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

Petition for Review of Regulations
Promulgated by the Administrator of
The United States Environmental Protection Agency

REPLY BRIEF FOR PETITIONER NRDC

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SUMMARY OF ARGUMENT

EPA admits that it has established an RMCL for fluoride at a level which will not protect sensitive subgroups against crippling skeletal fluorosis and other health effects. This clear violation of the Safe Drinking Water Act ("SDWA" or "the Act") should be remanded to the Agency for determination of an RMCL consistent with the Agency's duty to protect susceptible subgroups of the population.

EPA claims that only a small number of persons are likely to be harmed by exposure to fluoride at the RMCL. The record shows, however, that fluoride concentrations at and below 4 mg/L could cause crippling skeletal fluorosis and other clinical skeletal effects in a substantial number of people. EPA made no effort to determine the number of people who will be harmed. Instead of evaluating all pertinent information (as it says it did), the Agency ignored documentation of severe skeletal effects in kidney patients, failed to address dangers to other groups such as diabetics, and entirely overlooked potential dangers to children.

The Agency's own drinking water intake data show significant risk of crippling skeletal fluorosis in populations exposed to fluoride concentrations of 4 mg/l, even when the data are used cautiously. EPA did not mention or show any awareness of the implications of these data. EPA should have set an RMCL to provide a margin of safety for the highest consumers of water; instead, it provided a small margin of safety only for persons who drink 2 liters of water or less per day.

Finally, the two epidemiological studies of skeletal effects of fluoride heavily relied upon by EPA fall far short of demonstrating that fluoride concentrations up to 4 mg/L will not harm a substantial portion of the population. EPA made no effort to ascertain the reliability of the studies; and the Agency's brief erroneously assumes that the studies "necessarily account for" sensitive subgroups.

EPA's response to NRDC's challenge is to ask this Court to defer to the Agency's judgment and thereby create a judicial exception to the mandate of the SDWA that an RMCL must provide protection to all persons against known and anticipated health effects of drinking water contaminants. The RMCL should be set aside and remanded to EPA for failure to protect sensitive subgroups, as Congress intended.

EPA's determination that dental fluorosis is not an adverse health effect of fluoride in drinking water for purposes of the RMCL represents a reversal of Agency policy established in 1975 and reaffirmed in 1981 and 1983. Not only did EPA fail to provide a reasoned analysis of why its prior policy of considering dental fluorosis to be an adverse health effect was no longer well-founded, but the Agency also failed to address the single most important piece of evidence in the record indicating that dental fluorosis <u>is</u> an adverse health effect of fluoride. Ignoring the conclusions of an objective panel of medical experts convened to consider the medical effects of exposure to fluoride in drinking water, the Agency instead relied exclusively upon the advice and opinions of parties who have been major activists on the promotion side of the national controversy over fluoridation

of water supplies, despite obvious evidence of bias in their judgments. This Court should not uphold the Agency's unexplained and unjustifiable reversal of policy as a reasonable exercise of discretion consistent with the preventive intent of the SDWA.

Finally, EPA's imposition of a functional impairment test to define an adverse health effect of fluoride is not within the range of reasonable interpretations of the SDWA. The Agency made no claim in the rulemaking that it was changing its interpretation of the SDWA so as to require functional impairment as the definition of an adverse health effect of a contaminant -- with the exception of fluoride. This interpretation is not only contrary to the clear preventive intent of Congress, but it is also inconsistent with every other statement EPA has ever made of its duties under the Act. These include the particular duty to err on the side of safety when there are conflicting opinions about the medical significance of an effect. The creation of a special definition of an adverse health effect just for fluoride is not entitled to deference by this Court.

The Agency's treatment of evidence of other possible adverse health effects of fluoride was also tainted by the application of an erroneous evidentiary standard. Applying the unduly stringent functional impairment test and requiring a higher degree of proof than Congress intended, EPA failed to provide protection in the RMCL against a number of potential adverse health effects. Claiming erroneously that the SDWA doesn't protect against "possible" adverse health effects, EPA also pointed to an allegedly large negative human data base to rebut <u>all</u> evidence of other potential adverse health effects. The Agency's response ignores

other record evidence that the human data base is not extensive, and that critical information is lacking, especially with respect to adverse skeletal and cardiovascular effects in children.

The Agency's creation of a stringent and unprotective definition of the adverse health effects of fluoride, and its failure to rebut or demonstrate the invalidity of studies indicative of other potential adverse health effects of fluoride, violated the SDWA. The RMCL should be vacated and remanded to EPA for re-evaluation of the evidence consistent with the preventive intent of the Act.

ARGUMENT

I. Introduction

The present case will be the first time a court considers the Agency's strict statutory duties in setting an RMCL under the Safe Drinking Water Act. EPA in its brief incorrectly suggests that the standards for setting an RMCL are identical to the standards applicable to an interim MCL. EPA Br. at 26-27. As the following discussion shows, they clearly are not.

EPA established an interim MCL for fluoride in 1975, but under different regulatory criteria from those required for this rulemaking.[1] The interim MCL for fluoride was set at 1.4 mg/L to 2.4 mg/L, depending on temperature. 40 C.F.R. §141.11(c).

In Environmental Defense Fund v. Costle, 578 F.2d 337 (D.C. Cir. 1978), this Court upheld the Agency's interim MCL for fluoride, describing the Agency's task in promulgating the interim

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1/ The interim regulations were required to be promulgated within 180 days after passage of the Act in 1974, and were intended to "protect health to the extent feasible, using technology, treatment techniques, and other means, which the Administrator determines are generally available (taking costs into consideration) . . . ." 42 U.S.C. §300g-1(a)(1) and (2).

regulation for fluoride as one of "line drawing" and "determining the optimal balance between promotion of the public welfare and avoidance of unnecessary expense." 578 F.2d at 346. The Court also noted that Congress intended the Agency to promulgate more "comprehensive and demanding" revised regulations at a later time.

The standards for revised regulations are markedly different from those applicable to interim regulations. In reviewing the fluoride RMCL, this Court need not inquire whether the Agency struck the proper "balance" between costs and health protection. Costs are not relevant at the RMCL stage of promulgation of revised regulations. See 50 Fed. Reg. at 47148, App. Instead, this Court must ask whether the Agency met the following standards, specifically set forth by Congress:

(1) Did the Agency "decide whether any adverse effects can be reasonably anticipated, even though not proven to exist?" H.R. Rep. No. 93-1185, 93rd Cong., 2d Sess. 20 (emphasis added) ("House Report").

(2) When it compiled these effects, did it consider "synergistic effects, long-term and multi-media exposures, ... the existence of more susceptible groups in the population[,]" and "alterations to physiological function or structure in a manner reasonably suspected of increasing the risk of illness?" Id.; 42 U.S.C. 300g-1(e)(3).

(3) Did it determine a level which prevents "any known or anticipated adverse effect"? House Report at 20 (emphasis added).

(4) Did it then set an RMCL which "include[s] an adequate margin of safety"? Id.

(5) In fulfilling each of the above duties, did it resolve uncertainties "on the side of protecting public health"? 120 Cong. Rec. H10794 (daily ed. Nov. 19, 1974) (remarks of Rep. Rogers).

This is not a case where EPA examined all of the evidence and reasonably concluded that the RMCL will prevent any adverse health effects. The Agency ignored substantial evidence of other adverse effects of fluoride, and grossly misinterpreted its duties under the Act and under settled principles of administrative law. EPA estimates that 835,000 people in the United States are exposed to fluoride at drinking water concentrations greater than 2.0 mg/L. Criteria Doc. at IV-2. By doubling the existing standard for fluoride, EPA has substantially increased the likelihood of adverse health effects for all of these people. This Court should reverse the administrative action and remand to EPA for determination of an RMCL in accord with the law.

