, but EPA estimates that 1% of the population, or 2.8 million people, have a greater tap water consumption than the amount used in this calculation.

If one includes EPA's estimate of 1 mg/day of additional fluoride from dietary sources,[107] plus 0.63 mg from a hypothetical 2 cups of tea,[108] the population at risk rises to 2%.[109] Thus, EPA's finding that "an RMCL of 4 mg fluoride per liter will protect against crippling skeletal fluorosis with an adequate margin of safety"[110] is flatly contradicted by the drinking water consumption data upon which it is purportedly based.

4. EPA Admits that Persons with Higher than Average Drinking Water Consumption will not be Protected Against Crippling Skeletal Fluorosis by the RMCL

EPA has recognized its statutory obligation to protect sensitive subpopulations in developing an RMCL.[111] With respect to fluoride, however, the Agency has openly admitted that the RMCL

> provides an adequate margin of safety except in those very extreme cases involving severely renally impaired individuals

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107 Response to Comments, Appendix: Reference: Kinter; Response based on review of the reference.

108 EPA also acknowledges that its estimates of dietary exposure to fluoride "may overlook some sub-populations with higher intakes. For example, a person drinking 2 cups of tea may be receiving as much as .008 mg/kg of additional fluoride." [.008 mg/kg x 78.8 kg adult = 0.63 mg of fluoride] Proposed Fluoride RMCL at 20168, col. 1, App.

109 EPA's water intake figures in Att. F. show that 2% of the adult male population will ingest 4.73 liters of drinking water per day or 18.92 mg/day of fluoride at the RMCL of 4 mg/L. Adding 1.63 mg/day from dietary sources would bring the total to 20.55 mg of fluoride per day, which is above the threshold for crippling skeletal fluorosis.

110 Final Fluoride RMCL at 47142, col. 1, App.

111 See pages 26-27, supra.

who consume unusually high levels of fluoride due in part to polydipsia [excessive thirst] and other confounding factors.[112]

EPA also concedes that "[t]he margin of safety incorporated into the RMCL will not prevent crippling skeletal fluorosis in such individuals."[113] Furthermore, the Agency admits that individual exposures to fluoride "can vary widely" and be "vastly different."[114] Thus, "[t]he Agency agrees that certain segments of the general population may be at increased risk from waterborne fluoride."[115] These include "those with kidney disease,"[116] "individuals with renal impairment and drinking disorders,"[117] and "polydipsia and polyuria associated with diabetes insipidus and some forms of renal impairment...."[118]

In light of the Agency's own data on variable exposure and high consumption patterns, and the increased risk to especially sensitive populations, the Agency retreated in its Response to Comments from the conclusion that the RMCL of 4 mg/L is adequate to protect everyone. In that document, EPA states repeatedly that "4 mg/L is the level below which no known or anticipated adverse effects on the health of persons occur (given normal water intake levels)...."[119] These qualifications are tantamount to

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112 Final Fluoride RMCL at 47152, col. 1 (emphasis added), App.

113 Response to Comments at 131 (emphasis added).

114 Criteria Doc. at IV-1.

115 Response to Comments at 115.

116 Response to Comments, Appendix: Reference: Yudkin; Response based on review of the reference.

117 Response to Comments at 115.

118 Id.

[Cont. next pg.]

an admission by EPA that the RMCL will neither protect nor provide an adequate margin of safety against crippling skeletal fluorosis for persons whose drinking water consumption differs from the Agency's definition of "reasonable" and "normal".

The SDWA requires EPA to protect everyone, including sensitive subpopulations, against any known or anticipated adverse effects on health. To the extent that the RMCL for fluoride fails to meet this requirement, and EPA has effectively admitted that it does so fail, the Agency's decision to promulgate the RMCL at 4 mg/L was arbitrary, capricious and in violation of both the statute and the unambiguous Congressional intent.

III. EPA's Determination that Dental Fluorosis is No Longer an Adverse Health Effect within the Meaning of the Safe Drinking Water Act Lacks a Rational Basis in the Record

A. EPA Did Not Satisfy its Duty to Provide a Reasoned Explanation for its Radical Change of Position on Dental Fluorosis

The Supreme Court has held that a regulatory agency changing its course "is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance."[120] Moreover, "[i]f Congress established a presumption from which judicial review should start, that presumption...is not against safety regulation, but against changes

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119 Response to Comments at 2 (emphasis added); see also, Id. at 1 ("no other potentially adverse human health effects are known to occur at levels of 4 mg/l or less given normal water intake levels"); Id. at 7 ("4 mg/L is the level below which no known or anticipated adverse effects on the health of persons occur (given reasonable normal water intake levels) ...."); Id. at 8 (" ... (given reasonable water intake levels) ...."; Id. at 11 (" ... (given normal water intake levels) ....")

120 State Farm, 463 U.S. at 42.

in current policy that are not justified by the rulemaking record."[121] To overcome this presumption, this Court has stated that "'the agency must examine the relevant data and articulate a satisfactory explanation for its action'."[122] Indeed, "the arbitrary and capricious standard demands that an agency give a reasoned justification for its decision to alter an existing regulatory scheme."[123] Thus, there is a "burden upon the agency to set forth a reasoned analysis in support of the particular changes finally adopted."[124]

In the instant case, EPA set a health goal for fluoride in drinking water at twice the previously permissible exposure level, explaining only that it no longer regards dental fluorosis, the basis for the former standard, as an adverse health effect under the Safe Drinking Water Act.[125] In so doing, the Agency improperly shifted onto the beneficiaries of the protective interim Primary Regulation the burden of showing why dental fluorosis should continue to be considered an adverse health effect. Thus, the Agency stated:

> In that no adequate evidence to the contrary was received, the EPA reaffirms its conclusion, presented in the proposal, that dental fluorosis is not an adverse health effect under the SDWA.[126]

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121 State Farm, 463 U.S. at 42.

122 Center for Auto Safety v. Peck, 243 U.S. App. D.C. 117, 751 F.2d 1336, 1343 (1985), quoting State Farm, 463 U.S. at 42.

123 Farmers Union Central Exchange, Inc. v. FERC, 189 U.S. App. D.C. 250, 734 F.2d 1486, 1500 (1984).

124 Id.

125 Final Fluoride RMCL at 47142, col. 1, App.

[Cont. next pg.]

A review of the RMCL proposal shows, however, that it contains only EPA's conclusion, and no examination of the relevant data or satisfactory explanation to justify the Agency's decision to delete dental fluorosis from the category of adverse health effects of fluoride in drinking water.

B. The Record Does Not Support EPA's Unexpected Determination That Dental Fluorosis Is Not An Adverse Health Effect Of Fluoride

In establishing the RMCL for fluoride, EPA radically altered its definition of "adverse health effect" to exclude protection against dental fluorosis from the scope of the RMCL. The record shows that dental fluorosis is a permanent disfiguring condition of the teeth. According to a classification scale developed by H.T. Dean in 1942,[127] a "normal" tooth (zero on the numerical scale) is described as follows:[128]

> The enamel represents the usual translucent semiultriform type of structure. The surface is smooth, glossy, and usually of a pale creamy white color.

The initial stages of dental fluorosis involve opaque white spots scattered on the tooth's surface, contrasting with the normal enamel's translucency. When the disease reaches its "mild" (II) stage, these opaque spots cover up to 50% of the tooth. The more advanced stages are described as follows:[129]

Moderate (III): All enamel surfaces of the teeth are

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126 Final Fluoride RMCL at 47146, col. 3, App.

127 Dean, H.T. 1942. The investigation of physiological effects by the epidemiological method. In: Moulton, F.R., ed., Fluorine and dental health. Washington, D.C.: American Association for the Advancement of Science, Pub. No. 19, pp. 23-31, CI at III-C1.21.

128 Id.

[Cont. next pg.]

> affected, and surfaces subject to attrition show wear. Brown stain is frequently a disfiguring feature.
>
> Severe (IV): All enamel surfaces are affected and hypoplasia [arrested development] is so marked that the general form of the tooth may be affected. The major diagnostic sign of this classification is discrete or confluent pitting. Brown stains are widespread and teeth often present a corroded-like appearance.

The pitting is dark brown to black in color; at the severe stage of the disease, nearly the entire tooth surface may be pitted. Additional descriptions of the disease indicate, in addition to alteration of the tooth's form and wear in areas of attrition, fracturing of affected teeth.[130] The moderate and severe stages of the disease are often termed "objectionable" fluorosis. (See Att. C for photographic illustrations of the stages of dental fluorosis.[131])

Studies of dental fluorosis consistently show that its rates of incidence and severity increase as drinking water concentrations of fluoride increase.[132] (See table at Att. D.) These studies have led to a general consensus in the scientific community that fluoride concentrations of 0.8 to 1.6 mg/L and above in drinking water, depending on temperature, result in objectionable (moderate to severe) dental fluorosis.[133] EPA's Cri-

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129 Id.

130 Proposed Fluoride RMCL at 20169, col. 1, App.

131 CI at I.B2.2.

132 Proposed Fluoride RMCL at 20169, cols. 1, 2 and Table 8. App.

133 For example, the National Academy of Sciences concluded that "[n]o recent U.S. surveys or studies of communities have been found on which a sound decision could be made that greater concentrations [than 0.8 to 1.6 mg/L] are without objectionable effect." National Academy of Sciences, Drinking Water and Health, Washington, D.C., 1977, p. 395, CI at I-B1.1.

teria Document on fluoride concludes that moderate and severe dental fluorosis begin to impact a marked segment of the population when drinking water concentrations approach and exceed 2 mg/L.[134] The Agency's data further show that at 4 mg/L, as many as 44 percent of exposed children will develop moderate to severe dental fluorosis.[135]

For ten years, EPA considered dental fluorosis to be an adverse health effect. This condition provided the basis for the interim MCL for fluoride from 1975 until April, 1986. Although the record lacks any cogent, let alone persuasive, reason for EPA's reversal of ten years of precedent and decades of health concern, the Agency simply concluded that[136]

> dental fluorosis, which was formerly regarded as an adverse health effect and which was the basis for the interim drinking water standard, is not an adverse health effect under the Safe Drinking Water Act, but rather a cosmetic effect that would adversely affect public welfare.

The record lacks evidentiary support for EPA's reversal of its long-standing position on dental fluorosis. The evidence shows that many prestigious scientific organizations continue to consider dental fluorosis an adverse health effect. For example, the World Health Organization (WHO) includes fluoride in the category of "inorganic constituents of health significance" on the basis of dental fluorosis and other effects, and has estab-

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134 Criteria Doc. at I-5.

