

Comments on Fluoride to the National Toxicology Program Board of Scientific Counselors

Anthony R. Scialli, M.D.
Scialli Consulting LLC

Director, Reproductive Toxicology Center A Non-Profit Foundation

Clinical Professor, Department of Obstetrics and Gynecology, George
Washington University School of Medicine and Health Sciences

Adjunct Professor, Departments of Obstetrics & Gynecology and
Pharmacology & Physiology, Georgetown University School of Medicine

On behalf of the Consumer Healthcare Products Association





National Toxicology Program
U.S. Department of Health and Human Services

Proposed NTP Evaluation on Fluoride Exposure and Potential for Developmental Neurobehavioral Effects

Neurobehavioral Effects

and Potential for Developmental

Consumer products are minor sources of fluoride exposure

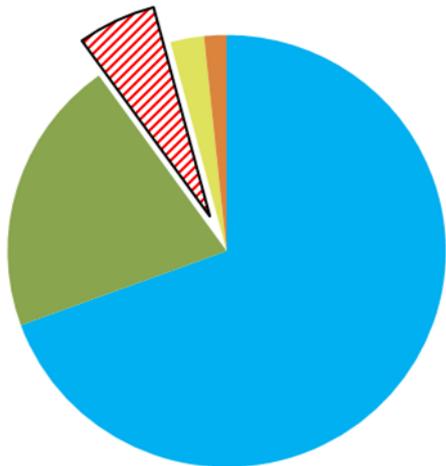
Table 1. Representative Values for Fluoride Intakes Used in Calculation of the Relative Source Contribution from Drinking Water

Age group (years)	DWI ^a (mg/day)	BI (mg/day)	FI (mg/day)	TI (mg/day)	SuF (mg/day)	SI (mg/day)	Total (mg/day)	RSC (%)
0.5 - <1	0.84	--	0.25 ^b	0.07	0.03	0.02	1.2	70
1 - <4	0.63	0.36	0.16	0.34	0.05	0.04	1.58	40
4 - <7	0.82	0.54	0.35	0.22	0.06	0.04	2.03	40
7 - <11	0.86	0.60	0.41	0.18	0.07	0.04	2.16	40
11-14	1.23	0.38	0.47	0.20	0.09	0.04	2.41	51
>14	1.74 ^b	0.59	0.38	0.10 ^c	0.08	0.02	2.91	60

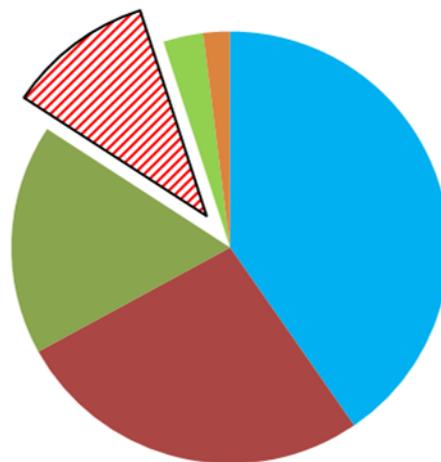
From Table 7-2 (US Environmental Protection Agency 2010b)

^a Consumers only; 90th percentile intake except for >14 years. The >14 year value is based on the Office of Water policy of 2 L/day. ^b Includes foods, fluoride in powdered formula, and fruit juices; no allocation for other beverages. ^c Assumed. 50% of the 11-14 year old age group. DWI = Drinking Water Intake; BI = Beverage Intake; FI = Food Intake (Solid Foods); TI = Toothpaste Intake; SuF = Sulfuryl Fluoride Intake; SI = Soil Intake; RSC = Relative Source Contribution.