II. Skeletal Fluorosis

A. EPA Acknowledges That the RMCL Will Not Protect All Members of the Population, and Offers No Basis to Conclude that the Incidence of Skeletal Effects Will Be Small

EPA has repeatedly acknowledged that it must protect sensitive populations in developing an RMCL. NRDC Br. at 25-27. The statutory standard is clear: the RMCL must protect against any known or anticipated adverse effect, including those in sensitive populations. "Any" means "any"; Congress never indicated that it meant differently when it enacted the statute, and in fact reinforced the statutory language when it explained that the

standard must provide an "adequate margin of safety." 42 U.S.C. §300g-1(b)(1)(B).

Yet, EPA asks this Court to create an exception to the statute's strict mandate. EPA argues that the RMCL should stand despite the Agency's acknowledgment that the standard "will not prevent crippling skeletal fluorosis" in individuals with "unusually high fluoride intake due in part to polydipsia [and] other medical complications." Response to Comments at 131, App. . EPA contends further that the SDWA "does not oblige the Administrator to base national regulation" on cases that will not occur frequently and have only been reported in the United States in persons with other medical conditions. EPA Br. at 43-44.

EPA's policy for regulating fluoride directly conflicts with the SDWA. EPA admits that cases of crippling skeletal fluorosis have occurred and will occur at the level of the RMCL; thus, it has not met its duty to prevent "any" adverse health effects with an adequate margin of safety.

Nor has EPA given this Court any basis on which to evaluate its claim that the number of persons affected will be small. It merely stated that "only two cases of crippling skeletal fluorosis associated with polydipsia have been observed in the U.S. thus suggesting that the incidence is very negligible." 50 Fed. Reg. at 47151, App. . As set forth below, the Agency's oft-repeated assertion that "only two cases" of clinical skeletal effects have been observed in the United States is contradicted by observations of severe skeletal effects of fluoride in six kidney patients which EPA never discussed during the rulemaking

proceeding. See pp. 9-11, infra.

It would be ludicrous for EPA to draw a definitive conclusion about the incidence of crippling skeletal fluorosis in sensitive populations from the mere fact that it knows of few such cases. A conclusion that the incidence of the disease is "very negligible," 50 Fed. Reg. at 47151, App. , would require either verification that EPA has received enough evidence concerning such effects to extrapolate to the entire population, or sound analysis of detailed studies of sensitive subgroups of the population. As this Court stated in American Petroleum Institute v. Costle, 665 F.2d 1176, 1187 (D.C. Cir. 1981), cert. denied, 455 U.S. 1034 (1982), the Administrator's conclusions "must be supported in the record, and he may not engage in sheer guesswork."

Yet "guesswork" appears to describe exactly what EPA engaged in. The record indicates that EPA's knowledge concerning cases of crippling skeletal fluorosis is far from comprehensive. According to the chairman of the Surgeon General's Medical Panel on fluoride, the scientific community is aware of few cases of crippling skeletal fluorosis in the United States only because "we haven't looked for it and we really don't know." Medical Panel Tr. at 413. After the Agency flatly stated in the RMCL proposal that it had conducted "an evaluation of all pertinent information" in the literature, 50 Fed. Reg. at 20168, App., and concluded that "water related crippling fluorosis has not been diagnosed in the United States..." 50 Fed. Reg. at 20171, App., the Agency was compelled to acknowledge in the final rulemaking that "crippling skeletal fluorosis has been observed in the U.S. associated with consumption of drinking water." 50 Fed. Reg.

47147, App. (emphasis in original). Both of these cases were reported in medical journals.[2]

Prior to final promulgation of the RMCL, a senior official in the Office of Drinking Water voiced EPA's concern that the discovery of two cases of crippling skeletal fluorosis "seem[s] to verify the potential for problems among high risk persons such as those with kidney disorders or high water consumption," and that "similar effects of a lesser degree might be passing unnoticed, especially among patients with reduced renal function."[3] EPA never discussed these concerns or cited any evidence suggesting that they were not valid. Moreover, a document to which EPA clearly had access during the rulemaking proceeding contains evidence that the concerns are valid. EPA's failure to review that evidence raises serious doubt whether the Agency actually looked for reports of skeletal symptoms in the available literature.

EPA's Response to Comments cites chapters 6 and 13 of Continuing Evaluation of the Use of Fluorides.[4] Uncited by EPA, however, is chapter 12 of the same book, "Fluoridation and Bone Disease in Renal Patients."[5] See Att. I. The chapter describes

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2/ See Goldman, et al., 1971. Radiculomyopathy in a southwestern Indian due to skeletal fluorosis. Arizona Medicine: 675-677; Sauerbrunn, et al., 1965. Chronic fluoride intoxication with fluorotic radiculomyelopathy, Ann. Intern. Med. 63: 1074-1078.

3/ Two letters expressing this concern are contained in the rulemaking record. See letter from Dr. Joseph Cotruvo to Dr. Robert Mecklenberg, Chief Dental Officer of the U.S. Public Health Service, July 30, 1985, App., and letter from Dr. Joseph Cotruvo to Dr. Jay Shapiro, Chairman of the Surgeon General's 1983 Medical Panel on the Non-dental Health Effects of Fluoride in Drinking Water, July 30, 1985, App.

4/ See Response to Comments at 49, 109. This volume was edited by Erling Johansen, Donald R. Taves, and Thor O. Olsen, and was published in 1979 in the Selected Symposia Series of the American Association for the Advancement of Science. Chapters 6 and 13, entitled "Is Fluoride Intake in the United States Changing?" and "Claims of Harm from Fluoridation", respectively.

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observations at the Mayo Clinic of severe skeletal effects of fluoride in six patients with end-stage renal disease "in whom fluoride may have been the cause of detectable clinical and roentgenographic effects." Id. at 279 (emphasis added). Although the chapter also describes skeletal symptoms in five kidney dialysis patients, these six patients were not undergoing dialysis. Id. at 279, 285. Most of them had "high urine volumes (> 3 [liters] per day), the fluid being replaced by copious intake of water or in one instance, tea." Id. at 279. The patients were exposed to 1.7 to 2.0 ppm fluoride in their drinking water, which the article describes as the patients' source of "high fluoride." Id. at 280, Table 3.

The patients had "severe symptomatic bone disease" with "severe skeletal changes or bone pain early in the course of renal failure...." Id. at 280. Four of the six patients "complained of arthralgia, especially in the knees, and of bone pain on weight-bearing involving the lower extremities;" and "three of the patients had spontaneous fractures of metatarsals, ribs, and hip." Id. at 281. The authors concluded that "[t]he available evidence suggests that some patients with long-term renal failure are being affected by drinking water with as little as 2 ppm fluoride." Id. at 290.[6]

5/ Chapter 12 was authored by William J. Johnson, Donald R. Taves, and Jenifer Jowsey.

6/ This clinical picture is highly consistent with signs of pre-crippling skeletal fluorosis, as reported extensively in India and other countries. See, e.g., Jolly, et al., 1968. Epidemiological, Clinical, and Biochemical Study of Endemic Dental and Skeletal Fluorosis in Punjab. Brit. Med. J. 4, 427-429. (This article is in the record as an attachment to C.I., but was never addressed by EPA. See C.I. at I-D.88.) In the United States, the Mayo Clinic may be unique in the experience investigators there have had with cases

[Cont. next pg.]

The authors of the chapter also point out that the extent of skeletal fluorosis in the U.S. is not known, and that "no systematic studies have been carried out in patients with renal insufficiency...." Id. at 275. They conclude further that water containing 1.0 ppm fluoride could produce skeletal fluorosis in some such patients. Id. at 291. Clearly, if cases have been reported at 2.0 ppm, and are deemed possible by experienced clinical investigators even at 1.0 ppm, the risk of skeletal fluorosis in patients with kidney disease whose water contains 4.0 ppm fluoride is appreciably higher. This risk is one the Act requires EPA to consider seriously. Instead, however, the Agency has attempted to dismiss it out of hand, and has overlooked readily accessible published reports that support the existence of this hazard.