135 Proposed Fluoride RMCL at 20169, Table 8, App.

136 Final Fluoride RMCL at 47142, col.1 (emphases in original), App. Contaminants which do not affect health but otherwise affect the public welfare may be the subject of unenforceable secondary regulations under the Act. Supra note 9.

lished a drinking water guideline for fluoride of 1.5 mg/L.[137] As EPA acknowledged in the Proposed RMCL for Fluoride, the WHO Guidelines "are intended as a basis for the development of standards which, if properly implemented, will ensure the safety of drinking water supplies."[138]

The panel of medical experts convened by the Surgeon General at EPA's request in 1983 to evaluate the non-dental health effects of fluoride in drinking water[139] reached much the same conclusion as the World Health Organization. The panel included recognized experts in bone metabolism, endocrinology, toxicology, fluoride metabolism, and pediatrics.[140] The transcript of their two-day meeting shows that the panel discussed dental fluorosis at length; their conclusion was "fairly close to unanimous that we all agreed [the] dental fluorosis problem..., in fact, has medical ramifications."[141] Hence, the original draft of their report to the Surgeon General states unequivocally:

> [T]here was a consensus that mottling or pitting of teeth could represent as yet unknown skeletal effects in children and that severe dental fluorosis per se constitutes an ad-

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137 World Health Organization, Guidelines for Drinking Water Quality, Volume I. Recommendations. Geneva, Switzerland, 1984.

138 Proposed Fluoride RMCL at 20167, col. 1, App.

139 Transcript of Proceedings, Ad Hoc Committee on the Non-Dental Effects of Fluoride in Drinking Water, April 18-19, 1983 (hereinafter cited as "Medical Panel Transcript"), CI at ____.

140 Report to the Surgeon General by the Ad Hoc Committee on the Non-Dental Health Effects of Fluoride in Drinking Water, September, 1983, page 2, CI at III-C1.135. See also Draft of Report to the Surgeon General of the Ad Hoc Panel on the Non-Dental Health Effects of Fluoride in Drinking Water, May 26, 1983, page 14 (hereinafter cited as "Draft Medical Panel Report"), CI at I.D.82, App.

141 Medical Panel Transcript at 455.

verse health effect that should be prevented.[142]

The transcript of the panel's final deliberations reflects awareness that the Surgeon General, the American Medical Association and the American Dental Association were on record saying that dental fluorosis is merely a cosmetic effect.[143] The transcript also reflects concern that opponents of fluoridation could use the panel's conclusion on dental fluorosis for their own purposes.[144] Nevertheless, these medical experts firmly concluded that "we regard dental fluorosis in the stage III level [moderate] as an adverse health effect and that is what the [interim Primary Drinking Water] regulation has been aimed to prevent;"[145] "the sense of the committee is that the cosmetic effect represents an adverse health effect...."[146]

The senior scientist in EPA's office of Drinking Water was present at the Medical Panel's two-day meeting and was certainly aware that these distinguished experts[147] virtually unanimously believed dental fluorosis was an adverse health effect. Yet, EPA never acknowledged this consensus or responded to it in reaching the opposite conclusion. Indeed, the Agency even suggested it was relying on the Medical Panel in determining that dental fluorosis is merely a cosmetic effect![148]

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142 Draft Medical Panel Report at 14 (emphasis added), App.

143 Medical Panel Transcript at 473.

144 Id. at 471-473.

145 Id. at 472.

146 Id. at 473 (emphasis added).

147 Id. at 40, 68.
[Cont. next pg.]

In 1984, a panel of psychiatrists and behavioral scientists convened by the National Institute of Mental Health at EPA's request evaluated the potential adverse psychological and behavioral effects of moderate and severe dental fluorosis. The panel concluded[149]

> with reasonable certainty that individuals who have suffered impaired dental appearance as the result of moderate to severe fluorosis are probably at increased risk for psychological and behavioral problems or difficulties.

Finally, the National Drinking Water Advisory Council, a statutory advisory committee, recommended to EPA, after hearing testimony on the issue in 1984, that moderate and severe levels of dental fluorosis should be considered adverse health effects because "these effects are associated with cosmetic deformity, dental dysfunction, and possible social and behavioral effects."[150]

EPA's determination that dental fluorosis is not an adverse health effect therefore contradicts the conclusion of a large body of highly credible scientific opinion. Yet, the EPA's only response to the judgments of the World Health Organization, the National Academy of Sciences, the National Institute of Mental Health panel, other health professionals, and the National Drinking Water Advisory Council, all of whom regard dental fluorosis as an adverse health effect, was that the Agency "disagrees"[151] and is "not obliged to uncritically accept such

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148 Final RMCL at 47143, col. 3, App.; Proposed Fluoride RMCL at 20166-7, col. 1, App.

149 Review Panel on the Psychological/Behavioral Effects of Dental Fluorosis, Dr. Robert E. Kleck, Chairperson, Nov. 17, 1984, p.7, App.

150 Proposed Fluoride RMCL at 20167, col. 1, App.

[Cont. next pg.]

advice or views."[152] As mentioned earlier, the Agency did not respond to the conclusions and recommendations to the same effect by the Surgeon General's Ad Hoc Medical Panel on fluoride.

EPA can point to no new data in the record on the medical implications of dental fluorosis to justify its decision to double the allowable level of fluoride in drinking water. On the contrary, data developed since the interim MCL was established in 1975 strongly suggest that the permissible level should have been lowered rather than raised. For example, after discussing many of the studies suggesting possible adverse health effects of fluoride at low levels, members of the Surgeon General's Medical Panel also cautioned that

> from all the available data, we can't state that there [are] no apparent adverse health effects [from] a water fluoride level of two parts per million or below....[W]e don't have enough data to recommend at this stage that a higher level [than] two parts per million is safe for all age groups.[153]

In addition, the New York State Health Department recommended that the RMCL not exceed 1 mg/L.[154] EPA made no response to these recommendations, but simply ignored them.

The Agency also rejected all suggestions that dental fluorosis was a sensitive indicator of fluoride toxicity, responding inappositely that "EPA received no relevant information on whether dental fluorosis in an individual progresses beyond

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151 Response to Comments at 4.

152 Id. at 3.

153 Medical Panel Transcript at 420-21 (emphasis added). See also Section IV, infra for discussion of some of the extensive record data indicating other adverse effects of fluoride at low levels.

154 Letter from Dr. David Axelrod, New York State Commissioner of Health, to Dr. Joseph A. Cotruvo, EPA Office of Drinking Water, July 25, 1985, App.

cosmetic effects to adverse health effects [i.e., crippling skeletal fluorosis]."[155] Although EPA acknowledges that fluoride readily accumulates in bones and teeth,[156] and that dental fluorosis and crippling skeletal fluorosis are related in that both are determined by the bone level of fluoride,[157] the Agency refused, absent conclusive proof, to take into account any possibility that dental fluorosis might be an indicator of systemic harm.[158] Thus, EPA simply ignored unrebutted studies in the record suggesting that "[f]requent exposure to low levels of fluoride over a prolonged period can produce manifestations of chronic fluoride intoxication."[159]

EPA similarly rejected potential psychological and behavioral effects of dental fluorosis as "not...significant enough to be adverse health effects under the Act."[160] Other evidence of permanent harm to teeth, dental dysfunction, chipping and cracking of teeth, and decay at the margins of the pits caused by dental fluorosis, was also discarded because there was "not enough con-

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155 Final Fluoride RMCL at 47146, col. 2, App.

156 Response to Comments at 76.

157 Id. at 83.

158 Id. at 83.

159 Heifetz, S.B. and Horowitz, H.S., The Amounts of Fluroide in Current Fluoride Therapies: Safety Considerations for Children, J.Dent. for Children 257, 260 (July-Aug. 1984), CI at ___. See also, Hodge, H.C. and Smith, F.A., Biological properties of inorganic fluorides. In: Fluorine Chemistry, Vol. IV, ed. Simons, J.H., New York Academic Press, 1965, pp.2-365, CI at ___; Smith, F.A. and Hodge, H.C., Fluoride Toxicity. In: Fluorine and Dental Health, Bloomington, Indiana U. Press, 1969; Hodge, H.C. and Taves, D.R. Chronic toxic effects on the kidneys. In: Fluorides and Human Health, Geneva: World Health Organization 1980: pp. 249-255.

160 Response to Comments at 78.

vincing evidence."[161]

According to the standards set forth in the cases cited above, EPA had an obligation to provide a cogent explanation why its prior conclusion of ten years' duration that dental fluorosis is an adverse health effect, is no longer valid. Instead, the Agency stated that it "agrees" with the Surgeon General, several professional medical and dental associations, and the State of South Carolina, "that the evidence is inadequate to conclude that dental fluorosis is an adverse health effect."[162] It is understandable that EPA would want to cite support for its position when relaxing an existing standard to a level that will produce such significant adverse effects. However, the Agency does not satisfy its duty to provide a reasoned explanation for its abrupt change in course merely by noting the opinions of various groups on the subject at hand. It is the Agency's responsibility to provide an explanation why it no longer considers dental fluorosis to be included in the SDWA's broad protection against "any known or anticipated adverse health effects." The Agency provided no basis for its conclusion except the statement that "adverse health effects, at least for fluoride, should be measured by functional impairment."[163]

Even beyond the total failure to explain its action, the Agency's reliance on these groups was badly misplaced. The groups EPA relied on included the American Medical Association,

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161 Id. at 82.

162 Final Fluoride RMCL at 47143, col. 3, App.

163 Final RMCL at 47146, col. 3 (emphasis added), App.

the Association of State and Territorial Health Officials, the American Dental Association, the Association of State and Territorial Dental Directors, and the National Institute of Dental Research. All of these groups had supported South Carolina's petition to EPA in 1981 to delete fluoride from the enforceable Primary Regulations. According to EPA, these groups were primarily concerned that[164]

> inclusion of fluoride in the primary regulations as a contaminant that poses health risks to consumers will undermine efforts to promote fluoridation of community water supplies where optimal levels of fluoride do not occur naturally.

The partisan nature of their involvement in the fluoride issue is readily apparent; it was openly recognized by EPA when the interim MCL was established in 1975. At that time, the Agency acknowledged that the merits of "[t]he fluoride question [have] been complicated by the fluoridation controversy."[165]

EPA's characterization of the position espoused by these dental and medical groups in the past indicates that their opposition to retaining fluoride in the Primary Regulations is not based upon scientific evidence about the health effects of fluoride. Rather, it is principally a reflection of their concern over the fact that organizations opposed to fluoridation of public water supplies have used EPA's findings about the health risks posed by fluoride in drinking water to advance their cause.

The groups favoring EPA's reversal of position offered no

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164 Proposed Fluoride RMCL at 20166, col. 1 (emphasis added), App.