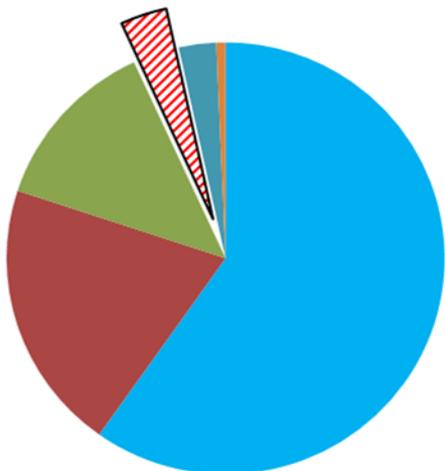
0.5-1 years



4-<7



>14

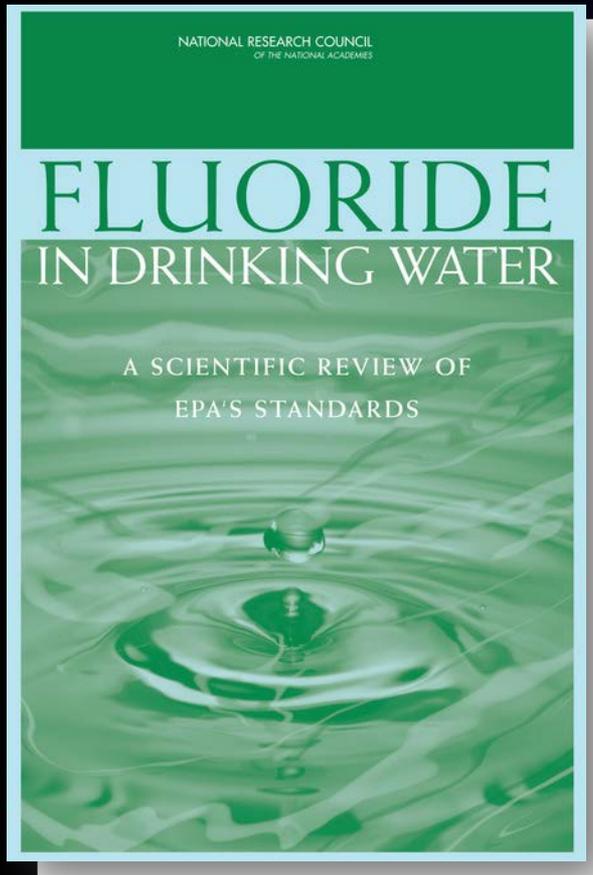


- Drinking water
- Other beverages
- Food
- Toothpaste
- Sulfuryl fluoride
- Soil

Evaluations past 10 years

- National Research Council 2006
- South Central Strategic Health Authority (Bazian, Ltd) 2009
- U.S. Environmental Protection Agency 2010
- Scientific Committee on Health and Environmental Risk (European Commission) 2011
- U.S. Public Health Service 2015
- U.S. Surgeon General 2015

National Research Council 2006



“A few epidemiologic studies of Chinese populations have reported IQ deficits in children exposed to fluoride at 2.5 to 4 mg/L in drinking water. Although the studies lacked sufficient detail for the committee to fully assess their quality and relevance to U.S. populations, the consistency of the results appears significant enough to warrant additional research on the effects of fluoride on intelligence.”

South Central Strategic Health Authority 2009

Bazian

Independent critical appraisal of selected studies reporting an association between fluoride in drinking water and IQ

A report for South Central Strategic Health Authority
Delivery date: 11th February 2009



Re: IQ studies

- Lack of consistent adjustment for:
 - Arsenic & iodine in water
 - Parental education
 - Socioeconomic measures
- One of the systematic reviews used statistically invalid methods
- High fluoride coal burning and eating contaminated grain not relevant to the UK setting



Scientific Committee on Health and Environmental Risks

SCHER

Critical review of any new evidence on the hazard profile, health effects, and human exposure to fluoride and the fluoridating agents of drinking water

SCHER 2011

Systemic exposure to fluoride through drinking water is associated with an increased risk of dental and bone fluorosis in a dose-response manner without a detectable threshold. Limited evidence from epidemiological studies points towards other adverse health effects following systemic fluoride exposure, e.g. carcinogenicity, developmental neurotoxicity and reproductive toxicity; however the application of the general rules of the weight-of-evidence approach indicates that these observations cannot be unequivocally substantiated.

The cariostatic effect of topical fluoride application, e.g. fluoridated toothpaste, is to maintain a continuous level of fluoride in the oral cavity. Scientific evidence for the protective effect of topical fluoride application is strong, while the respective data for systemic application via drinking water are less convincing. No obvious advantage appears in favour of water fluoridation as compared with topical application of fluoride. However, an advantage in favour of water fluoridation is that caries prevention may reach disadvantaged children from the lower socioeconomic groups.