The documentation of the additional cases of clinical skeletal effects from fluoride described by Johnson, et al. is hardly surprising. The record shows that EPA and the scientific community possess little knowledge concerning renal disease and fluoride beyond the fact that renal impairment can increase the level of fluoride in the body by increasing thirst and reducing the body's ability to excrete the contaminant.[7] Members of the 1983

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of skeletal fluorosis, and in their consequent ability to recognize the disease. In the absence of such clinical expertise, pre-crippling skeletal fluorosis may often go undetected, since many signs of the disease are general in nature (bone fractures, arthralgia, etc.) and can be attributed to other causes.

7/ Response to Comments at 115. EPA's brief disingenuously describes persons with renal impairment and excessive thirst as "hypothetical individuals with multiple medical conditions...." EPA Br. at 43-44. The Agency's own description of renally-impaired individuals and examples from the literature show that renal impairment is often associated with excessive thirst. See, e.g., Response to Comments at 115: "polydipsia and polyuria associated with some forms of renal impairment...." See also Juncos and Donadio (1972): "Both of our patients had renal diseases that resulted in polydipsia and polyuria.... [S]ystemic fluorosis developed in our patients

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Medical Panel stated that (1) renal patients have suffered adverse effects from fluoride, Medical Panel Tr. at 47, 468-69; (2) an RMCL of "[t]hree wouldn't protect the individual with renal insufficiency," id. at 425; (3) there is a need for studies on the effects of fluoride on kidney patients, id. at 459, and the general population, id. at 413; and (4) epidemiological studies cannot detect effects on sensitive persons such as kidney patients. Id. at 124-125. Other medical experts have noted the need for research on the effects of fluoride in kidney patients. Johnson, et al., at 275, 291.

EPA never made any effort to estimate the number of kidney patients who will be exposed to high levels of fluoride. Its estimate that the population of renally-impaired persons at risk from crippling skeletal fluorosis is "negligible" appears inconsistent with the fact that a large number of Americans suffer from chronic kidney disease.[8] EPA never estimated the fluoride intake levels of these persons except to describe such levels as "excessive" and "unusually high." Criteria Doc. at IX-31, App. ; 50 Fed. Reg. at 47152, App.

The Agency's treatment of persons which it considers "at increased risk" from waterborne fluoride because of diabetes

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because of their renal disease...." Juncos, L.I., Donadio, J.V. 1972. Renal failure and fluorosis. J. Am. Med. Assn. 222:783-785, at 785. And the available evidence indicates that the number of persons suffering from polydipsia due to renal impairment and other diseases is high. (See discussion at pp. 12-14, infra.)

8/ For example, a factsheet published by the American Kidney Fund estimated that "[o]ver 78,000 Americans of both sexes and all ages will die of kidney and urologic diseases this year" and that "[o]ver 60,000 Americans are currently being sustained on artificial kidney machines." The 1985 edition of The Torchbearer, the newsletter of the American Kidney Fund, estimates that kidney stones affect over 1 million Americans each year, with one in every ten males and one in every forty females developing the condition. See Att. II.

insipidus is equally arbitrary. One member of the Medical Panel stated that persons with diabetes insipidus drink 10 liters of water per day. Medical Panel Tr. at 467. Dr. Cotruvo, EPA's senior drinking water scientist, also estimated that diabetics drink "two or three or four times as much water as the average person." Medical Panel Tr. at 444. These estimates of drinking water intake for diabetic patients predict a fluoride intake higher than EPA's estimate for onset of crippling skeletal fluorosis of 20 mg/day fluoride for 20 years.[9]

EPA apparently never made these calculations, nor ever mentioned any estimate for the water intake of those with diabetes insipidus. It simply concluded that such persons are not at "significantly greater risk" for crippling skeletal fluorosis because only two cases of the disease "have been observed" in the United States. Response to Comments at 115.

Once again, EPA's casual assertion regarding the paucity of these cases is flatly contradicted by the record. One member of the Medical Panel stated that

> [i]n the diabetes literature which I do deal a lot with, it was only a couple of years ago that it was pointed out to us that kids were starting to get stiff joints. We never even saw it happening until someone pointed out to us that it was happening.... I think you really have to be looking for it because we have missed it for years with the diabetics.

Medical Panel Tr. at 275-276. EPA never acknowledged this statement or reported any facts which would invalidate the reports of adverse health effects from waterborne fluoride. Further, the record indicates that more than 11 million Americans are current-

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9/ Ten liters of water at a fluoride concentration of 4 mg/L would yield 40 mg of fluoride per day; four times an intake of 1.5 L/day (which is below the average intake), or 6 L/day, yields 24 mg fluoride per day.

ly afflicted with diabetes. American Diabetes Association, "1984 Fact Sheet on Diabetes," Att. II. EPA never attempted to calculate how many of these diabetics are at risk from waterborne fluoride.

EPA also failed to address adequately the dangers of fluoride to children. The concerns of the Medical Panel in this regard were included in the Committee's final report to the Surgeon General. The report states:[10]

> The effects of various levels of fluoride intake on rapidly developing bone in young children are not well understood.... Therefore, the committee strongly recommends that the Public Health Service and the EPA join to enlarge the body of information relative to skeletal maturation and growth in children ingesting more than the recommended daily intake of fluoride [ranging from 0.5 mg/day for infants to 2.5 mg/day for teenagers].

EPA never mentioned the Committee's recommendation, or the lack of knowledge regarding the effects of fluoride on children.

At a minimum, EPA must look at the evidence. In this rulemaking, the Agency ignored most of the evidence concerning fluoride's clinical effects on the skeleton. This Court should not create an exception to the Act's clear instructions on the basis of EPA's unsubstantiated and irresponsible claim that the RMCL will allow only a small number of adverse health effects to occur.[11]

10/ Report to the Surgeon General by the Ad Hoc Committee on the Non-Dental Health Effects of Fluoride in Drinking Water, September 1983, at 7. This recommendation is supported by the statement by a member of the expert panel that "we know nothing about [the safety, efficacy and toxicity of fluoride] in the childhood population." Medical Panel Tr. at 274.

11/ The Court should also refrain from creating an exception to the Act because such an exception would be difficult to administer, requiring determination in each case whether the numbers affected are consistent with this Court's intent in creating the exception. Because the RMCL must not allow any adverse health effects, determination of the broadness of the exception could not be made with reference to the Act or its legislative history.

B. EPA's Drinking Water Intake Data Show a Significant Portion of the Population at Risk from Crippling Skeletal Fluorosis at a Drinking Water Concentration of 4 mg/L

Drinking water intake data analyzed by EPA's Office of Pesticide Programs (OPP) and summarized by EPA's Office of Drinking Water (ODW)[12] give a direct estimate of the percentage of the population likely to be afflicted with crippling skeletal fluorosis at a drinking water fluoride concentration of 4 mg/L. See NRDC Br. at 33-35. Even when used cautiously, the figures indicate that a portion of the population ingests enough fluoride to contract crippling skeletal fluorosis after 20 years if they drink water with a fluoride concentration of 4 mg/L. The data also show that a large portion of the population drinks substantially more water than the 2 liters per day consumption estimate on which the RMCL is based.