165 Interim Primary Drinking Water Regulations, 40 Fed. Reg. 59566, 59576, col. 2 (Dec. 24, 1975).

medical data to support their position that dental fluorosis is only a cosmetic effect. The dental groups and the Association of State and Territorial Health officials generally confined their statements to the dental rather than the medical implications of dental fluorosis, relying on the Surgeon General's opinion of the medical effects of exposure to fluoride.[166] And the contribution of the American Medical Association was a two-page letter to the EPA Administrator urging him to drop the mandatory drinking water standard for fluorosis, endorsing fluoridation of public water supplies, and asserting the belief that dental fluorosis is not an adverse health effect.[167]

It is clear from the Agency's final RMCL notice that the principal basis for its conclusion that dental fluorosis is not an adverse health effect is the current Surgeon General's opinion to that effect. EPA's reliance on the current Surgeon General's opinion, however, is especially suspect, and warrants the closest

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166 The American Dental Association submitted undocumented testimony, letters and a 1982 resolution offering their "opinion that the natural fluoride levels of drinking water in the United States do not constitute a health hazard." CI at I-D.48; The Association of State and Territorial Dental Directors offered materials prepared in 1982 containing no data but including a one-page 1980 resolution seeking to have EPA drop fluoride from the Primary Drinking Water Regulations and resolving that "mottling itself [does not] pose a health hazard warranting mandatory imposition of burdensome and costly defluoridation...." The Resolution also stated that "the continued labeling of fluoride as a contaminant and health hazard will undoubtedly undermine the efforts of the dental profession to promote fluoridation...." Id. The Association of State and Territorial Health Officials submitted an almost identical resolution, CI at II-H.217. The National Institute of Dental Research similarly submitted no data relevant to the issue of whether dental fluorosis is an adverse health effect, although it did submit data on the subject of mutagenicity.

167 Letter from James H. Sammons, American Medical Association to Anne M. Gorsuch, May 7, 1982, CI at I-D.47, App.

scrutiny by this Court.

The current Surgeon General is not the definitive authority on the significance of dental fluorosis. First, his views on this issue are not in accord with the opinions of former Surgeons General.[168] Second, the factual basis for the Surgeon General's opinion is questionable. His opinion that dental fluorosis is merely a cosmetic effect and not an adverse health effect was purportedly based on the reports of two panels that he convened to discuss the health effects of fluoride. The first, the Ad Hoc Panel of Dentists convened at EPA's request in 1982, reported to the Surgeon General that "[n]o sound evidence exists which shows that drinking water with the various concentrations of fluoride found naturally in public water supplies in the United States has any adverse effect on dental health as measured by loss of function and tooth mortality."[169] The report contained this same conclusion with regard to general health as well,[170] although the dentists on the panel had no particular medical competence to reach such a conclusion.

It is clear that EPA did not initially regard as dispositive the Ad Hoc dental panel's report and recommendations regarding the effects on general health of fluoride in drinking water. Seeking additional advice on this question, the Agency requested

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168 See, e.g., letter from Surgeon General Julius Richmond to the American Dental Association, July 4, 1980, CI at I-D.26. ("[S]evere levels of fluorosis are characterized by anatomical defects in dental enamel. The gross enamel defects that often occur with this level of fluorosis not only are unattractive but may also require clinical treatment.")

169 Ad Hoc Committee Report on Dental Fluorosis, n. 22, supra, at 6.

170 Id.

in 1983 that the Surgeon General convene a second panel, this time of medical experts, to consider the non-dental health effects of fluoride in drinking water. As discussed above, the medical panel recommended against any fluoride level in drinking water greater than 2 ppm.[171] In direct disagreement with the prior conclusions of the Surgeon General and the Ad Hoc dental panel, the draft of the medical panel's report, which followed the transcript of their meetings, flatly stated:

> The committee favors continuation of fluoride in the primary regulations because of a lack of information regarding fluoride['s] effect on the skeleton in children (to age 9) over 3 ppm, and potential cardiotoxic effects at that level. While not specifically addressing dental effects, there was a consensus that mottling or pitting of teeth could represent as yet unknown skeletal effects in children and that severe dental fluorosis per se constitutes an adverse health effect that should be prevented. There was some sentiment (especially among the pediatricians) in the committee that the age limit for children...should be as high as 18 years because of continued rapid bone development between ages 9 and 18....[172]

When the Surgeon General transmitted the Panel's report and recommendations to EPA in 1984, however, the latter statement was not included. Instead, the Surgeon General reiterated his prior opinion that there is "essentially no likelihood of even non-adverse medical effects where drinking water supplies contain up to four times the optimum concentration of fluoride [i.e., 4-8 mg/L]."[173]

The record contains the transcript of the medical panel's meetings as well as the draft version of their report. Both of

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171 Medical Panel Transcript at 420-21.

172 Draft Medical Panel Report at 14 (emphasis added), CI at I-D.82.

173 Quoted in Proposed Fluoride RMCL at 20166, col. 3, App.

these documents directly contradict the opinion of the Surgeon General on the significance of dental fluorosis, and on the other hazards of fluoride in drinking water above 2 mg/L. However, EPA did not respond to or even acknowledge the serious medical concerns raised by the panel. Nor did the Agency address the glaring discrepancy in views between the Surgeon General and the expert medical panel.

EPA's position on the issue of dental fluorosis does violence to the preventive orientation of the Safe Drinking Water Act. It also contravenes the clear intention of Congress that EPA err on the side of safety in evaluating evidence of adverse health effects. The Agency's mandate in establishing RMCLs, which are health goals, is to protect against any known or anticipated adverse health effects with an adequate margin of safety. With regard to dental fluorosis, however, the Agency opted for far less protection of the public than it believed to be necessary for the past decade, despite extensive evidence and opinion in the record that caution against such a change.

This Court has held that "sudden and profound alterations in an agency's policy constitute 'danger signals' that the will of Congress is being ignored."[174] Where, as here, the Agency has "swerve[d] from prior precedents,"[175] has made a decision that clearly "deviates from and ignores the ascertainable legislative

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174 Small Refiner Lead Phase-Down Task Force v. EPA, 227 U.S. App. D.C. at ____, 705 F.2d at 526, citing State Farm Mutual Ins. Co. v. DOT, 243 U.S. App. D.C. 117, 680 F.2d 206, 221 (1982), aff'd, 103 S.Ct. 2856 (1985).

175 Electricity Consumers Resource Council v. F.E.R.C., 241 U.S. App. D.C. 397, 747 F.2d 1511, 1517 (1984).

intent,"[176] and cannot point to persuasive evidence in the record for support, that decision should be overturned.

IV. The RMCL of 4 mg/L Fails to Protect Against a Series of Known and Potential Health Risks Posed by Exposure to Fluoride in Drinking Water

EPA established the health goal for fluoride in drinking water at 4 mg/L even though in 1980 the National Academy of Sciences had warned that

> until more precise measures of the margin of safety for the use of fluoride are available, the levels of fluoride in drinking water should not exceed the optimal levels for anticariogenic benefits [0.7 to 1.4 mg/L]."[177]

Moreover, because of the inordinately narrow definition of "adverse health effect" adopted by EPA for fluoride, the Agency rejected a very large body of evidence documenting or suggesting various chronic adverse health effects associated with exposure to low levels of fluoride.

By the Agency's own admission, "numerous articles were submitted dealing with chronic toxicities associated with exposure to fluoride."[178] In addition to evidence indicating that dental fluorosis is an adverse health effect, the Agency rejected all of

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176 Ethyl Corp. v. EPA, 176 U.S. App. D.C. 373, 541 F.2d 1, 36, cert. denied, 426 U.S. 941 (1971), quoting Greater Boston Television Corp. v. F.C.C., 143 U.S. App. D.C. 383, 392, 444 F. 2d 841, 850 (1970), cert. denied, 403 U.S. 923 (1971).

177 National Academy of Sciences, Drinking Water and Health 282 (Washington, D.C., 1980).

178 Response to Comments at 74. These toxicities included "carcinogenicity, teratogenicity, mutagenicity, allergic responses, cardiovascular effects, dental fluorosis, enzyme inhibition, hepatotoxicity, renal effects, metabolic effects, inhibition of protein synthesis, reproductive effects, protoplasmic poisoning, skeletal effects, thyroid effects, urinary tract effects, adverse effects on animals, and cAMP effects [influences on rate of protein synthesis]." Id. at 74-75.

the evidence about all of the other adverse health effects as either not conclusive, not demonstrated in humans, not widespread in the United States population, or not causative of clinically significant impairment of function. Thus, EPA effectively found that none of the numerous studies submitted raised even a possibility of an adverse health effect.

The administrative record in this case is very large, containing more than 400 written comments, many with attachments, and involving two public hearings.[179] It also contains written comments, testimony and scientific documentation from two prior administrative proceedings related to revision of the fluoride MCL.[180] Certainly, in such a large record, some and perhaps many of the studies submitted were poorly conducted, not statistically significant, deficient in design, or otherwise questionable. It defies credulity, however, for EPA to assert that none of the voluminous body of scientific studies on the health effects of fluoride satisfied the Agency's criteria for valid evidence of an actual or potential adverse health effect "within the meaning of the SDWA."[181] Nevertheless, EPA found that "with the exception of crippling skeletal fluorosis,..."no sound evidence exists which shows that drinking [water] with the various concentrations of fluoride found naturally in public water supplies in the U.S. has

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179 Final Fluoride RMCL at 47145, cols. 2-3, App.

180 MCL for Fluoride, Response to Petition for Rulemaking, 46 Fed. Reg. 58345 (Dec. 1, 1981); National Revised Primary Drinking Water Regulations; Advance Notice of Proposed Rulemaking, 48 Fed. Reg. 45502 (Oct. 5, 1983).

181 Response to Comments at 10.

an adverse effect on health."[182] NRDC submits that this finding is suspect on its face. A brief survey of the grounds for EPA's arbitrary and capricious rejection of all of that "unsound" evidence follows.

A. Osteosclerosis

The Agency admits that "chronic ingestion of high levels of fluoride can result in osteosclerosis,"[183] an increase in bone density which is the "mildest form" of skeletal fluorosis.[184] Indeed, ample evidence in the record suggests that osteosclerosis is an early effect of skeletal fluorosis, which causes arthralgias (stiff and painful joints) and crippling in its most severe form.[185] EPA concedes that all of the manifestations of fluorosis, i.e., mild dental fluorosis, osteosclerosis, severe skeletal fluorosis, and crippling skeletal fluorosis, are related because they "are determined by the bone level of fluoride."[186] The Agency also does not dispute that "fluoride readily accumulates in bones and teeth,"[187] that osteosclerosis can occur in humans at levels as

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182 Final RMCL at 47144, col. 3 (emphasis added), App. (quoting 1982 statements by the Surgeon General and the Chief Dental Officer of the U.S. Public Health Service).

