

Response to Critique by Fluoridation Opponents of the 2019 CADTH Report on Fluoridation

July, 2019

In a recent document, a group of members, former members, and close affiliates of one or both of the antifluoridation groups, Fluoride Action Network (FAN), and International Academy of Oral Medicine and Toxicology (IAOMT), provided information claimed to be a "refutation" of the 2019 report of the *Canadian Agency for Drugs and Technologies in Health* (CADTH), *Community Fluoridation Programs.* To point out the false claims, misrepresentations, and misinformation of this "refutation", the American Fluoridation Society has provided facts, evidence, and peer-reviewed science in the following document.

Initial Points

- The term "the authors" is used in reference to Hardy Limeback, Paul Connett, and the peripheral group of other fluoridation opponents who have signed onto the document in question.
- The group, "Safe Water Calgary" appears to be a local antifluoridation group led by activist Bob Dickson.
- The IAOMT is an activist group which, as with its antifluoridation beliefs, has similarly long attempted to impose its flawed beliefs against dental amalgam onto the public via advocacy and court action. A 2016 rejection of such IAOMT claims by the District Court of the District of Columbia may be viewed in *International Academy of Oral Medicine and Toxicology v*. Food and Drug Administration, Civil Action No. 2014-0356 (D.D.C. 2016) District Court, District of Columbia.
- While the authors put forth a flurry of invalid and/or irrelevant studies which they claim were "omitted" by CADTH, in actuality, it is not possible or necessary to include every such study fluoridation opponents claim to support their position, with no regard to the quality or source of those studies. With 6000 studies on fluoridation in existence, responsible reviewers must focus on those which are pertinent and credible. Within this document are cited numerous valid, peer-reviewed studies refuting claims of the authors, which they themselves have omitted from their paper.
- While the authors deceptively seek to differentiate between "artificial" and "natural" fluoridation, fluoride ions are all identical, regardless of whether they become incorporated into surface water as it passes over rocks ("natural fluoridation"), or whether they are added into water systems at a later time ("artificial fluoridation").

The following document addresses the claims made by the authors within each of their sections.

I. Ethics

1. Authors: "Health Canada defines a drug as any substance used for "the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or its symptoms, in human beings or animals." Fluoride added to water to prevent cavities, is, therefore, being used as a drug."

Facts:

The definition of a "drug" misrepresented by the authors to be that of Health Canada is, as clearly stated in the document to which a link was provided by the authors, a definition of the "Food and Drugs Act". It is nothing more than a legislative definition to differentiate between groups of substances which fall under the jurisdiction of this ACT. Ethics are not determined by legislative definitions. They are set by moral beliefs and philosophy. The moral and ideological beliefs of the authors of this document no more establish broad ethical boundaries than do those of any other individuals.

Fluoride ions in water do not fall under the jurisdiction of the "Food and Drugs Act". The contents of drinking water supplies are under the jurisdiction of local governments. Therefore, definitions of the "Food and Drugs Act" are of no relevance to fluoride in water supplies.

2. Authors: "As Dr. Arvid Carlsson, 2000 Nobel Prize winner in physiology or medicine, stated, water fluoridation is 'obsolete" and "against all modern principles of pharmacology.' "

Facts:

Arvid Carlsson was a fluoridation opponent whose unsubstantiated opinions on the issue were not supported by the peer-reviewed science, or the consensus opinion of the worldwide body of respected science and healthcare.

3. Authors: "Several European nations, including France, Germany, Belgium and the Netherlands, have cited the improper and/or unethical nature of adding any drug to drinking water as one reason they have banned fluoridation."

Facts:

Neither France, Germany, Belgium, nor the Netherlands has banned fluoridation, as is falsely claimed by the authors. That a country chooses not to fluoridate its water for any of numerous reasons does not constitute the initiative having been banned. The statements cited by the authors are sourced from "fluoridealert", the website of the NY antifluoridation group, FAN. They are not official government decrees but simply unsubstantiated opinions solicited by FAN from individuals within those countries. These opinions are subject to, and biased by, the same antifluoridation misinformation as are those of fluoridation opponents within the US and Canada.