Explaining that "a careful review" of the "detailed" data "allowed OPP to estimate actual tap water consumption," Price memo at 11, EPA presented the data in units of ml/kg/day (milliliters per kilogram per day) in a series of eight tables. Five of these tables present the figures according to categories that can affect intake levels, such as age and sex. However, the first three tables present data for all age categories. For these first three tables only, EPA warned that

> It is extremely difficult to convert from ml/kg/day to l/day. For populations with a highly varying weight, it is necessary to adjust each individual consumption.... As shown in the plot of consumption and age the highest 1% of consumption is composed solely of infants, with an average weight of 7.6 kg. The actual consumption of the highest

12/ EPA Office of Drinking Water memorandum from Paul S. Price to Arthur H. Perler, November 12, 1985 ("Price Memo").

> percentile of consumption on a ml/day basis is therefore only 1 liter.

Id. at 12. However, of the tables which concern this case, EPA explained:

> For categories in which weight does not vary such as, adult males, adult females, [and] pregnant and lactating females the reported consumption volumes can be multiplied by an average weight to give a direct estimate of drinking water consumption. For the purposes of direct comparison this calculation has been performed in some of the attached charts.

Id. In its brief, EPA erroneously suggests that EPA's warning that "[i]t is extremely difficult to convert from ml/kg/day to l/day" applies to the data for adult males in Table 7. EPA Br. at 40. As the above quote shows, it clearly does not. Morever, despite the caution that use of an average weight could tend to overestimate actual volume consumed, the memorandum never suggested that its "direct estimate[s]" of drinking water consumption were not valid.

In Table 7 (NRDC Br. at Att. F), EPA estimated that one out of every one-hundred adult males drinks 70 ml/kg or 5.52 liters or more of water per day. Multiplication of that figure by 4 mg/L yields 22.08 mg fluoride per day, which is 2.08 mg/day higher than EPA's estimate of the onset level for crippling skeletal fluorosis. Without contesting the validity of these data, EPA's brief argues that this figure may be an overestimation because the Agency used an average weight to arrive at the 5.52 L/day estimate. However, the table shows that 1% of a 4 mg/L adult male population will ingest more than 20 mg/day even if a substantially lower weight is used in the calculation. The average weight for an adult male used by EPA in its original calculation was 78.8 kg, or 173.7 pounds. A lower weight of 70.0 kg, or

154.0 lbs., multiplied by the 70 ml/kg intake figure yields a water intake of 4.90 liters per day. At a fluoride concentration of 4 mg/L, consumption of 4.90 liters of water results in a fluoride intake of 19.6 mg fluoride. EPA's estimate of an additional 1 mg/day from dietary sources yields more than the 20 mg/day onset level for crippling skeletal fluorosis.[13]

EPA's brief also claims that the data may be misleading because the figures include other beverages as well as drinking water, many of which, the Agency contends, "contain little, if any, fluoride." EPA Br. at 41. However, the memorandum which analyzes the data estimates the average intake of such beverages as only 0.45 liters,[14] and warns that those estimates should not be used to adjust total intake because intake of those beverages "var[ies] greatly." Price Memo at 12. Moreover, EPA's unsupported assertion that these beverages "contain little, if any, fluoride" is belied by the fact that the Agency never determined whether high-fluoride water is used in manufacture of these beverages. EPA also criticizes NRDC's consideration in its opening brief of two cups of tea in an individual's diet because the cups of tea are "already accounted for" in the 5.52 L/day figure. EPA Br. at 41. Obviously, the volume of fluid contained in the two cups of tea is already accounted for by the 5.52 L/day figure, but the additional fluoride is not. Failure to include

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13/ Use of a weight of 72.7 kg, or 160.0 lbs., results in fluoride intake higher than 20 mg/day from water alone. In addition, use of a weight of 68.2 kg, or 150.0 lbs., results in a daily fluoride intake of 19.1 mg.

14/ EPA misleadingly states in its brief that non-drinking water beverages can constitute "a third or more of an individual's daily intake...." (EPA Br. at 41.) EPA apparently bases this estimate on the 0.45 liter average for non-drinking water intake estimated on page 12 of the Price memorandum. However, 0.45 liters is one-third of only 1.35 liters; it is less than one-tenth of 5.52 liters.

the fluoride contained in tea in an estimate of total intake would result in an inaccurate figure for tea drinkers.[15]

If EPA had taken seriously its mandate to "err on the side of safety" in setting an RMCL, it would have heeded the estimates in Table 7 and set a standard which provided an adequate margin of safety for the highest consumers of water. Instead, it has found itself in the uncomfortable position of quibbling with its own estimates of water consumption, which were used in the RMCL proceeding as support for the 4 mg/L RMCL.[16]

The RMCL is also flawed because the consumption figure on which it was based is far too low. EPA assumed that "the majority" of persons drink 2 liters of water per day or less. 50 Fed. Reg. at 47147, App. . Assuming that crippling skeletal fluorosis occurs only after exposure to 20 mg/day of fluoride for 20 years, the Agency reasoned that the disease will result only from a drinking water fluoride concentration of 10 mg/L or higher. Thus, EPA concluded that the RMCL of 4 mg/L provides a margin of safety of 2.5.

Beyond EPA's choice in this case of a uniquely low margin of

15/ EPA also contends that NRDC overestimated the fluoride intake from tea in its calculations showing 2% of the population at risk from crippling skeletal fluorosis because it used "the improper calculation of multiplying a ml/kg value [for tea consumption] by an average body weight." See NRDC Br. at 35 n. 108, 109. However, NRDC's calculation shows 2% of the 4 mg/L population at risk even if fluoride consumption from tea is only 0.1 mg/day. Use of a body weight only one-sixth the average value of 78.8 kg (or 28.9 lbs) results in an estimated fluoride intake of 0.1 mg/day.

EPA also criticizes "NRDC's extrapolation of [the 1% and 2% figures] to the entire population...." EPA Br. at 41. Examination of NRDC's opening brief shows no prediction of crippling skeletal fluorosis in 1% of the U.S. population as a whole; the brief simply projects that 1% of a population drinking water at a fluoride level of 4 mg/L will contract the disease.

16/ Without questioning the validity of the data in the Price Memo, the Agency stated that "[o]ver 95% of the population are believed to consume 4 liters per day or less; over 99% of the population are believed to consume 5.5 liters or less." 50 Fed. Reg. at 47147, (citations omitted).

safety[17] and the fact that the Agency chose the highest estimate in the record for the onset level of crippling skeletal fluorosis,[18] this calculation is worthless because a large portion of the population drinks more than 2 L/day. Table 7 (NRDC Br. at Att. F) shows that 28% of the population drink more than 2.36 L/day, and 10% of the population drink more than 3.15 L/day. The Environmental Health Directorate of Canada, on whose data EPA also claimed it based the 2 L/day figure, estimated that 9% of persons aged 18 and over consume more than 2.5 L/day, and 2% consume more than 3.9 L/day.[19]

EPA's citation to the National Academy of Sciences as support for the 2 L/day consumption figure should be evaluated in light of that body's recommendation in 1980 that

> [u]ntil more precise measures of the margin of safety for the use of fluoride are available [concerning crippling skeletal fluorosis and other aspects of fluoride toxicity], the levels of fluoride in drinking water should not exceed the optimal levels for anticariogenic benefits [or 0.7 mg/l to 1.4 mg/l, depending upon temperature].

1980 NAS at 282.[20]

In its brief, EPA offers as justification for the 2 L/day

17/ See n. 20, infra.

18/ For example, in a study which appears in the record but which EPA never mentioned, Jolly noted crippling skeletal fluorosis resulting from drinking water concentrations as low as 3.0 mg/l. See Jolly, et al. (1968) cited supra note 6.

19/ Environmental Health Directorate, "Tapwater Consumption in Canada," 1981, at 31. EHD's estimates do not include non-tapwater fluid intake.