183 Final Fluoride RMCL at 47152, col. 1, App.

184 Response to Comments at 130.

185 See, e.g., Roholm, K., 1937, FLuorine Intoxication: a clinical hygienic study, with a review of the literature and some experimental investigations, London: Lewis and Co., pp. 140-147, cited in CI at II-H.366; Smith, F.A. and Hodge, H.C., 1959. Chapter 1. Fluoride toxicity. IN: Muhler, J.C., Hine, M.K., eds. Fluorine and Dental Health, the pharmacology and toxicology of fluorine. Bloomington, IN: U. of Indiana Press, pp. 19-20, cited in CI at II-H.366; see also, Medical Panel Transcript at 390-391, 394-395.

186 Response to Comments at 48, 130.

[Cont. next pg.]

low as 3 mg/L, [188] and that skeletal fluorosis "increases in severity with both dose of fluoride and duration of exposure...."[189] Like dental fluorosis, osteosclerosis is an indicator of fluoride-induced physiological changes in the body.[190]

For this reason, the World Health Organization set its drinking water guideline for fluoride at 1.5 mg/L to protect against osteosclerosis and dental fluorosis as well as crippling skeletal fluorosis.[191] Nevertheless, applying its unduly exclusionary criteria for an 'adverse health effect,' the Agency concluded that it could find

> no evidence that fluoride induced increases in bone density, osteosclerosis, result in bodily harm or impaired functioning of the body. ...[Therefore,] osteosclerosis is not an adverse health effect within the meaning of the SDWA.[192]

This conclusion by EPA stands in dramatic contrast to the approach the Agency has adopted in setting primary, i.e., health-protective, standards for other environmental contaminants. For example, in establishing a primary standard for exposure to air-

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187 Response to Comments at 76.

188 Proposed Fluoride RMCL at 20167, col. 2, App.; Response to Comments at 128; see also National Academy of Sciences, Drinking Water and Health 380 (Washington, D.C., 1977), CI at II-C3.8.

189 Proposed Fluoride RMCL at 20170, col. 2, App.

190 EPA should have given serious consideration to the significance of the physiological changes represented by osteosclerosis (and dental fluorosis), since one of the considerations Congress directed EPA to take into account in setting RMCLs is "contaminant exposure and body burden levels which alter physiological function or structure in a manner reasonably suspected of increasing the risk of illness." See discussion at pp. 20-21, supra.

191 World Health Organization, Guidelines For Drinking Water Quality, Vol. I, Recommendations, WHO, Geneva, Switzerland, 1984; cited in Proposed Fluoride RMCL at 20167, col. 2, App.

192 Final Fluoride RMCL at 47152, col. 1 (emphasis added) App.

borne lead under an analogous standard-setting provision of the Clean Air Act,[193] the Agency set the protective exposure level at a concentration which is indicative of a significant body burden of lead. To provide an adequate margin of safety against serious effects that appear at higher concentrations, the Agency characterized as an adverse health effect a lower blood lead concentration that "indicates that lead has already begun to affect basic biological functions in the body."[194] In upholding the Agency's action against a challenge that it was controlling a merely "subclinical effect," this Court stated:

> [The] "subclinical" effect in no way implies that it is improper to consider it adverse to health.... [I]t indicates a lead-related interference with basic biological functions. Expert medical testimony...confirms that the modern trend in preventive medicine is to detect health problems in their "subclinical" stages, and thereupon to take corrective action.[195]

In the instant case, there is extensive evidence in the record that many medical experts consider osteosclerosis to be not merely a subclinical effect, but an adverse health effect per se.[196] At the very least, that evidence suggests the clear

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193 Section 109(b)(1) of the Clean Air Act, 42 U.S.C. §7409(b)(1), provides that "National primary ambient air quality standards... shall be ambient air quality standards the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health."

194 Lead Industries, 208 U.S. App. D.C. at ___, 647 F.2d at 1157.

195 Id. at 1158; The National Academy of Sciences has similarly cautioned that "[d]rinking water contains low concentrations of many chemicals, some of which, if ingested for a long time, could have delayed toxic effects. The insidious effect of chronic exposure to low doses of toxic agents is difficult to recognize, because often there are few early warning signs and, when signs are ultimately observed, the effects may have become irreversible." National Academy of Sciences, Drinking Water and Health 21 (Washington, D.C., 1977), CI at I-B1.1.

[Cont. next pg.]

possibility that osteosclerosis may be an adverse health effect. Yet, EPA rejected all of the substantial body of evidence on osteosclerosis, despite its admission that osteosclerosis is the first stage of a disease that can lead to crippling skeletal fluorosis.

The reason offered to justify the Agency's conclusion that "osteosclerosis is not an adverse health effect within the meaning of the SDWA"[197] is that it "does not appear to cause clinically significant effects and does not impair the functioning of the body."[198] Congress did not require that "clinically significant" effects and "impaired function" be demonstrated before an effect can be considered an "adverse health effect." EPA's rigid adherence to these criteria as prerequisites for a finding of adverse health effect contravenes the precautionary and preventive intent of the statute and is, therefore, arbitrary, capricious and in excess of the Agency's statutory authority.

B. Growth stunting

Evidence of another adverse skeletal effect of low-level exposure to fluoride, growth stunting, was also rejected by EPA despite valid studies showing skeletal retardation in Japanese and Tanzanian children exposed to fluoride concentrations of 3.4 and 3.6 mg/L, respectively.[199] The record also contains studies

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196 The Agency reviewed and rejected more than 25 separate scientific papers documenting pathological skeletal changes attributable to fluoride-induced osteosclerosis and more severe stages of skeletal fluorosis. See Response to Comments at 117-132, App.

197 Final Fluoride RMCL at 47152, col. 1, App.

198 Response to Comments at 15; see also Id. at 75, 88, 127, 128, 130.

199 Takamori, T., 1955, Recent studies on fluorosis, Tokushima J. Exptl. [Cont. next pg.]

showing possible fluoride-related adverse growth effects in cattle.[200] EPA's Criteria Document on fluoride further acknowledges that prescribed therapeutic dosages of fluoride used for treating hearing loss are limited in children to only "1.5 to 10 mg/day...to avoid stunting growth."[201]

All of these studies were ignored by EPA in setting the RMCL at 4 mg/L because the effects had not been observed in the United States,[202] because another study did not identify a similar effect in Danish girls exposed to lower levels of fluoride in their drinking water, and because the evidence did not conclusively prove that "fluoride in U.S. drinking water is associated with stunting the growth."[203] Thus, rather than erring on the side of safety as Congress directed, EPA chose to resolve the uncertainty by ignoring the evidence.

Not only is the conclusive proof standard illegal, but in making this determination, the Agency also arbitrarily and capriciously failed to address, and, indeed, neglected even to mention the concerns about growth stunting that were also raised by the Surgeon General's Medical Panel on Fluoride in 1983. The transcript of their meeting contains several references to the

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Med. 2:25-44, Response to Comments at 129; Wenzel, et al., 1982, The relationship between water-borne fluoride, dental fluorosis and skeletal development in 11-15 year old Tanzanian girls. Archs. Oral Biol. 27:1007-1011, Response to Comments at 129.

200 See, e.g., Suttie, et al., 1957, Studies of the effects of dietary sodium fluoride on dairy cows, I. The physiological effects and the development of symptoms of fluorosis. J. Nutr. 63:211-224, C.I. at ___.

201 Criteria Doc. at VI-9 (emphasis added).

202 Response to Comments at 128.

203 Response to Comments at 129.

Panel's concerns about the skeletal maturation studies,[204] and the need to determine whether similar adverse effects are occurring in this country.[205] That these experts, who were brought together at EPA's request to review the medical effects of fluoride in drinking water, considered the possibility of growth stunting to be real and immediate, is beyond dispute. That EPA violated its duty under the law by ignoring these concerns in setting the RMCL is also beyond dispute.

C. Adverse Cardiovascular effects

The entire record in this case shows EPA's pattern of rejecting all studies but those conclusively documenting an adverse effect in the United States population. Another egregious example of the Agency's irrational disregard of the scientific evidence involves studies indicating possible cardiotoxic effects of fluoride in drinking water.

The record contains two Japanese studies[206] describing cardiovascular changes in children and adults at drinking water concentrations as low as 2.5 mg/L. Changes observed at this dose level, which is significantly lower than the RMCL of 4 mg/L, included "myocardial damage, sinus tachycardia and prolonged P-R and Q-T intervals."[207] Animal studies reviewed by EPA also showed

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204 Medical Panel Transcript at 354-358, 361.

205 Medical Panel Transcript at 274, 361, 453-4, 459, 470.

206 Okushi, I., 1954, Changes of the heart muscle due to chronic fluorosis. Part I. Electrocardiogram and heart X-ray picture made in inhabitants of high-fluorine zone. Shikoku Acta. Med. 5: 159-165, CI at __; Takamori, T., 1955, Recent studies on fluorosis, Tokushima J. Exptl. Med. 2:25-44. CI at __.

207 Criteria Doc. at VI-31.

fluoride-induced "hypotension, electrocardiogram irregularities and slowing of the heart in dogs",[208] and similar adverse cardiovascular effects in rabbits.[209] The Surgeon General's Medical Panel on Fluoride discussed the significance of these effects at some length,[210] expressing concern that one "would not expect to find these kind of EKG [electrocardiogram] changes in some 15-odd children."[211]

Despite this evidence of reasonable medical concern, EPA summarily dismissed the possibility of fluoride-related adverse cardiovascular effects because "there is inadequate evidence to conclude"[212] that an association exists with exposure to fluoride in United States drinking water. NRDC submits that the existence of such evidence, indicating potential adverse health effects in humans at levels lower than the RMCL, suffices to invalidate the RMCL as violative of the Safe Drinking Water Act.

D. Carcinogenicity and Mutagenicity

EPA received thirteen scientific papers concerning epidemiological evidence of the potential carcinogenicity of fluoride;[213]

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208 Response to Comments at 72.

209 Criteria Doc. at V-26.

210 Medical Panel Transcript at 165-168, 338, 459.

211 Id. at 339. Members of the panel further observed that their concerns were answerable "if somebody would go into one...or several of the communities in this country where fluoride intake is between 2 and 8 mg/L in drinking water and do some EKG studies and do some skeletal turnover studies and do some skeletal maturity studies and try to determine what is really going on with these kids." Id. at 361. To date, such studies have not been conducted.

212 Final Fluoride RMCL at 47152, col. 3.

213 Final Fluoride RMCL at 47150, col. 2, App.

the record also contains 4 occupational studies showing excess deaths possibly attributable to fluoride exposure,[214] and several controversial animal studies, [215] including one that the Agency agrees suggests a tumorigenic response.[216] In addition, the National Toxicology Program currently has an animal bioassay underway to determine whether fluoride is carcinogenic. The results are expected in 1988.[217]

The human epidemiological studies claiming to show a link between cancer incidence and fluoridation of municipal water supplies are extremely controversial and have been criticized by EPA and others.[218] Nevertheless, the National Academy of Science's caveat regarding the lesson to be drawn from the available cancer studies remains pertinent:[219]

> [s]ome linkage [between fluoridation and cancer] may not be unreasonable...for fluoride will exist primarily as hydrofluoric acid, a highly penetrating and irritating chemical, in the acidic stomach.