U.S. Public Health Service Recommendation for Fluoride Concentration in Drinking Water for the Prevention of Dental Caries

Surgeon General's Perspectives

COMMUNITY WATER FLUORIDATION: ONE OF CDC'S "10 GREAT PUBLIC HEALTH ACHIEVEMENTS OF THE 20TH CENTURY"

VIVEK H. MURTHY, MD, MBA

Seventy years ago, nearly everyone in the United States had tooth decay. No one knew how to prevent it. It was not uncommon for 13-year-olds to have lost one or more permanent teeth to decay.¹ As recently as the late 1950s, about half of Americans older than 65 years of age lost all their natural teeth, which many replaced with dentures.²

In some areas of the United States, dentists observed that the enamel on many of their patients' teeth looked stained or mottled. However, these same teeth appeared to be protected from tooth decay. After some sleuthing, it was determined that fluoride in the local water supply was the reason for both phenomena.



Vivek H. Murthy, MD, MBA
VADM U.S. Public Health Service
Surgeon General

Community Water Fluoridation and Intelligence: Prospective Study in New Zealand

Jonathan M. Broadbent, PhD, W. Murray Thomson, PhD, Sandhya Ramrakha, PhD, Terrie E. Moffitt, PhD, Jiayu Zeng, PhD, Lyndie A. Foster Page, PhD, and Richie Poulton, PhD

Community water fluoridation (CWF) is a cost-effective,^{1,2} safe,³ and environmentally friendly⁴ means of reducing dental caries rates³ and

Objectives. This study aimed to clarify the relationship between community water fluoridation (CWF) and IQ.

Methods. We conducted a prospective study of a general population sample of

These findings do not support the assertion that fluoride in the context of CWF programs is neurotoxic.

govern... It is likely... lobbied against C...

Since the 1960s, an... population has had access...

average fluoride intakes remain below the adequate intake level for dental caries protection, and CWF schemes are only 1 (albeit important) source of community fluoride.⁸ The... exposure and low IQ reported in previous studies may have been affected by confounding, particularly by urban or rural status. (*Am J Public Health.* 2015;105:72-76. doi:10.2105/AJPH.2013.301857)

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TABLE 4—IQ Subtest Scores by Fluoride Exposure: Dunedin Multidisciplinary Health and Development Study; Dunedin, New Zealand; 1972–2012