20/ Moreover, NAS has never used or recommended a safety factor as low as the factor of 2.5 used in this proceeding. The Academy considers a factor of 10 appropriate when "chronic human exposure data [are] available and [are] supported by chronic... data in animal species." (1980 NAS at 36). EPA defends the factor of 2.5, one fourth the commonly accepted factor, as appropriate because it "believes the uncertainty concerning the levels at which fluoride may present risks is relatively small...." 50 Fed. Reg. at 47144, App. . However, in arriving at the 20 mg/day level for crippling skeletal fluorosis, EPA failed either to heed NAS's warning that "more precise measures of the margin of safety" of fluoride are needed or to examine other estimates of onset levels for crippling skeletal fluorosis.

consumption estimate the fact that it used such a level in the interim regulations. At the time, EPA defended the 2 L/day figure on the basis of cost. See 40 Fed. Reg. at 59566, 59575 (Dec. 24, 1975). As explained supra (see pp. 4-5), an RMCL is not an interim regulation. The cost/benefit balancing required for the interim regulations is not relevant to EPA's task in setting an RMCL to prevent "any known or anticipated adverse effects."[21]

C. The Limited Epidemiological Evidence in the Record Falls Far Short of Demonstrating the Adequacy of the RMCL

In its brief, EPA argues that two epidemiological studies conducted in the 1950s "flatly refute[ ]" any evidence that the RMCL will allow significant harm to a portion of the population. EPA Br. at 39. The record indicates, however, that the studies do not conclusively establish the safety of the RMCL for all persons and were at best of marginal value to the rulemaking proceeding.

The Agency's brief makes an unsupported assertion that epidemiological studies "necessarily account for" sensitive subgroups in the population. EPA Br. at 35. EPA never made this extraordinary claim in the rulemaking proceeding, although, obviously, a finite population may or may not include some persons at special risk from fluoride. Moreover, the transcript of the

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21/ House Report at 20. EPA in its brief also states without documentation that the Public Health Service (PHS) used the 2L/day estimate when publishing its non-enforceable standards in 1962. PHS had no mandate from Congress when it issued its standards 24 years ago. Nevertheless, the 1962 PHS standard of 1.2 to 2.4 mg/l was far lower that the RMCL in order to protect against dental fluorosis osteosclerosis, crippling skeletal fluorosis and other effects. U.S. Public Health Service Drinking Water Standards, Revised 1962, Department of Health, Education, and Welfare, at 7, App.

Medical Panel's meeting suggests that the epidemiological studies on fluoride do not account for such subpopulations:

> DR. ROWE: Would these [epidemiological] studies ever have detected whether there is a subgroup that is unusually prone, such as patients with chronic renal disease?
>
> DR. SHARRETT: No. None of these studies have dealt with things like this. These are all population-based on general populations.[22]

Medical Panel Tr. at 124. In fact, EPA has never cited to any evidence indicating that epidemiological studies do account for sensitive populations. Thus, the Agency has left untouched a substantial issue: do any of the studies which it cites as support for the 4 mg/L RMCL bear any relevance to sensitive subgroups?[23]

EPA's brief describes the study reported in 1955 by Leone, et al. as the "most significant study analyzing U.S. residents consuming high fluoride water for prolonged periods...." EPA Brief at 35. Yet, that study compared only 116 people in an area with 8 mg/L of fluoride in the water to 121 people in an area with 0.7 mg/L fluoride in its water. Further, as noted by NAS, the report does not identify whether the subjects of the study drank community or bottled water. 1977 NAS at 397.

22/ Later, Dr. Sharrett reaffirmed the conclusion that "there [are] no studies" on the effects of fluoride that address the aspect of "special risk.". Id. at 125.

23/ EPA also never assessed the results of the two studies in light of the inherent limitations of epidemiological surveys. The National Academy of Sciences has observed that epidemiological studies "suffer from a number of limitations and difficulties." These studies "lack the desirable experimental control of extraneous factors... since many of the relevant risk factors are either unknown or cannot be adequately measured or controlled." The Academy also noted that studies attempting to associate medical effects with past exposure to a contaminant are limited by "the questionable validity of retrospective information concerning exposure that may have occurred over a long period in the past." Thus, the Academy concluded, "the quantitative results of such studies are always open to question." 1980 NAS at 54-55.

In the rulemaking proceeding, EPA never claimed that observations of 116 people with uncertain fluoride exposure could lead to firm conclusions regarding exposure to sensitive populations; it merely cited the study as evidence that scientists have "examined the effects of fluoride on bone." 50 Fed. Reg. 47144, App. This Court should therefore not credit unsupported claims about the study in EPA's brief.

The second study, a survey by Stevenson and Watson of the records and x-rays of 170,000 people on file at a medical clinic in Arizona, is also of limited relevance to this proceeding. As with the study by Leone, et al., EPA did not claim in the rulemaking that this study showed that sensitive populations would be protected by an RMCL of 4 mg/L. The study never specified the levels of fluoride in the patients' drinking water beyond an indication that some of the patients lived in Texas and Oklahoma, where many communities have 0.7 ppm or more of fluoride in the water. Stevenson and Watson at 14. The record indicates that the clinic treated people from many areas of the world, not necessarily from Texas and Oklahoma. Criteria Doc. at VI-42, Waldbott, G.L., Hydrofluorosis in the U.S.A., Fluoride 1:94-102 (1968).

Investigation of 23 cases of osteosclerosis found by the survey revealed that 15 of the 23 patients drank water containing 4 ppm to 8 ppm fluoride; however, there is no way of knowing whether any others in the study were exposed to such levels. In a moment of objectivity rare for this proceeding, EPA admitted that the lack of information in the study concerning exposure levels prevented any determination of a "meaningful incidence

rate." Criteria Doc. at IX-16. The study could also have overlooked significant clinical effects. Stevenson and Watson never indicated whether they looked for clinical effects in any patients except the twenty-three they diagnosed as having osteosclerosis.

The record contains uncontradicted evidence that the RMCL will allow clinical skeletal effects in a substantial portion of populations exposed at 4 mg/L. EPA never satisfied its duty to address this evidence.[24] This Court should not uphold the Agency's action on the basis of two limited epidemiological studies which are of little relevance to the variety of dangers associated with exposing a large population to high levels of fluoride. At the least, the Court should remand to the Agency for its own explanation of why it believes that the studies establish the adequacy of the RMCL.

24/ In dramatic contrast to EPA's absurd claim that two limited epidemiological studies in the United States conclusively prove the safety of the RMCL is the Agency's arbitrary dismissal of Indian epidemiological studies showing crippling skeletal fluorosis at levels below 4 mg/L. EPA dismisses these studies by speculating that "Indians are believed to have higher fluoride content in their foods, greater consumption of water, higher fluoride levels in drinking water, and poorer diets than U.S. citizens." EPA Br. at 38 (emphasis added). The discussion in the Response to Comments to which EPA's brief refers offers no support for this statement except one oblique reference to a thirty year-old article allegedly supporting the proposition that poor diet may have contributed to crippling skeletal fluorosis in some Indian patients. As noted supra note 6, a study by Jolly, et al. found crippling skeletal fluorosis associated with drinking water fluoride concentrations below 4 mg/L. Further, the authors of the study note that their findings do not support the possibility that poor nutrition contributes to crippling skeletal fluorosis because the area studied "is the best-nourished area in India and yet has the highest incidence of fluorosis." Jolly, et al. at 429. EPA never mentioned this study.

III. Dental Fluorosis

A. EPA's Recent Determination That Dental Fluorosis Is Not An Adverse Health Effect Is Not Entitled To Deference As An Issue Of First Impression

In its brief, EPA argues for deference from this Court as if the rulemaking at issue were the first time EPA ever addressed the question of whether dental fluorosis is an adverse health effect. EPA Br. at 46-52. In fact, the issue was directly confronted in 1975 when the interim MCL for fluoride was established.[25] At that time, EPA stated:

> Suggestions that the MCLs be raised or eliminated were based on the interpretation of dental fluorosis as an esthetic condition rather than as a health problem.... [T]he Administrator believes that the MCLs in these regulations are adequate for the protection of the health of consumers....