The same NAS report also concluded that "[o]ther observations of possible positive correlations between fluoride intake and cancer, although not conclusive, deserve attention and further investigation."[220]

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214 Response to Comments at 61-62.

215 Id. at 62.

216 Response to Comments at 62.

217 Criteria Doc. at V-33.

218 Final Fluoride RMCL at 47150, col. 2, App. __; Response to Comments at 51-60.

219 National Academy of Sciences, Drinking Water and Health 385 (Washington, D.C., 1977).

[Cont. next pg.]

Despite the controversy, EPA concluded decisively that fluoride does not cause or contribute to cancer.[221] While it is certainly true that the available evidence does not show conclusively that fluoride poses a cancer risk to humans, a serious question of fluoride's potential carcinogenicity remains. Eleven of the 13 papers cited by EPA concluded that fluoride is oncogenic; the ongoing bioassay by the National Cancer Institute also shows that the issue remains open. So also does correspondence between EPA and a distinguished epidemiologist who has studied the potential link between fluoride and occupational cancer, Dr. Philippe Grandjean. Although the Agency cited a recent Grandjean article to support its conclusion that fluoride is not carcinogenic,[222] Dr. Grandjean specifically advised EPA in August, 1985, in reply to an inquiry from the Agency's senior drinking water scientist, that "[t]he question of carcinogenicity has not been solved."[223] This critically important question should have been answered before EPA decided to relax the Primary Regulation for fluoride and to allow exposure levels in drinking water to double.

Evidence of fluoride's activity at a molecular level raises additional questions concerning its role as a possible carcinogen or mutagen. Among more than 40 mutagenicity references in the record are many studies suggesting that fluoride is mutagenic in

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220 Id. at 387.

221 Final Fluoride RMCL at 47150, col. 2, App.

222 Id.

223 Letter from Dr. Philippe Grandjean to Dr. Joseph Cotruvo dated August 21, 1985, CI at II-H.395; App.

some test systems.[224] Although there are several negative studies, EPA concedes that fluoride has been shown to be mutagenic in "a few properly conducted positive studies."[225] The record also shows that positive results were reported in unscheduled DNA synthesis (UDS) assays, which EPA has characterized as "quite sensitive"[226] and "shown to detect a wide range of chemical carcinogens and mutagens."[227]

The Agency's rationale for excluding mutagenicity from the category of potential adverse health effects of fluoride was that "an unequivocal determination of the mutagenicity of [fluoride] cannot be made."[228] The reasons given included "the variability of responses in various test systems, limitations in the quality of the studies evaluated and the lack of a clear trend of adequate evidence demonstrating either a positive or negative mutagenic reponse...."[229] Yet, the Agency's Mutagenicity Guidelines indicate that "often one does not find consistent positive or negative results across all tests. Chemicals may show positive effects for some end points in some test systems, but negative responses in others."[230]

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224 Response to Comments at 96-110.

225 Id. at 102.

226 Id. at 100.

227 Id.

228 Id. at 102.

229 Id.

230 EPA Proposed Guidelines for Mutagenicity Risk Assessment; 49 Fed. Reg. 46314, at 46319, col. 3 (Nov. 23, 1984).

EPA's treatment of the positive mutagenicity evidence on fluoride provides yet another example of the arbitrary and capricious decisionmaking that characterized this rulemaking. After conceding that the record contains valid positive evidence that fluoride is mutagenic in some test systems, the Agency rejected all of the mutagenicity evidence, refusing to acknowledge that the more than 40 scientific papers evaluated on this issue suggest even a possibility of mutagenicity.

Congress did not intend the public to bear the risk that fluoride in drinking water might pose a mutagenic or carcinogenic risk to humans. EPA's improper exclusion of carcinogenicity and mutagenicity from the category of possible adverse health effects of fluoride imposed that risk squarely on the public, in flagrant violation of the clear intent of the Safe Drinking Water Act.

E. Adverse reproductive effects

The record includes evidence that fluoride produced adverse reproductive effects in cattle, and in laboratory studies on Drosophila melanogaster (flies used in genetic testing). EPA acknowledged that cows receiving 5 mg/L of fluoride in their drinking water, a level that barely exceeds the RMCL, "evidenced a significant decrease in calving rates compared to controls."[231] Significantly,

> the decrease in calving rates preceded the development of dental or skeletal fluorosis. This suggests that the reproductive effects of fluoride are primary rather than a consequence of impaired health due to dental effects or skeletal fluorosis.[232]

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231 Response to Comments at 113, citing a 1966 study by Van Rensburg and De Vos (emphasis added), CI at III-F.1.

[Cont. next pg.]

The Agency also acknowledged that the Drosophila studies demonstrated a "highly significant difference in...fecundity" at low levels of fluoride exposure, i.e., 1.3 to 2.9 ppm for six weeks.[233] In addition, "hatchability was depressed...by increasing the fluoride concentration or by prolonging the duration of treatment."[234]

Despite the Agency's recognition that the cattle study clearly showed adverse reproductive effects due to fluoride exposure, it was excluded by EPA in setting the RMCL because "the results are not conclusive in predicting reproductive effects in heifers at levels found in U.S. drinking water."[235] The positive Drosophila evidence was disregarded because fluoride-related adverse reproductive effects have not been documented in humans.[236] Once again, well-conducted studies indicating a risk of potentially serious adverse effects in humans were totally ignored by EPA in setting the RMCL because of the Agency's improperly narrow definition of an adverse health effect of fluoride.

EPA's insistence that animal studies be conclusive and that laboratory evidence be corroborated by human evidence as a prerequisite to consideration in setting health goals (RMCLs) is flatly contrary to the preventive approach mandated by the Safe Drinking Water Act. It also departs radically from EPA's well-

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232 Response to Comments at 113 (emphasis added).

233 Id.

234 Id. at 113.

235 Id. (emphasis added).

236 Id. at 37.

established practice of utilizing animal and laboratory evidence to predict potential adverse health effects in humans.[237]

Congress did not give EPA the discretion to ignore admittedly valid animal and laboratory evidence in establishing RMCLs under the statute. The House Report specifically states that a determination of whether a contaminant causes adverse health effects may be based on "evidence of either animal or human toxicity or disease."[238] In the instant case, animal data suggest the existence of a health risk to humans. The "large human exposure data base"

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237 For example, in announcing the interim Primary Drinking Water Regulations for trihalomethanes, the Agency followed the four principles on human risk assessment set forth in the 1977 report of the National Academy of Sciences, Drinking Water and Health, which EPA stated "are representative of the consensus of scientific opinion." National Interim Primary Drinking Water Regulations; Control of Trihalomethanes in Drinking Water; Final Rule, 50 Fed. Reg. 68627, col. 2 (Nov. 29, 1979); App. The first principle states that "[e]ffects in animals, properly qualified, are applicable to man." According to the third principle, "[e]xposure of experimental animals to toxic agents in high doses is a necessary and valid method of discovering possible carcinogenic hazards in man." Id. The trihalomethanes notice also stated that EPA had extrapolated from the results of animal studies to protect against the risk posed by these contaminants to humans because "epidemiology [i.e., studies of the incidence of disease in human populations exposed to varying contaminant levels] per se cannot 'prove' causality, and because it may well be impossible to epidemiologically establish a strong causal association that THMs [trihalomethanes] and related chemicals in drinking water contribute to higher cancer rates...." Id. at 68627, col. 3, App.

Similarly, in promulgating the final RMCL for eight volatile synthetic organic chemicals, the Agency set the RMCL at zero for chemicals for which there is "sufficient human or animal evidence of carcinogenicity to warrant their regulation as known or probable human carcinogens." Final RMCLs for Volatile Organics at 46885, col. 3, App. EPA established final RMCLs at zero based only on animal studies for carbon tetrachloride (Id. at 46886, col. 3, App.), 1,2-dichloroethane (Id. at 46886, col. 3, App.), and trichloroethylene (Id. at 46887, col. 2, App.). In addition, the Agency stated that its policy is to establish RMCLs for chemicals "for which some limited but insufficient evidence of carcinogenicity exists from animal data." (Id. at 46885, col. 3, App. __ (emphasis added).)

238 House Report at 10, App.

from which EPA alleges these effects are absent[239] consists primarily of examinations of children's teeth for evidence of dental fluorosis.[240] No systematic attempt has ever been made to identify a relationship between fluoride exposure and adverse reproductive effects in the human population -- nor could such an effect easily be identified.

Under these circumstances, EPA had a duty to err on the side of safety and to protect against the possibility of such effects in humans in setting the RMCL. The Agency failed to do so because there is not conclusive proof that the effect will occur in humans. In the context of the Safe Drinking Water Act's precautionary orientation, EPA's decision to exclude adverse reproductive effects from the category of potential adverse health effects of fluoride was arbitrary, capricious and an abuse of discretion.

F. Adverse kidney effects

The Agency admitted that exposure to fluoride poses special risks to the renally-impaired:[241]

> The Agency agrees that certain segments of the general population may be at increased risk from waterborne fluoride. For example, polydipsia and polyuria associated with diabetes insipidus and some forms of renal impairment may result in an excessive intake of drinking water and waterborne fluoride. The renal clearance of fluoride...may be markedly reduced in some patients with kidney disease....

The record also includes case studies of "four fatalities in

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239 Response to Comments at 37.

240 Medical Panel Transcript at 463.

241 Final Fluoride RMCL at 47151, cols. 2-3 (citations omitted), App. ; see also Response to Comments at 115.

which fluoride levels in drinking water were 1 to 4 ppm."[242] Nevertheless, EPA determined that "there is no data - whether human data or experimental animal data - adequate to conclude that exposure to fluoride in U.S. drinking water leads to renal toxicity."[243] Applying the erroneous "conclusive proof" standard, the Agency excluded all of this evidence from consideration in setting the RMCL. The Agency also failed to explain why the studies did not at the very least suggest the existence of a risk of renal toxicity.

The illogic of EPA's flawed decisionmaking is well illustrated by the reason given for rejecting the report showing four fatalities at fluoride levels between 1 and 4 ppm. Although renal impairment was involved in each case,

> [t]he authors failed to demonstrate...whether these fatalities represent renal impairment due to the ingestion of fluoridated water or are examples of increased retention of fluoride because of impaired kidneys.[244]

Either way, the clear evidence of risk represented by these cases was not rebutted by EPA or by other record evidence. Whether the fluoride drinking water exposure caused the kidney disease that resulted in death, or merely exacerbated it, the association with fluoride in drinking water and the resulting risk should not have been disregarded by EPA.