In Reality:

- France- Fluoridation of water is neither banned nor prohibited. "Fluoridated salt is available in France, and 3% of the population uses naturally fluoridated water, but the water is not artificially fluoridated." (3) (7)
- Germany- Fluoridation is neither banned nor prohibited. "Public drinking water supplies are not currently fluoridated in any part of Germany, however for children and adolescents use of

fluoridated salt and toothpaste, as well as fluoride tablets and washes are strongly encouraged by the German Ministry of Health." (1) (7)

• Belgium- Fluoridation of water is neither banned nor prohibited. It is simply not necessary. According to Vandevijvere, et al., "The legal norm for [existing] fluoride concentration in tap water is 1.5 mg/L (Directive 98/93/CE). (6) (7)

Water is fluoridated at 0.7 mg/L, less than one half this mean level which already exists in the waters of Belgium.

 Netherlands- Water fluoridation was "unauthorized" in 1973 due simply to an interpretation of Dutch law. "Dutch authorities had no legal basis for adding chemicals to drinking water if they would not contribute to a sound water supply." (7)

4. Authors: "Adding fluoride to drinking water because some people may get cavities makes no more sense than adding aspirin because some people have headaches or adding a statin drug because some people have high cholesterol."

Facts:

Water fluoridation is not the addition of a drug to water supplies. It is the simple adjustment of the existing level of fluoride ions in water by a minuscule amount up to that level at which has been determined that maximum dental decay prevention will occur in the population served by that water, with no adverse effects upon anyone. The fluoride ions added in this adjustment are identical to those which have always existed in water.

Fluoride ions are ingested from water regardless of whether additional ones are added or not. Fluoridation just ensures that maximum benefit is attained while so doing.

The attempt by the authors to equate the adjustment of existing fluoride levels in water to an addition of aspirin and statins to water, is disingenuous, at best. Aspirin and statins do not already exist in water, as do fluoride ions. The addition of them would therefore be the addition of foreign substances which, unlike fluoride at the optimal level, do have documented side effects.

5. Authors: With fluoridation, there is no control whatsoever over who ingests the drug and how much they drink,...".

Facts:

Control over fluoride ingestion from optimally fluoridated water is far more strictly controlled than is that from non-fluoridated water systems. Water is fluoridated, and strictly maintained, at a concentration of 0.7 mg/liter. This means that for every one liter of fluoridated water consumed, 0.7 mg fluoride is ingested. The recommended maximum allowable fluoride level in Canada is 1.5 mg/liter, or 1.5 mg fluoride ingested per every one liter of such water consumed. Therefore, fluoride ingested in non-fluoridated water can be twice as high as that in fluoridated systems.

Additionally, when the maximum amount of a substance which can be ingested falls below the level of adverse effects tor that substance then intake level is of no concern in regard to adverse effects. Prior to the threshold of adverse effects being attained from ingestion of optimally fluoridated water in addition to that ingested from all other normal sources of fluoride,

water toxicity would be the concern, not fluoride. This is true for not only fluoride but chlorine, ammonia, and the numerous other substances routinely added to drinking water supplies.

6. Authors: "...making it especially risky to vulnerable sub-populations like pregnant women, children and those who consume a lot of water such as diabetes and kidney patients, athletes and manual laborers"

Facts:

There is no valid, peer-reviewed scientific evidence of risk of adverse effects to "vulnerable sub-populations like pregnant women, children and those who consume a lot of water such as diabetes and kidney patients, athletes and manual laborers.", or anyone else, from optimally fluoridated water in conjunction with that ingested from all other normal sources of fluoride.

7. Authors: "Moreover, people are exposed to fluoride from numerous sources including food, pesticide residues, dental products (particularly toothpaste swallowed by young children), medications, and proximity to fluoride-emitting industries. All add to the toxic load."

Facts:

As estimated by the US CDC, of the total amount of fluoride ingested from all normal sources, 75% is from water and beverages. (10). This includes "fluoride from numerous sources including food, pesticide residues, dental products (particularly toothpaste swallowed by young children), medications, and proximity to fluoride-emitting industries."

There is no valid, peer-reviewed scientific evidence of any adverse effects of fluoride from optimally fluoridated water in addition to that from all the other sources cited by the authors.