40 Fed. Reg. at 59576, App. (emphasis added). The Agency reaffirmed its position that dental fluorosis is an adverse health effect when it stated in the 1983 Advance Notice of Proposed Rulemaking for the fluoride proceeding that[26]

25/ Primary regulations by definition "specif[y] contaminants which, in the judgment of the Administrator may have any adverse effect on the health of persons...." SDWA §1401(1)(B), 42 U.S.C. §300f(1)(B) (emphasis added). In that initial rulemaking, therefore, EPA determined that dental fluorosis was an adverse health effect of fluoride to be controlled by a primary regulation. Thus, in proposing the interim Primary Regulations, EPA stated that "all of the maximum contaminant levels for inorganic chemicals [including fluoride] are based upon data addressed to possible health effects that may occur after a lifetime of exposure...." 40 Fed. Reg. 11990, 11991 (Mar. 14, 1975) (emphasis added), App. ___.

26/ 48 Fed. Reg. 45502, 45514 (Oct. 5, 1983) (emphasis added). EPA had similarly stated in 1981 that the 1975 interim MCL "was designed to be protective against the more severe levels of [dental] fluorosis and not against the merely cosmetic staining that also occurs." 46 Fed. Reg. 58345 (Dec. 1, 1981) (emphasis added), App. ___.

The MCL for fluoride was also based upon the Public Health Service's treatment of dental fluorosis since 1962 - and possibly since 1942 - as a risk to health. The assertion in EPA's Brief at 11 that the Public Health Service's concern about dental fluorosis was directed only at cosmetic concerns is contradicted by the language of those standards. The Public Health Service Drinking Water Standards of 1962 list fluoride in the category

[Cont. next pg.]

> MCLs for fluoride were based on the occurrence and severity of dental fluorosis, a condition manifested by both cosmetic and physiological alterations in tooth enamel. The standard was designed to protect against severe fluorosis which is manifested by pits and destruction of dental enamel.

Given that EPA defined dental fluorosis as an adverse health effect for a decade, this Court should not, without further inquiry, accord deference to the Administrator's recent change of definition.[27]

B. EPA Ignored Critical Evidence In Reversing Its Long-Standing Policy That Dental Fluorosis Is An Adverse Health Effect

The Agency's new definition of an "adverse health effect" of fluoride represents a radical change in Agency policy. As the cases cited in NRDC's Brief at 37-38 hold, the Agency must overcome a presumption against its shift to a less protective posture by articulating a satisfactory explanation for the change. Yet, apart from the mere assertion that the Agency made a "comprehensive" examination and analysis of the scientific evidence and concluded that dental fluorosis is no longer considered an adverse health effect, EPA Br. at 51-53, EPA has not provided any specific reasons why the Agency's previous conclusion about den-

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of chemical impurities "which may be hazardous to the health of the consumers." U.S. Public Health Service Drinking Water Standards at 7 (emphasis added), App.___.

27/ EPA's claim that Congress was silent on how the Administrator's judgment was to be exercised with respect to fluoride (and other contaminants) is simply incorrect. The Agency's discretion to define adverse health effects and protect against them, must be exercised within the limits proscribed by Congress in the legislative history. There is no ambiguity as to Congress' intent that EPA is to maximize protection of public health in setting RMCLs. See NRDC Br. at 20-23. EPA's brief also claims that setting an unenforceable secondary MCL to account for dental fluorosis is consistent with the federal-state relationships created by Congress for minor esthetic problems associated with drinking water. EPA Br. at 46. If NRDC is correct that EPA's treatment of dental fluorosis violates the preventive intent of the law, these arguments are irrelevant.

tal fluorosis was erroneous or not well-founded.

The most egregious example of the Agency's failure to adequately explain its reversal in policy is its continuing refusal to address the single most important piece of scientific evidence in the record on the issue of whether dental fluorosis should be considered an adverse health effect. That evidence is contained in the transcript of the two-day meeting of the Surgeon General's panel of medical experts convened at EPA's specific request to evaluate the medical effects of fluoride in drinking water. The Medical Panel's overwhelming conclusion, reached after lengthy discussion and a 12-2 vote on the issue, was that dental fluorosis is, per se, an adverse health effect. Medical Panel Tr. at 456. See also id. at 448-456. The transcript of the meeting shows clearly that the medical experts were also concerned that dental fluorosis could represent unknown adverse skeletal effects in children. They further expressed concern about studies indicating possible cardiotoxic effects in children from low-level exposures to fluoride. Medical Panel Tr. at 165-68, 338-39. The result of these concerns was a recommendation that fluoride exposures of children up to 9 years old should not exceed twice the optimum level (or 2.4 mg/L). Medical Panel Tr. at 448-52.

Why the Panel's recommendation appears in both the transcript and the draft of their report to the Surgeon General but not in the version sent to EPA is unexplained. Of greater import is the fact that EPA had a high-level scientific representative at the meetings and knew, or reasonably should have known what the panel had concluded about dental fluorosis. Yet, EPA never

addressed the conclusions and concerns of the Medical Panel.[28] If EPA had done so, NRDC submits that the Agency could not have concluded that the record contains "no adequate evidence" contravening the decision to revise the definition of adverse health effects of fluoride to exclude dental fluorosis. 50 Fed. Reg. at 47146, col. 3, App.

Counsel for EPA chided NRDC for allegedly relying upon biased studies and the opinions of "zealous advocate-scientists" on one side of the controversy over fluoridation of water supplies. EPA Br. at 58. Apparently, the Agency did not heed its own advice. Rather than explaining why EPA's prior policy on dental fluorosis was not well-founded, EPA simply notes its "agreement" with the opinions of dental and medical officials and organizations that are major activists on the promotion side of the national fluoridation controversy. See NRDC Br. at 47-52. The existence of strong pro-fluoride bias in their arguments is described in a recent article in Atlantic. Att. III.

The Agency also places great weight upon an unpublished, unpeer reviewed draft of a report by Eklund, et al., which claims to have found that a fluoride level of 4 mg/L has no "clinically significant effect on teeth, such as chipping and cracking...." EPA Br. at 47. In the introduction to the report, the authors reveal a strong bias in favor of deleting fluoride from the primary standards because of the economic impact on small

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28/ The Agency's brief does no more than gloss over the Medical Panel's conclusions with a disparaging reference to NRDC's citation of "transcript references of panel discussions, minority views, and draft reports...." EPA Br. at 54. It never addresses the fact that the conclusion that dental fluorosis is per se an adverse health effect was a majority view, which was carefully considered by the panel of experts.

communities of compliance with the interim MCL. Not only did the authors indicate their acute awareness that EPA was currently considering revising the existing fluoride MCL, but they also stated their intention to influence those revisions through their conclusions. The substance of the draft report also reflects the authors' bias. For example, they didn't count cavities caused by erosion, abrasion and fractures,[29] although these are believed by some experts to result from dental fluorosis. See, e.g., Driscoll, W.S., et al., Prevalence of dental caries and dental fluorosis in areas with optimal and above-optimal water fluoride concentrations, J.A.D.A. 107: 42-47 (1983).

Despite the stated bias of the investigators, the report does document significantly higher attrition, gingival (gum) rescission and loss of tooth attachment in the higher fluoride community as well as "mostly moderate, severe or very severe" dental fluorosis. Eklund, et al. at 32, 45, 48. Nevertheless, the authors concluded in a political statement that the "real difference remains the cosmetic one, and those affected by fluorosis are perhaps the people in the best position to decide how important it is to them." Id. at 58.

