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

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On behalf of the Consumer Healthcare Products Association
Proposed NTP Evaluation on Fluoride Exposure and Potential for Developmental Neurobehavioral Effects
Consumer products are minor sources of fluoride exposure

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

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

<sup>a</sup> 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.  
<sup>b</sup> Includes foods, fluoride in powdered formula, and fruit juices; no allocation for other beverages.  
<sup>c</sup> 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.
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
“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.”
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
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.
Reports and Recommendations

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
These findings do not support the assertion that fluoride in the context of CWF programs is neurotoxic.
<table>
<thead>
<tr>
<th>Exposure</th>
<th>Verbal Comprehension Index</th>
<th>Perceptual Reasoning Index</th>
<th>Working Memory Index</th>
<th>Processing Speed Index</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>Area of residence in childhood</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Area with CWF</td>
<td>100.1 (14.9)</td>
<td>100.2 (15.1)</td>
<td>100.3 (15.0)</td>
<td>100.1 (15.1)</td>
</tr>
<tr>
<td>Area without CWF</td>
<td>98.9 (15.5)</td>
<td>98.0 (14.1)</td>
<td>97.7 (15.0)</td>
<td>98.9 (14.3)</td>
</tr>
<tr>
<td>Fluoride toothpaste in childhood</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Always</td>
<td>100.0 (15.0)</td>
<td>100.0 (15.2)</td>
<td>99.8 (14.8)</td>
<td>100.1 (15.1)</td>
</tr>
<tr>
<td>Sometimes/never</td>
<td>100.0 (15.0)</td>
<td>100.0 (14.7)</td>
<td>100.3 (15.1)</td>
<td>99.9 (14.9)</td>
</tr>
<tr>
<td>Fluoride tablets in childhood</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ever</td>
<td>99.3 (14.7)</td>
<td>100.2 (15.7)</td>
<td>99.5 (15.6)</td>
<td>100.8 (15.5)</td>
</tr>
<tr>
<td>Never</td>
<td>100.1 (15.1)</td>
<td>100.0 (14.9)</td>
<td>100.1 (14.9)</td>
<td>99.9 (14.9)</td>
</tr>
</tbody>
</table>

Note. CWF = community water fluoridation.
Hazard identification

Figure 8. Hazard Identification Scheme

Level of Evidence for Health Effects in Non-Human Animal Studies

High

Moderate

Low or Inadequate

“Known”

“Suspected”

“Presumed”

“Not classifiable”

“Suspected”

“Presumed”

From OHAT Handbook, 2015
“...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.”

“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.”

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.