The record shows that millions of diabetics and other known or likely to be renally-impaired individuals consume large vol-

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242 Response to Comments at 94, citing Zanfagna, 1966, CI at __.

243 Response to Comments at 95 (emphasis added).

244 Id. at 94.

umes of water daily;[245] EPA admits they are at increased risk of retaining "more fluoride than normal."[246] The law requires EPA to protect these individuals against both known and anticipated adverse effects with an adequate margin of safety. The Agency erred in failing to do so. The exclusion of kidney impairment from the category of adverse health effects associated with fluoride in drinking water provides still another example of EPA's arbitrary and capricious decisionmaking in setting the fluoride RMCL.

G. Enzyme inhibition

EPA acknowledges that the record contains significant evidence showing that "a number of enzymes are inhibited by fluoride under in vitro conditions [i.e., cells or tissues in culture]...."[247] This evidence was rejected, however, because "there is no convincing evidence that significant enzyme inhibition associated with fluoride in U.S. drinking water occurs in humans...."[248] Once again, admittedly valid experimental evidence was entirely disregarded for lack of "convincing" human evidence.

EPA made no effort to explain why this evidence did not meet the statutory "may have any adverse effect" requirement.[249] Nor did

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245 Final Fluoride RMCL at 47151, cols. 2-3, App. _____; NRDC Comments at 12.

246 Final Fluoride RMCL at 47151, col. 3, App.

247 Final Fluoride RMCL at 47152, col. 3, App. ; Response to Comments at 84, citing National Academy of Sciences, Drinking Water and Health, 1980, CI at I-B1.1, and other studies.

248 Final Fluoride RMCL at 47152, col. 3 (emphasis added) (citations omitted), App.

249 §1412(b)(1)(B), 42 U.S.C. §300g-1(b)(1)(B). The provision requires that [Cont. next pg.]

the Agency explain how its conclusion was consistent with the preventive standard of proof set forth in the House Report on the Safe Drinking Water Act, which states:[250]

> Because of the essentially preventive purpose of the legislation,...the Committee did not intend to require conclusive proof that any contaminant will cause adverse health effects....Rather, all that is required is that the Administrator make a reasoned and plausible judgment that a contaminant may have such an effect.

The Supreme Court has held that an agency "must cogently explain why it has exercised its discretion in a given manner,"[251] and that, absent findings and analysis to justify the choice made, the agency action is arbitrary and capricious.[252] In the instant case, EPA failed to provide any reasoned explanation of why the enzyme inhibition evidence in the record indicates absolutely no risk to humans. The only reason offered was that there is not convincing and significant human evidence, and "even if such were the case, there is no evidence to suggest that such inhibition leads to some adverse health effect not previously identified (i.e., crippling skeletal fluorosis)."[253]

The absurdity of the Agency's position is painfully apparent. EPA does not deny that the enzyme inhibition data are valid. Instead, the Agency argues that no human evidence is

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EPA establish RMCLs and MCLs for contaminants which "may have any adverse effect on the health of persons."

250 House Report at 10 (emphasis in original), App.

251 State Farm, 463 U.S. at _____, 103 S. Ct. at 2869.

252 Burlington Truck Lines v. U.S., 371 U.S. 156, 167 (1962), cited for definition of the arbitrary and capricious standard in State Farm, 463 U.S. at _____, 103 S.Ct. at 2869.

253 Response to Comments at 84.

available, and even if it were, it has not been shown to lead to crippling skeletal fluorosis. The fact is that enzyme inhibition may lead to other chronic effects such as adverse liver and kidney effects[254] or birth defects.[255] These effects are in themselves of concern and have nothing to do with crippling skeletal fluorosis. NRDC submits that EPA cannot ignore this evidence without explanation simply because it is unrelated to crippling skeletal fluorosis. The Agency's conduct in doing so was patently arbitrary and capricious.

H. Other chronic effects

The Agency's pattern of cursory review and dismissal of evidence for failure to show conclusive proof of significant harm or functional impairment in humans or a direct relationship to crippling skeletal fluorosis, was repeated for several other chronic effects. Among these were sensitivity and allergic effects,[256] adverse metabolic effects,[257] and collagen (protein)

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254 Response to Comments at 85.

255 Id. at 46-47. (Summary dismissal of a recent warning in the New England Journal of Medicine regarding fluoride-related enzyme inhibition and birth defects. See Response to Comments, Appendix: Reference: Villee, C.A., 1984. Birth defects and glycolysis. N. Engl. J. Med. 310(4):254-255.)

256 Strongly suggestive studies and reports in the record showing allergic sensitivity were rejected as not "unequivocally" shown or "lacking a true cause-effect relationship." See Final Fluoride RMCL at 47152, col. 2, App. ; Response to Comments at 38, 39, 41, 43. EPA even refused to credit cautions about allergic reactions to fluoride appearing in widely-recognized references such as the Physicians Desk Reference. Response to Comments, Appendix Reference: Physicians Desk Reference, 1985.

257 Evidence of adverse metabolic effects was disregarded for the following reasons: "while fluoride may interefere with various metabolic roles....there is no convincing evidence to suggest that such interruption leads to some adverse effect not previously identified

[Cont. next pg.]

synthesis inhibition.[258] The same cavalier treatment of potentially serious adverse health effects evidence is also apparent in the Agency's rejection of studies suggesting or statistically documenting adverse liver effects,[259] and white blood cell inhibition.[260]

Consistent with relevant standards of judicial review,[261] EPA

(e.g., crippling skeletal fluorosis)." Response to Comments at 96.

258 The record contains two recent rat studies documenting fluoride-related interference with collagen synthesis and fracture healing, and with collagen synthesis and connective tissue metabolism. See Uslu, B. 1983. Effect of fluoride on collagen synthesis in the rat. Res. Exp. Med. (Berl.) 182:7-12, cited in Response to Comments at 112; and Response to Comments, Appendix Reference: Drozdz, M., et al. 1981. Studies on the influence of fluoride compounds upon connective tissue metabolism in growing rats. Tox. Envir. Res. 3:237-41. The former study was rejected because "inadequate data are available to conclude that exposure to low levels of fluoride in drinking water results in adverse effects upon collagen. However, even if such were the case, there is no evidence to suggest that such inhibition leads to some adverse health effect not previously identified (e.g., crippling skeletal fluorosis)." Response to Comments at 112. The latter study was rejected as an inhalation study that was "not relevant" to ingestion via drinking water. Response to Comments, Appendix Reference: Drozdz, Response based on review of the reference. This is another example of EPA's arbitrary use of a special stringent standard for fluoride. The day before the Final Fluoride RMCL was published, EPA had stated in the notice setting eight RMCLs for volatile organics in drinking water that "while a drinking water study is preferred, an inhalation study may be useful for assessing drinking water effects and may be the basis for an RMCL...." Final RMCLs for Volatile Organics at 46894, col. 3, App.

259 Final Fluoride RMCL at 47152, col. 3, App. ; Response to Comments at 92: "[T]his disease [of the liver] appears to have no clinical significance (i.e., there is no significant impairment of the functioning of the human body) and therefore, is not considered an adverse health effect." The question of whether this "benign constitutional liver disorder," associated with fluoride exposure at 0.9-1.2 mg/L, could lead to more serious liver disease was not addressed.

260 An in vitro study of white blood cell inhibition by fluoride was rejected as "not necessarily relevant" because "[t]here is, at present, no in vivo evidence to corroborate the potential occurrence of these effects in humans or other populations." Response to Comments, Appendix Reference: Gabler, Response based on review of the reference.

261 See discussion of the applicable standard of review and cases cited in Section II.A., supra pp. 24-25.

was required to provide more of a justification for rejecting evidence of potentially serious adverse health effects of fluoride than simply lack of conclusive proof of harm to humans. Nor can EPA impose irrational requirements that all adverse effects must be shown to lead to crippling skeletal fluorosis in order to qualify as adverse health effects "within the meaning of the SDWA."[262] In setting forth the basis for the fluoride RMCL, the Agency utterly failed to provide any reasonable explanation for an action that appears "manifestly contrary to the statute," and is judicially reversible for that reason.[263]

V. Conclusion

EPA's establishment of the RMCL for fluoride at twice the level previously allowed in drinking water, a level at which the record shows harm will occur, represents a flagrant instance of arbitrary and capricious agency decisionmaking. The Agency's action was not only a drastic and unjustified reversal of ten years of preventive health protection against dental fluorosis, but it also directly contravenes the specific intent of C
that health goals under the SDWA
of safety for everyone against all known and anticipated adverse health effects. Moreover, by intentionally defining "adverse health effects" of fluoride so narrowly as to preclude protection against any other disease except crippling skeletal fluorosis,

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262 Response to Comments at 10.

263 Chevron, U.S.A. v. Natural Resources Defense Council, 104 S. Ct. at 2782.

EPA totally ignored extensive evidence that at the very least suggests other serious risks of harm to human health from exposure to fluoride in drinking water.

If this decision is allowed to stand, the record shows that a significant portion of the population will suffer permanent injury to their health from crippling skeletal fluorosis and dental fluorosis. Such a result is directly contrary to the stated intent of Congress in enacting the SDWA as a preventive health statute. The Agency's decision to establish the RMCL for fluoride at 4 mg/L should be reversed.

Respectfully submitted,

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April 18, 1986

ATTACHMENTS

ATTACHMENT A

SAFE DRINKING WATER ACT - Section 1401, 42 U.S.C. §300f:

For purposes of this subchapter:

(1) The term "primary drinking water regulation" means a regulation which—

(A) applies to public water systems;

(B) specifies contaminants which, in the judgment of the Administrator, may have any adverse effect on the health of persons;

(C) specifies for each such contaminant either—

(i) a maximum contaminant level, if, in the judgment of the Administrator, it is economically and technologically feasible to ascertain the level of such contaminant in water in public water systems, or

(ii) if, in the judgment of the Administrator, it is not economically or technologically feasible to so ascertain the level of such contaminant, each treatment technique known to the Administrator which leads to a reduction in the level of such contaminant sufficient to satisfy the requirements of section 300g–1 of this title; and

(D) contains criteria and procedures to assure a supply of drinking water which dependably complies with such maximum contaminant levels; including quality control and testing procedures to insure compliance with such levels and to insure proper operation and maintenance of the system, and requirements as to (i) the minimum quality of water which may be taken into the system and (ii) siting for new facilities for public water systems.

(2) The term "secondary drinking water regulation" means a regulation which applies to public water systems and which specifies the maximum contaminant levels which, in the judgment of the Administrator, are requisite to protect the public welfare. Such regulations may apply to any contaminant in drinking water (A) which may adversely affect the odor or appearance of such water and consequently may cause a substantial number of the persons served by the public water system providing such water to discontinue its use, or (B) which may otherwise adversely affect the public welfare. Such regulations may vary according to geographic and other circumstances.