EPA's exclusive reliance on such partisan reports, and on the opinions of major participants on the promotion side of the national fluoridation controversy, while ignoring the patently more objective opinion of the experts on the Medical Panel, is not entitled to deference from this Court. On the contrary, the Agency's arbitrary and capricious treatment of the evidence

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29/ Eklund, et al., Effect of Severe Dental Fluorosis on the Oral Health of Adults, Draft Comprehensive Report, November 24, 1984 at 20, App.

warrants a remand to EPA to consider the Medical Panel's recommendations, and to explain the Agency's decision to reverse its prior policy on dental fluorosis in light of that evidence.

IV. Incorporation of a Functional Impairment Test into the EPA's Definition of Adverse Health Effect Under the SWDA Contravenes the Legislative Intent

In establishing the RMCL for fluoride, the Agency stated that "adverse health effects, at least for fluoride, should be measured by function[al] impairment". 50 Fed. Reg. at 47146, App. This redefinition of an adverse health effect of fluoride was not described in the rulemaking as a major change in the Agency's interpretation of the SDWA. Nevertheless, EPA's brief defends the Agency's reinterpretation as a valid exercise of administrative discretion which "need only fall within the range of reasonable interpretations." EPA Br. at 53.

This Court should reject the Agency's new interpretation as unreasonable for two reasons. First, EPA neither said it was changing its interpretation of the statute, nor explained why the new standard is consistent with the clear intent of the SDWA, which is to be preventive. This Court has held that agencies must explicitly indicate when they are changing an established policy or standard, Greater Boston Television Corp. v. FCC, 444 F.2d 841, 852 (D.C. Cir. 1970) cert. denied, 403 U.S. 923 (1971); Committee for Community Access v. FCC, 737 F.2d 74, 77 (D.C. Cir. 1984) and must "supply a reasoned analysis for the change." Motor Vehicle Manufacturers Association v. State Farm Mutual Automobile Insurance Co., 463 U.S. 29, 42 (1983).

In this case, EPA indicated that it was no longer consider-

ing dental fluorosis as an adverse health effect "under the Safe Drinking Water Act," 50 Fed. Reg. at 47143, App. , because dental fluorosis allegedly does not result in functional impairment. EPA Br. at 53. All further explanation for the change merely cited the agreement of persons and organizations supporting EPA's conclusion.[30]

The second reason the Agency's reinterpretation is unreasonable is that it is directly contrary to the express preventive intent of the SDWA, and inconsistent with every other statement EPA has made about its duties under the Act. EPA's determination that under the SDWA an adverse health effect must cause functional impairment constitutes an unduly narrow definition of "adverse health effect." As set forth in NRDC's Brief at 20-23, Congress clearly intended that an RMCL protect against possible injuries to human health. EDF v. Costle, 578 F.2d at 344. Citing Reserve Mining Co. v. United States, 496 F.2d 1073 (8th Cir. 1974), which had held that the scientific uncertainties present in that case should not be resolved on the side of protecting health, Rep. Rogers, the author of the SDWA, emphasized that the Act constitutes a legislative policy judgment that the Administrator is to err on the side of safety in protecting public health. 120 Cong. Rec. H10793 (daily ed., Nov. 19, 1974). Thus, regulation must proceed even in the light of evidence that is "inconclusive and inconsistent" as long as there is "some basis to believe" that public health may be endangered. Id. Given Rep. Rogers'

30/ Counsel's post hoc attempt to justify EPA's action as a policy change constituting a reasonable exercise of discretion does not suffice for the purpose of satisfying the Agency's burdens of acknowledging and justifying the change. State Farm, 463 U.S. at 41-42.

preeminent role in the passage of the 1974 Act, his views on legislative intent are entitled to substantial weight. See, e.g., Federal Energy Administration v. Algonquin SNG, Inc., 426 U.S. 548, 564 (1976); E.I. duPont de Nemours Co. v. Train, 430 U.S. 112, 129-30 (1977); Symons v. Chrysler Corp. Loan Guarantee Board, 670 F.2d 238, 242-3 (D.C. Cir. 1981).[31]

Measured against this unambiguous legislative intent, EPA's determination that an "adverse health effect" under the Act must at least result in functional impairment falls outside the range of reasonable interpretations. The functional impairment test, by definition, improperly excludes evidence of physiological alterations, such as dental fluorosis and osteosclerosis (changes in bone density). It also excludes evidence of subchemical effects indicative of interfence with normal phsyiological processes. The new interpretation, moreover, improperly excludes evidence for which there is medical disagreement as to its significance.[32] It is, therefore, not a preventive standard.

The Agency's interpretation is also inconsistent with every other statement EPA has ever made about its duties under the Act, including a review of those duties made only one day before the fluoride RMCL was published. In promulgating final RMCLs for 8 drinking water contaminants and proposing RMCLs for several other

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31/ These indications of legislative intent were reinforced in the House Report on the 1986 amendments to the Act. The latter Report states that under the 1974 Act, "[t]he Administrator must regulate if there is a rational basis to believe that a contaminant may have an adverse effect on the health of persons." H.R. Rep. No. 168, 99th Cong., 1st Sess. 22 (1985).

32/ For example, EPA's brief acknowledges that the "opposite conclusion" (that dental fluorosis is an adverse health effect) is "rational" and that "reasonable people may differ." This acknowledgment constitutes an admission that "there is some basis to conclude" that dental fluorosis is an adverse health effect. EPA Br. at 53. Thus, in declining to regulate to prevent dental fluorosis, the Administration committed reversible error.

chemicals on November 13, 1985, EPA recognized that "Congress expected EPA to protect public health before adverse effects occurred." 50 Fed. Reg. 46899, App. , (emphasis added). Consistent with this Congressional intent, the Agency acknowledged its duty to regulate compounds where there is a possibility of an adverse health effect. Id. at 46900, App. .[33]

EPA's articulation of a strict "functional impairment" test exclusively for fluoride cannot be considered a rational policy choice consistent with the Agency's other articulations of policy under the SDWA. The interpretation EPA asks this Court to defer to and uphold is a swerve from prior precedents that unquestionably "deviates from and ignores the ascertainable legislative intent." Ethyl Corp. v. EPA, 541 F.2d 1, 36, cert. denied, 426 U.S. 941 (1971). See also discussion and cases cited at NRDC Br. at 52-53 and notes 174-176.[34]

33/ In stark contrast to the approach used in the Fluoride RMCL, the Agency proposed an RMCL for lead in drinking water which protects against subclinical effects, such as enzyme inhibition and red blood cell impacts, and subtle neuropsychological and electrophysiological effects the medical significance of which is controversial. The Agency explained that:

> "[M]any of the different effects reported as being associated with lead exposure might be argued as separately not being of clear medical significance, although each are indicative of interference by lead with normal physiological processes. On the other hand, the collective impact of all of the observed effects (representing potentially impaired functioning and depleted reserve capacities of many different tissues and organs) may...be seen as representing an adverse pattern of effects worthy of avoidance with some added margin of safety."

Proposed RMCLs for Synthetic Organic Chemicals, Inorganic Chemicals and Microorganisms, 50 Fed. Reg. 46936, 46971 (Nov. 13, 1985) (emphasis added). By comparison, the fluoride RMCL identifies only the most severe stage of skeletal fluorosis as the first effect of concern and disregards all other lesser indications of harm. This is analogous to defining lead encephalopathy (irreversible brain damage) as the threshold of conern, and ignoring all other readily detectable biochemical and metabolic changes that occur before such obvious brain damage.

34/ The precedential import of the Agency's new interpretation is also significant. By characterizing disfiguring physiological alterations as "merely cosmetic" and therefore not deserving of protection as adverse health effects, the Agency has begun a course of action which allows potentially

[Cont. next pg.]