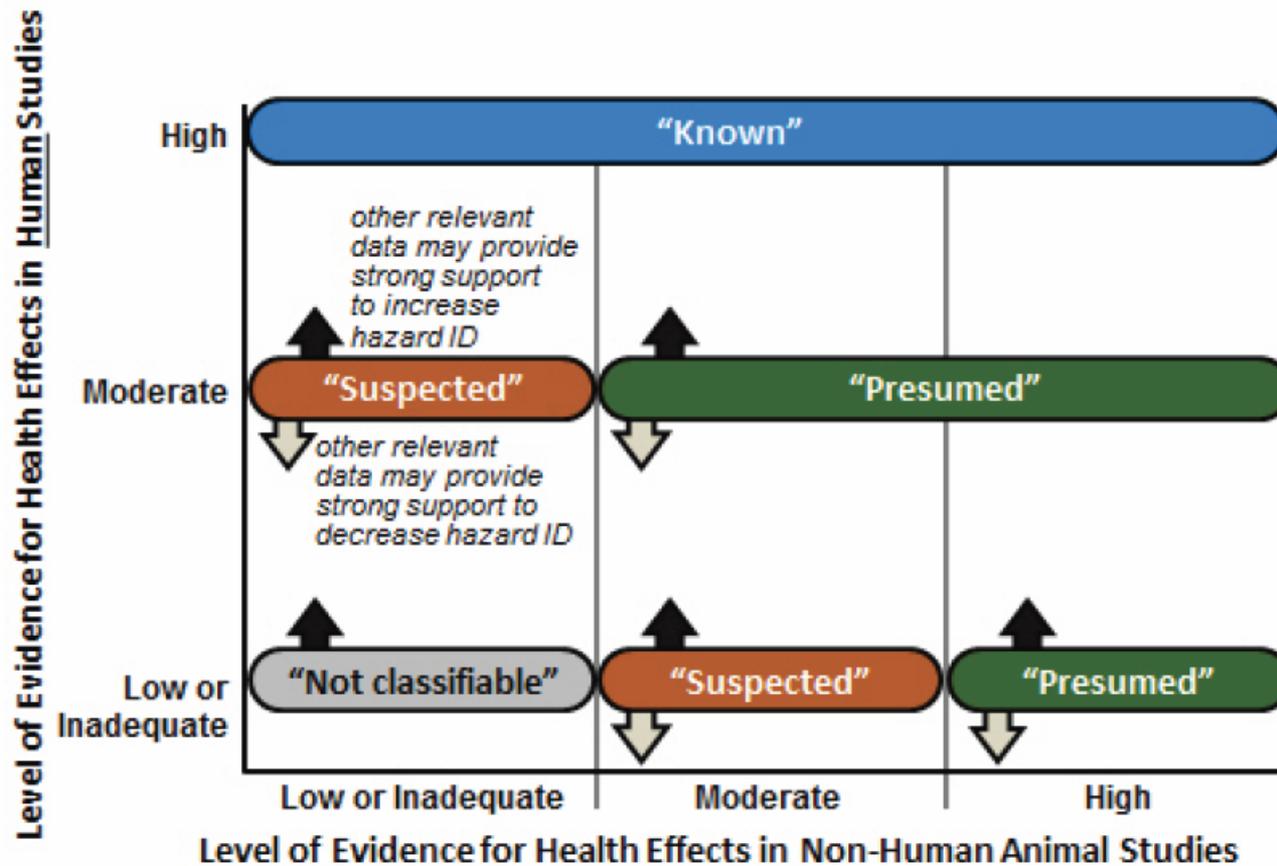
Exposure	Verbal Comprehension Index		Perceptual Reasoning Index		Working Memory Index		Processing Speed Index	
	Mean (SD)	<i>P</i>	Mean (SD)	<i>P</i>	Mean (SD)	<i>P</i>	Mean (SD)	<i>P</i>
Area of residence in childhood		.51		.18		.12		.47
Area with CWF	100.1 (14.9)		100.2 (15.1)		100.3 (15.0)		100.1 (15.1)	
Area without CWF	98.9 (15.5)		98.0 (14.1)		97.7 (15.0)		98.9 (14.3)	
Fluoride toothpaste in childhood		.97		.96		.61		.87
Always	100.0 (15.0)		100.0 (15.2)		99.8 (14.8)		100.1 (15.1)	
Sometimes/never	100.0 (15.0)		100.0 (14.7)		100.3 (15.1)		99.9 (14.9)	
Fluoride tablets in childhood		.59		.86		.66		.51
Ever	99.3 (14.7)		100.2 (15.7)		99.5 (15.6)		100.8 (15.5)	
Never	100.1 (15.1)		100.0 (14.9)		100.1 (14.9)		99.9 (14.9)	

Note. CWF = community water fluoridation.

Broadbent et al., Am J Public Health 2015;105:72-76

Hazard identification

Figure 8. Hazard Identification Scheme



From OHAT Handbook, 2015

Hazard in the setting of exposure level

“...hazard identification for developmental toxicity and other noncancer health effects is usually done in conjunction with an evaluation of dose-response relationships, since the determination of a hazard is often dependent on whether a dose-response relationship is present (Kimmel et al., 1990b). One advantage of this approach is that it reflects hazard within the context of dose, route, and duration and timing of exposure, all of which are important in comparing the toxicity information available to potential human exposure scenarios. Second, this approach avoids labeling of chemicals as developmental toxicants on a purely qualitative basis.”

US EPA. Guidelines for Developmental Toxicity Risk Assessment 1991

NTP CERHR Guidelines

“Conclusions. This section is based on an integration of the toxicity and exposure data and, when possible, evidence on the mechanism of action. Conclusions are presented in narrative form and present the panel’s best scientific judgment on the likelihood that adverse reproductive and/or developmental effects may occur **under the exposure circumstances specified.**”

Shelby MD. Birth Def Res (Part B) 2005;74:9-16.

Hazard calls

- May be interpreted by third parties without regard to exposure level;
- May lead to a reduction in fluoride in drinking water and dental products, resulting in adverse effects on public health.

Are **YOU USING**
This Top-Selling
TOXIC
TOOTHPASTE?



Conclusions

- Fluoride exposure as it occurs in the U.S. has been demonstrated to be safe.
- Several government agencies have reviewed the epidemiology data, and additional NTP activity is not needed.
- If NTP goes forward, care should be taken that all hazard conclusions are expressed only in the context of specific exposure scenarios.
- Naked hazard calls can have adverse public health consequences.