(3) The term "maximum contaminant level" means the maximum permissible level of a contaminant in water which is delivered to any user of a public water system.

(4) The term "public water system" means a system for the provision to the public of piped water for human consumption, if such system has at least fifteen service connections or regularly serves at least twenty-five individuals. Such term includes (A) any collection, treatment, storage, and distribution facilities under control of the operator of such system and used primarily in connection with such system, and (B) any collection or pretreatment storage facilities not under such control which are used primarily in connection with such system.

(5) The term "supplier of water" means any person, who owns or operates a public water system.

(6) The term "contaminant" means any physical, chemical, biological, or radiological substance or matter in water.

(7) The term "Administrator" means the Administrator of the Environmental Protection Agency.

(8) The term "Agency" means the Environmental Protection Agency.

(9) The term "Council" means the National Drinking Water Advisory Council established under section 300j–5 of this title.

(10) The term "municipality" means a city, town, or other public body created by or pursuant to State law, or an Indian tribal organization authorized by law.

(11) The term "Federal agency" means any department, agency, or instrumentality of the United States.

(12) The term "person" means an individual, corporation, company, association, partnership, State, municipality, or Federal agency (and includes officers, employees, and agents of any corporation, company, association, State, municipality, or Federal agency).

(13) The term "State" includes, in addition to the several States, only the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands.

July 1, 1944, c. 373, Title XIV, § 1401, as added Dec. 16, 1974, Pub.L. 93–523, § 2(a), 88 Stat. 1661, and amended June 23, 1976, Pub.L. 94–317, Title III, § 301(b)(2), 90 Stat. 707; Oct. 12, 1976, Pub.L. 94–484, Title IX, § 905(b)(1), 90 Stat. 2325; Nov. 16, 1977, Pub.L. 95–190, § 8(b), 91 Stat. 1397.

(a)(1) The Administrator shall publish proposed national interim primary drinking water regulations within 90 days after December 16, 1974. Within 180 days after December 16, 1974, he shall promulgate such regulations with such modifications as he deems appropriate. Regulations under this paragraph may be amended from time to time.

(2) National interim primary drinking water regulations promulgated under paragraph (1) shall protect health to the extent feasible, using technology, treatment techniques, and other means, which the Administrator determines are generally available (taking costs into consideration) on December 16, 1974.

(3) The interim primary regulations first promulgated under paragraph (1) shall take effect eighteen months after the date of their promulgation.

(b)(1)(A) Within 10 days of the date the report on the study conducted pursuant to subsection (e) of this section is submitted to Congress, the Administrator shall publish in the Federal Register, and provide opportunity for comment on, the—

(i) proposals in the report for recommended maximum contaminant levels for national primary drinking water regulations, and

(ii) list in the report of contaminants the levels of which in drinking water cannot be determined but which may have an adverse effect on the health of persons.

(B) Within 90 days after the date the Administrator makes the publication required by subparagraph (A), he shall by rule establish recommended maximum contaminant levels for each contaminant which, in his judgment based on the report on the study conducted pursuant to subsection (e) of this section, may have any adverse effect on the health of persons. Each such recommended maximum contaminant level shall be set at a level at which, in the Administrator's judgment based on such report, no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety. In addition, he shall, on the basis of the report on the study conducted pursuant to subsection (e) of this section, list in the rules under this subparagraph any contaminant the level of which cannot be accurately enough measured in drinking water to establish a recommended maximum contaminant level and which may have any adverse effect on the health of persons. Based on information available to him, the Administrator may by rule change recommended levels established under this subparagraph or change such list.

(2) On the date the Administrator establishes pursuant to paragraph (1)(B) recommended maximum contaminant levels he shall publish in the Federal Register proposed revised national primary drinking water regulations (meeting the requirements of paragraph (3)). Within 180 days after the date of such proposed regulations, he shall promulgate such revised drinking water regulations with such modifications as he deems appropriate.

(3) Revised national primary drinking water regulations promulgated under paragraph (2) of this subsection shall be primary drinking water regulations which specify a maximum contaminant level or require the use of treatment techniques for each contaminant for which a recommended maximum contaminant level is established or which is listed in a rule under paragraph (1)(B). The maximum contaminant level specified in a revised national primary drinking water regulation for a contaminant shall be as close to the recommended maximum contaminant level established under paragraph (1)(B) for such contaminant as is feasible. A required treatment technique for a contaminant for which a recommended maximum contaminant level has been established under paragraph (1)(B) shall reduce such contaminant to a level which is as close to the recommended maximum contaminant level for such contaminant as is feasible. A required treatment technique for a contaminant which is listed under paragraph (1)(B) shall require treatment necessary in the Administrator's judgment to prevent known or anticipated adverse effects on the health of persons to the extent feasible. For purposes of this paragraph, the term "feasible" means feasible with the use of the best technology, treatment techniques, and other means, which the Administrator finds are generally available (taking cost into consideration).

(4) Revised national primary drinking water regulations shall be amended whenever changes in technology, treatment techniques, and other means permit greater protection of the health of persons, but in any event such regulations shall be reviewed at least once every 3 years.

(5) Revised national primary drinking water regulations promulgated under this subsection (and amendments thereto) shall take effect eighteen months after the date of their promulgation. Regulations under subsection (a) of this section shall be superseded by regulations under this subsection to the extent provided by the regulations under this subsection.

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

(c) The Administrator shall publish proposed national secondary drinking water regulations within 270 days after December 16, 1974. Within 90 days after publication of any such regulation, he shall promulgate such regulation with such modifications as he deems appropriate. Regulations under this subsection may be amended from time to time.

(d) Regulations under this section shall be prescribed in accordance with section 553 of Title 5 (relating to rulemaking), except that the Administrator shall provide opportunity for public hearing prior to promulgation of such regulations. In proposing and promulgating regulations under this section, the Administrator shall consult with the Secretary and the National Drinking Water Advisory Council.

(e)(1) The Administrator shall enter into appropriate arrangements with the National Academy of Sciences (or with another independent scientific organization if appropriate arrangements cannot be made with such Academy) to conduct a study to determine (A) the maximum contaminant levels which should be recommended under subsection (b)(2) of this section in order to protect the health of persons from any known or anticipated adverse effects, and (B) the existence of any contaminants the levels of which in drinking water cannot be determined but which may have an adverse effect on the health of persons.

(2) The result of the study shall be reported to Congress no later than 2 years after December 16, 1974, and revisions thereof reflecting new information which has become available since the most recent previous report shall be reported to the Congress each two years thereafter. The report shall contain (A) a summary and evaluation of relevant publications and unpublished studies; (B) a statement of methodologies and assumptions for estimating the levels at which adverse health effects may occur; (C) a statement of methodologies and assumptions for estimating the margin of safety which should be incorporated in the national primary drinking water regulations; (D) proposals for recommended maximum contaminant levels for national primary drinking water regulations, based on the methodologies, assumptions, and studies referred to in clauses (A), (B), and (C) and in paragraph (4); (E) a list of contaminants the level of which in drinking water cannot be determined but which may have an adverse effect on the health of persons; (F) recommended studies and test protocols for future research on the health effects of drinking water contaminants, including a list of the major research priorities and estimated costs necessary to conduct such priority research; and (G) periodic assessments and evaluations of unregulated contaminants which may require continuous monitoring or regulation.

(3) In developing its proposals for recommended maximum contaminant levels under paragraph (2)(D) the National Academy of Sciences (or other organization preparing the report) shall evaluate and explain (separately and in composite) the impact of the following considerations:

(A) The existence of groups or individuals in the population which are more susceptible to adverse effects than the normal healthy adult.

(B) The exposure to contaminants in other media than drinking water (including exposures in food, in the ambient air, and in occupational settings) and the resulting body burden of contaminants.

(C) Synergistic effects resulting from exposure to or interaction by two or more contaminants.

(D) The contaminant exposure and body burden levels which alter physiological function or structure in a manner reasonably suspected of increasing the risk of illness.

(4) In making the study under this subsection, the National Academy of Sciences (or other organization) shall collect and correlate (A) morbidity and mortality data and (B) monitored data on the quality of drinking water. Any conclusions based on such correlation shall be included in the report of the study.

(5) Neither the report of the study under this subsection nor any draft of such report shall be submitted to the Office of Management and Budget or to any other Federal agency (other than the Environmental Protection Agency) prior to its submission to Congress.

(6) Of the funds authorized to be appropriated to the Administrator by this subchapter, such amounts as may be required shall be available to carry out the study and to make the report directed by paragraph (2) of this subsection.

July 1, 1944, c. 373, Title XIV, § 1412, as added Dec. 16, 1974, Pub.L. 93–523, § 2(a), 88 Stat. 1662, and amended Nov. 16, 1977, Pub.L. 95–190, §§ 3(c), 12(a), 91 Stat. 1394, 1398.

SAFE DRINKING WATER ACT - Section 1448(a), 42 U.S.C. §300j-7(a):

(a) A petition for review of—

(1) action of the Administrator in promulgating any national primary drinking water regulation under section 300g—1 of this title, any regulation under section 300g—2(b)(1) of this title, any regulation under section 300g—3(c) of this title, any regulation for State underground injection control programs under section 300h of this title, or any general regulation for the administration of this subchapter may be filed only in the United States Court of Appeals for the District of Columbia Circuit; and

(2) action of the Administrator in promulgating any other regulation under this subchapter, issuing any order under this subchapter, or making any determination under this subchapter may be filed only in the United States court of appeals for the appropriate circuit.

Any such petition shall be filed within the 45-day period beginning on the date of the promulgation of the regulation or issuance of the order with respect to which review is sought or on the date of the determination with respect to which review is sought, and may be filed after the expiration of such 45-day period if the petition is based solely on grounds arising after the expiration of such period. Action of the Administrator with respect to which review could have been obtained under this subsection shall not be subject to judicial review in any civil or criminal proceeding for enforcement or in any civil action to enjoin enforcement.