V. EPA's Failure to Err on the Side of Safety in Evaluating Evidence of Other Known and Potential Health Effects of Fluoride Warrants a Reversal and Remand in This Case

A. The Agency Applied an Erroneous Standard to the Evidence

NRDC's opening brief details many examples of EPA's application of an impermissibly stringent standard to the extensive evidence in the record indicating that exposure to fluoride may pose serious risks to human health. See NRDC Br. at 53-74. In a responding brief replete with factual and interpretive errors, misstatements of the record and distortion of NRDC's arguments, EPA contends that it consistently followed the mandate of the Act, and is entitled to deference by this Court.

Nowhere does the Agency's brief recognize the preventive intent of the Act or the Administrator's duty to resolve uncertainties in the evidence on the side of protecting health. Nor does the Agency acknowledge that the action at issue in this case represents a significant relaxation of the protection against dental fluorosis, osteosclerosis, and all other risks of exposure to fluoride provided since 1975 by the interim MCL (1.4 - 2.4 mg/L). The Agency's brief provides no explanation or justification for the relaxation beyond articulation of a standard which directly contradicts the express intent of Congress that RMCLs must protect against "known" and "anticipated" adverse effects with an adequate margin of safety. 42 U.S.C. §300g-1(b)(1)(B). In fact, the Agency contends that the burden is on NRDC to show

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serious harm to occur in the population. With fluoride as a precedent, the Agency has now proposed to redefine as "merely cosmetic" the permanent blue disfigurement of skin and internal organs resulting from exposure to silver in drinking water. 50 Fed. Reg. at 46978-9.

why the level of protection provided by the interim MCL should not be relaxed. See EPA Br. at 60.

The examples pointed out by NRDC show EPA applying an evidentiary standard that generally requires documented human evidence of an effect, widespread occurrence in the U.S. population, observable "clinically significant" functional impairment related to the accumulation of fluoride in bones and teeth, and/or preponderant or conclusive evidence of the effect. EPA's response is that the Administrator consistently interpreted the statutory term "anticipated effects" to cover those "likely to occur in humans" or for which the evidence is "equivocal." EPA Br. at 59. Contending erroneously that NRDC can point to nothing in the statute or legislative history to the contrary (id.), EPA argues further that adverse health effects which are "merely possible" are not covered by the preventive scope of the SDWA.

EPA's contention that RMCLs need not protect against "possible" adverse health effects reflects a fundamental misunderstanding of the Agency's duty under the SDWA. As NRDC has shown, Congress specifically directed the Agency to protect against adverse effects that "may" occur. See NRDC Br. at 20-23. In rejecting the rationale of the Reserve Mining decision, and specifying that questions involving possible medical dangers must be resolved in favor of health protection, Congress told the Administrator how protective RMCLs were to be. Possible adverse health effects were and are intended to be covered by an RMCL; EPA's interpretation to the contrary is wrong.

The Agency's frequent recitation that it utilized a "weight of evidence" approach provides no additional justification for

the erroneous standard EPA applied. Mere repetition that a "weight of evidence" approach was used, without further explanation, strongly suggests that EPA was imposing a requirement of preponderant or conclusive evidence, although Congress specifically directed that such proof should not be a precondition for standard-setting. 120 Cong. Rec. H10794 (daily ed., Nov. 19, 1974).[35]

B. EPA's Responses to NRDC's Arguments on Other Potential Health Effects of Fluoride Underscore the Pattern of Arbitrary and Capricious Decisionmaking that Pervaded the Fluoride RMCL Rulemaking

NRDC's Brief documents instance after instance where EPA rejected, i.e., did not credit, admittedly valid evidence indicating potential adverse health effects of fluoride. In response, EPA's brief repeatedly claims that the Agency conducted an "exhaustive" evaluation of the evidence on all of the other potential effects of fluoride. EPA Br. at 57 ff. Serious questions about the validity and the extent of that evaluation have been raised by the National Federation of Federal Employees, which contends, inter alia, that the Agency's scientific support documents have serious deficiencies. See NRDC Br. at Att. E, and Att. IV to this brief. Although page limitations are a constraint, a few of EPA's more unpersuasive arguments warrant a brief reply. For other effects not addressed here, NRDC rests on the arguments set forth in its opening brief.

1. Skeletal Growth and Cardiovascular Effects in Children

EPA relied heavily on "the large human exposure data base

35/ The Agency's brief characterizes NRDC's position as "unthinking," EPA Br. at 61, and cites API v. Costle, supra, as authority for the principle that valid positive evidence of an effect does not require EPA to regulate for that effect. Id. This argument overlooks the fact that it was Congress and not NRDC that directed EPA to resolve uncertainties on the side of health protection.

and the absence of these adverse effects," EPA Br. at 63, to conclude that the evidence indicating that skeletal and cardiovascular effects from fluoride exposures below the RMCL did not warrant a more protective RMCL. The Agency's brief states that the Surgeon General didn't believe the skeletal effects were significant enough even to mention in his report to EPA, EPA Br. at 63, and that the cardiovascular evidence was outweighed by the "negative human evidence." EPA Br. at 64. Not only does this response ignore the extreme concern the Surgeon General's panel expressed about both of these potential effects, see NRDC Br. at 60-61, but the Agency's claim of extensive "negative human evidence," is directly contradicted by the Surgeon General's Report itself. The latter report specifically "emphasize[s] the current lack of information" on these questions, and, with particular regard to the skeletal effects, warns that the impacts of fluoride on children "are not well understood." Medical Panel Report at 6,7. The Agency's heavy reliance on a virtually non-existent human data base regarding these effects in children, is misplaced.

2. Adverse Kidney Effects

EPA's Brief attempts to justify the failure of the RMCL to prevent adverse kidney effects on two grounds. The first, that the sensitive sub-group of renally-impaired persons need not be protected by a national regulation, is directly contrary to the stated Congressional intent. See NRDC Br. at 20-23. The second ground offered by EPA is that record evidence of four fatalities involving renal impairment apparently due to fluoride in drinking water "have not been adequately related to renal injury from

fluoride...." EPA Br. at 68. The latter argument is also without merit.

The Agency's "rebuttal" of the study documenting the four fatalities following exposure to fluoride at concentrations below the RMCL consists of two papers published before the fatalities were reported. The Agency has made no claim that the later study is invalid. EPA's principal criticism is that it does not demonstrate that fluoride in U.S. drinking water leads to renal toxicity. EPA Br. at 68. Since the SDWA requires that the RMCL prevent an adverse health effect even where the evidence of its causation is not clear, the Agency's criticism does not justify its decision not to protect against possible renal toxicity in setting the RMCL.

3. Carcinogenicity and Mutagenicity

EPA's contention that certain of the carcinogenicity evidence in the record is not credible, EPA Br. at 64-65, is not responsive to NRDC's argument that there is other valid record evidence suggesting that the question of fluoride's carcinogenicity has not been solved. See NRDC Br. at 61-63. The Agency cannot simply ignore this evidence in the context of a decision allowing fluoride exposures via drinking water to double. With regard to the mutagenicity evidence, which can be indicative of either potential carcinogenicity or mutagenicity, or both, the Agency's brief concedes that "there were several validly conducted positive and negative [mutagenicity] studies," EPA Br. at 65, and that the overall evidence is "equivocal." Id. By EPA's own admission, "equivocal" evidence is deemed to be an "anticipated" adverse health effect, and the RMCL should

therefore have protected against this effect. See EPA Br. at 59.

EPA's insistence on a higher degree of proof of adverse effects on health than Congress intended or the SDWA requires should not be countenanced by this Court. EPA has not and cannot show how its interpretation of the statute is consistent with the SDWA, the overriding purpose of which is to "maximize protection of the public health." House Report at 12.

VI. Conclusion

For the foregoing reasons, EPA's decision to establish the RMCL at 4 mg/L should be reversed and remanded for establishment of an RMCL for fluoride consistent with the requirements of the Act.

Respectfully submitted,

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ATTACHMENT I