

Chapter 11

Margin of Safety

Paul Connett, PhD, Director, Fluoride Action Network reported the following in October 2020.

When fluoride levels in the public drinking water supply are artificially increased, usually by around 350%, using fluoridation chemicals such as fluorosilicic acid, our utility employees and politicians take on the role of a physician or dentist. Their intent is not to treat the water, but to treat the water *consumer* as a patient being prescribed a drug for the ostensible purpose of reducing dental decay.

In a clinical setting, practitioners prescribing a drug or treatment to patients work to successfully treat the patient without causing any adverse reactions. Their goal is to prescribe a dose high enough to be effective, but below what is toxic. The range between these two doses is referred to as the Margin of Safety (sometimes called Margin of Exposure) of a drug or treatment.

Unlike a clinical setting, however, water fluoridation is a treatment administered to an entire community rather than an individual, and there is no control over intake (dose) since people vary greatly in their water consumption and overall exposure to fluoride from all sources.

Everyone is exposed, many for their entire lives, regardless of age, weight, diet, genetics, medical history, total fluoride exposure, or even caries risk. No consent is given and, by the design of those promoting fluoridation, very few consumers have been informed of potential side effects or risks associated with overexposure. There is also no follow-up by the 'practitioner' in this case or monitoring for adverse reactions.

This chaotic and unregulated dispensing of fluoride makes the importance of applying a regulatory margin of safety to fluoridation critical in an effort to protect whole populations, including the most vulnerable. An adequate margin of safety has to take into account the wide range of individual sensitivity expected in a large population and the wide range of doses to which people are exposed.

Hundreds of published peer-reviewed animal and human studies now link fluoride exposure to significant side effects. According to Chapter 20 of 'The Case Against Fluoride':

"It is not disputed that, at moderate to high doses, fluoride can cause serious health problems and other adverse effects. The crucial question is whether there is a sufficient margin of safety between the doses that cause those effects and the doses experienced in fluoridated communities... this margin of safety has to be sufficiently large to protect everyone, including the most vulnerable, not just the average person. Moreover, it has to be large enough to protect the whole population over a lifetime of exposure."

Taking just these higher-fluoride-dose studies into account, if the EPA applied the normal toxicological procedures and appropriate margins of safety to fluoridation, the practice would be prohibited. This is because, in toxicology, a standard safety factor of 10 is generally used to extrapolate from the result of a small study group (say of 100 - 200 individuals) to find a dose which is protective of everyone in a large population (say several million). This is called the 'intra species safety factor'. In protecting public health, you have to be conservative. In short, regulators have to assume that there are individuals in the large population who are 10 times more sensitive to the toxic chemical in question than anyone in the small study group.

Fluoride and neurotoxicity

Turning now to the current situation (2020) with fluoride and neurotoxicity, key studies published since 2017 indicate that effects are being observed at the current fluoride exposure levels experienced in fluoridated communities

(Ref: Bashash 2018; 2017; Riddell 2019; and Till 2020).

Adding to the significance here is the fact that nearly all of these studies have been funded by the NIH and, as such, their methodologies have been extremely rigorous, leaving little wriggle room for doubt on the matter.

This subset of the data (involving exposure to the foetus and the bottle-fed infant) is damning as far as the practice of water fluoridation is concerned, and that is why we are seeing such desperate efforts by the die-hard fluoridation promoters who are doing everything to discredit these studies. These efforts include hounding one of the key authors (Prof Christine Till). But even if we go beyond this subset and examine the totality of all the neurotoxicity studies, there is no salvation for this outdated practice.

The NTP Review

The updated draft of the NTP (National Toxicology Program *in the USA*) systematic review confirms that fluoride is a presumed developmental neurotoxicant. While claiming that the evidence is stronger and more consistent for studies in which subjects were consuming water at or above 1.5 ppm, this conclusion by itself should end fluoridation as a public health policy.

These are the documents released by the NTP:

- September 16, 2020. Draft NTP Monograph on the Systematic Review of Fluoride Exposure and Neurodevelopmental and Cognitive Health Effects.
- September 16, 2020. Protocol for the Systematic Review of Fluoride Exposure and Neurodevelopmental and Cognitive Health Effects. Project Leader: Kyla Taylor, PhD.
- September 16, 2020. Literature Search Results for the Systematic Review of Fluoride Exposure and Neurodevelopmental and Cognitive Health Effects.
- Clearly, returning to the subject of this bulletin, there is no adequate margin of safety when exposing millions of foetuses, infants and children to concentrations of fluoride in water at 1.5 ppm. This is just a factor of *TWO* times larger than levels that are typically used in fluoridation programs (0.7 ppm) and does not come close to providing the necessary and standard safety factor of *TEN*.

In conclusion, as confirmed by the National Toxicology Program (the premier toxicological body in the US), the scientific literature is clear and consistent in showing that harm occurs to the developing brain at or above 1.5 ppm and thus there is no adequate margin of safety currently between the fluoride levels that residents in fluoridated communities are being exposed to and those that are causing harm in NIH-funded studies. Water fluoridation needs to be discontinued immediately.

“Drinking water with fluoride above 0.15 ppm should no longer be considered safe”, states Prof Paul Connett, in FAN’s 16th October Press Release, 2020, in response to the NTP’s admission that the harm to the brain from fluoride is worse than they had realised. Many or most areas have a ‘background’ level of fluoride well above this level. To reach the level below 0.15 ppm fluoride for drinking water and for cooking, individual households would need to install a Reverse Osmosis system at the kitchen sink.

The scientific review, May 2020, from Christine Till looks at the controversy.

The Evolving Science of Fluoride: When New Evidence Doesn’t Conform with Existing Beliefs by Christine Till

Abstract

Over the past 75 years, health authorities have declared that community water fluoridation – a practice that reaches over 400 million worldwide – is safe. Yet, studies conducted in North America examining the safety of fluoride exposure in pregnancy were non-existent. When a Canadian study reported that higher fluoride exposure in pregnant women was associated with lower IQ scores in young children, critics attacked the methodology of the study and discounted the significance of the results. Health authorities continued to conclude that fluoride is unequivocally safe, despite four well-conducted studies over the last three years consistently linking fluoride exposure in pregnancy with adverse neurodevelopmental effects in offspring. We describe the challenges of conducting fluoride research and the overt cognitive biases we have witnessed in the polarised fluoride debate. The tendency to ignore new evidence that does not conform to widespread beliefs impedes the response to early warnings about fluoride as a potential developmental neurotoxin. Evolving evidence should inspire scientists and health authorities to re-evaluate claims about the safety of fluoride, especially for the foetus and infant for whom there is no benefit.

(Refs: Review *Pediatr Res* . 2020 May 22. doi: 10.1038/s41390-020-0973-8. Online ahead of print. Controversy: ‘The Evolving Science of Fluoride: When New Evidence Doesn’t Conform With Existing Beliefs’, Christine Till 1, Rivka Green 2 Affiliations expand PMID: 32443137 DOI: 10.1038/s41390-020-)