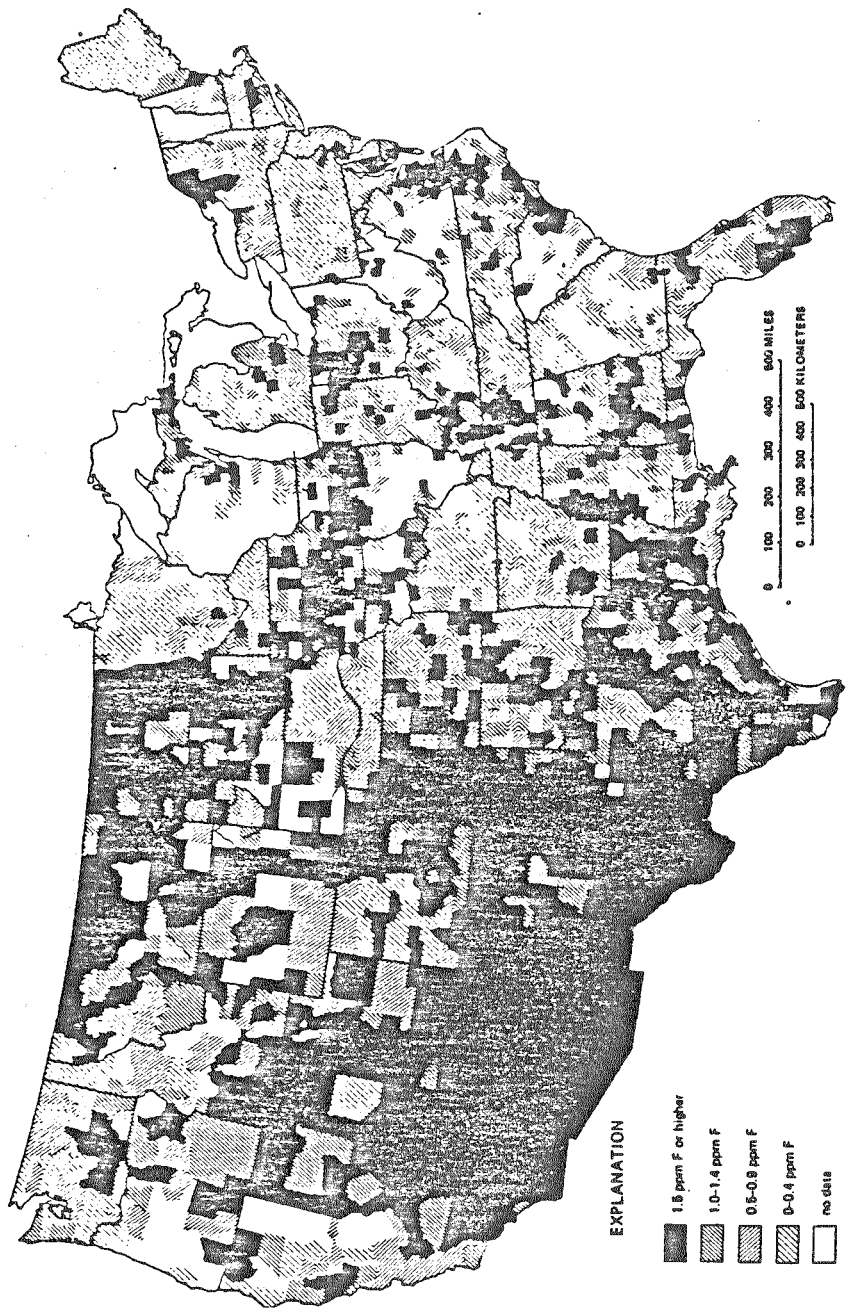


Figure 3. Fluoride content in groundwater, 1972 (maximum reported value for each county).

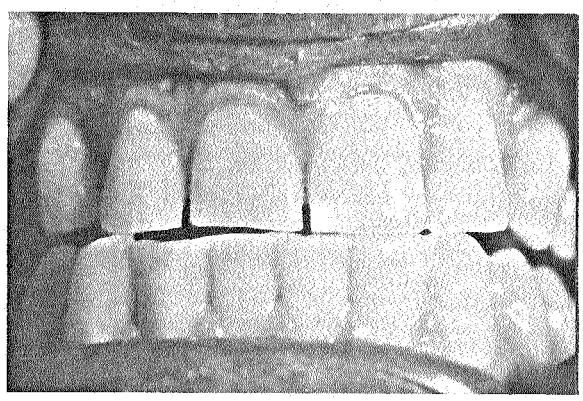
Source: Fleischer et al. 1974

Source: EPA Occurrence Document

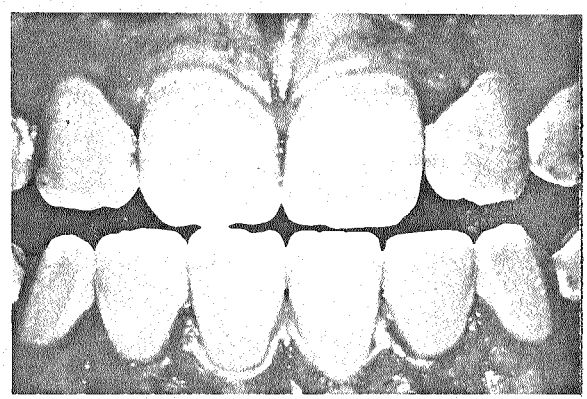
ATTACHMENT C

DENTAL FLUOROSIS CLASSIFICATION

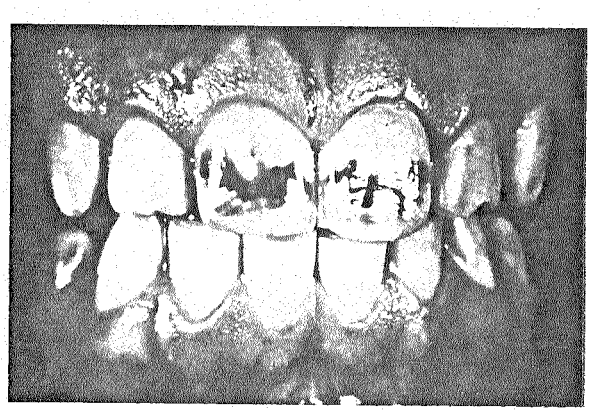
Dental Fluorosis



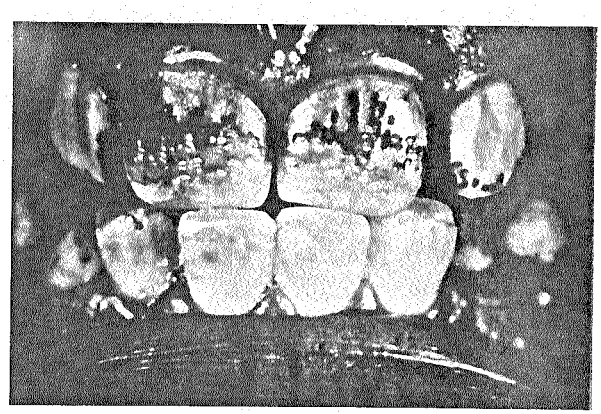
Normal Teeth



Mild Dental Fluorosis



Moderate Dental Fluorosis



Severe Dental Fluorosis

ATTACHMENT D

INCIDENCE OF MODERATE AND SEVERE DENTAL FLUOROSIS VS. WATER FLUORIDE LEVEL

Water fluoride level (mg/L)	Number of children	Moderate fluorosis (pct.)	Severe fluorosis (pct.)
2.0	109	14.7	0.0
2.0	200	4.0	0.0
2.1	143	8.4	4.9
2.2	179	13.4	0.0
2.2	138	11.0	0.7
2.3	90	6.7	0.0
2.3	67	32.8	0.0
2.4	113	4.4	0.0
2.5	148	14.2	3.4
2.6	404	8.9	1.5
2.9	192	7.8	8.3
2.9	97	23.7	3.1
3.2	190	31.1	0.5
3.8	21	9.0	0.0
3.9	136	7.4	22.8
3.9	289	33.9	13.2
4.0	39	38.0	6.0
4.0	101	40.0	2.0
4.0	59	23.7	11.9

Source: Proposed Fluoride RMCL, Table 8.

ATTACHMENT E

NATIONAL FEDERATION OF FEDERAL EMPLOYEES

SERVING FEDERAL EMPLOYEES...AND THE NATION...SINCE 1917

Local_____

DEC 10 1985

Honorable Lee M. Thomas, Administrator
U.S. Environmental Protection Agency
Washington, D.C. 20460

Dear Mr. Thomas,

In our letter of November 15, I detailed our Union's concerns for the quality of scientific support documents for the newly authorized Recommended Contaminant Level (RMCL) for fluoride in drinking water, and the implications for the reputation of the EPA professional community. In response, a member of your staff informed us that high level personnel in the Agency do not share our concern.

The point of our letter, which detailed errors of fact and distortions in the support documents, was that there should be concern -- for the Agency's reputation as well as for that of the professional community. In fact, a close reading of the November 14, 1985, Federal Register notice makes us wonder if we should change our conclusions from "concern" to "alarm."

Apparently, in the crush of public comments and a court-ordered deadline, new information that completely negates any claim that the RMCL of 4 mg/L is safe was overlooked. The Federal Register states that:

> "... the EPA agrees with the Surgeon General that crippling skeletal fluorosis is an adverse health effect which results from intakes of fluoride of 20 mg/day over periods of 20 years or more..."

The new information documents that the drinking water consumption of the American public is much greater than anticipated, and that 1% of the population -- if they drink water containing fluoride at the RMCL -- will ingest 20 mg/day or more from drinking water alone. This means that the Agency proposes to set a standard which it knows in advance will cause crippling skeletal fluorosis to some people in the U.S.

As painful as it may be to admit an error, this is what needs to be done and the effective date of the regulation (December 16, 1985) suspended.

The problem presented above is not the only problem with the science behind the regulation. Suspending the effective date will give EPA the opportunity to completely reassess the entire basis for the standard. We professionals want EPA to produce the best posssible scientific and legal products. We offer our assistance in helping to achieve this goal.

Sincerly,

Robert J. Carton, Ph.D.
President-elect
NFFE Local 2050

cc Michael Cook
Robert Wayland

ATTACHMENT F

Table 7. DRINKING WATER CONSUMPTION: Adults

Male			Female		
Consumption ml/kg	Consumption l/day*	Percent Population with a Greater Consumption	Consumption ml/kg	Consumption l/day*	Percent Population with a Greater Consumption
0	0	100	0	0	100
10	0.78	96	10	0.64	97
20	1.58	65	20	1.28	68
30	2.36	28	30	1.92	29
40	3.15	10	40	2.56	10
50	3.94	3	50	3.20	4
60	4.73	2	60	3.84	1
70	5.52	1	70	4.48	1
80	6.30	0	80	5.12	0

Average Weight	
kg	kg
78.8	64.0

Average Consumption			
mg/kg	l/day	mg/kg	l/day
25.5	2.01	26.1	1.67

* Fluid consumption in this Table can not be readily converted to ml/day by the multiplication of a single body weight. Individuals in this study and in the general population exhibit increasing tap water intakes (on a ml/kg basis) with decreasing body weights. Therefore, use of an average weight will result in an overestimate of consumption for the upper end of this distribution.

Source: Price, P., EPA Office of Drinking Water, Memo to Arthur Perler from Paul Price, October 1985, p. 19.

CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing Reply Brief for Petitioner NRDC have been served by first class mail this 3rd day of September, 1986 upon the following:

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