8. Authors: "CADTH's ethics claim is built on the premise that its benefits outweigh its risks. But this argument is totally unsupported by the scientific evidence. "

Facts:

Contrary to the claim of the authors, as there are no risks of adverse effects from optimally fluoridated water, the CADTH claim that benefits outweigh risks is correct. While there is well-documented, peer-reviewed scientific evidence (11) of significant disease preventive benefit of optimally fluoridated water, there is no such evidence of risk of any adverse effects.

9. Authors: "First, fluoridation's benefits are minimal, at best less than one cavity reduction per child in permanent teeth (see Effectiveness section for documentation)...."

Facts:

The authors' implication that a "one cavity reduction" is a "minimal" benefit reflects a profound lack of understanding of oral health disease. Dental decay is a very serious bacterial infection occurring in close proximity to the brain, with a direct pathway to the rest of the body via the blood stream. A periapical abscess directly resultant of but one untreated cavity in one tooth can cause a lifetime of extreme pain, debilitation, black discoloration and loss of multiple, if not all, teeth, development of serious medical conditions, and life-threatening infection. People can, and do, die from one untreated cavity in one tooth.

From the Journal of Endodontics:

"During the 9-year study period, a total of 61,439 hospitalizations were primarily attributed to periapical abscesses in the United States. The average age was 37 years, and 89% of all

hospitalizations occurred on an emergency/urgent basis. The mean length of stay was 2.96 days, and a total of 66 patients died in hospitals." (12)

As an example of the distorted use of individual averages, the Brunelle/Carlos study cited by the authors is routinely read superficially by folks eager to discount fluoridation. The paper can be quoted as averages to minimize the effect because the 0.6 surface is the effect averaged over both age and geography. 5 year olds have only 1 or two permanent teeth and there is essentially no difference between cavity rates at that early age yet they are counted in calculating the 'average'

By age 17 the difference between fluoridated and non-fluoridated is about 1.6 surfaces and the benefit curve is sharply accelerating with a benefit just under 3 times higher than the 0.6 so commonly quoted." (14)

10. Authors: "...with no credible documentation that it significantly helps socioeconomically disadvantaged children or adults."

Facts:

This claim is false. A recent study in JAMA Pediatrics by Sanders, et al. concluded:

"This is the first U.S. study to show evidence that water fluoridation attenuates income-related inequalities in dental caries. The degree of attenuation was less pronounced in the permanent dentition, possibly because the level of decay was about half that of primary teeth. Greater attenuation in the permanent dentition might be seen in early adulthood, as the burden of DMFS doubles between adolescence and early adulthood." (15)

11. Authors: "Second, the chemical used to fluoridate most water, fluorosilicic acid, is, according to water regulation agency NSF International (5), legally allowed to contain low levels of lead and arsenic. Health Canada cites arsenic as a carcinogen and lead as a neurotoxin that can lower IQ. The U.S. EPA has determined there are no safe levels of either. Drinking water may already naturally contain these contaminants, but it is clearly unethical to knowingly add them to drinking water."

The statement by the authors that "the chemical used to fluoridate most water, fluorosilicic acid, is, according to water regulation agency NSF International, legally allowed to contain low levels of lead and arsenic." is an egregious half-truth which misrepresents the accepted levels of contaminants in drinking water.

In actuality, the regulations regarding contaminants in water apply to all drinking water, not simply to fluorosilic acid. Due to the ubiquity of arsenic and other contaminants throughout nature, it is inevitable that they will be present in drinking water supplies. Understanding this, the US EPA and regulatory bodies in Canada and other countries have set maximum levels for these contaminants which they have established to be safe for human consumption. As clearly noted in the "Fact Sheet on Fluoridation Substances" located on the website of NSF International, the amount of contaminants in tap water fluoridated with fluorosilic acid is nearly negligible, far below US EPA mandated maximum allowable levels of safety. (16)

In addition, contrary to the claim of the authors, the US EPA has not established there "to be no safe levels of arsenic and lead". The EPA maximum allowable contaminant level (MCL) of arsenic is 10 parts per billion, with that of lead being 15 parts per billion. Stringent NSF testing of water fluoridated with fluorosilic acid has shown no significant amount of any contaminant, with only a barely detectable amount of lead, or arsenic, far below the MCL for each 12. Authors: "Third, no one questions that ingested fluoride can be toxic. The only question that remains is how toxic it is at levels in fluoridated water. As shown in the Health Risk section, there is substantial evidence that it poses serious threats to our health."

Facts:

As will be discussed further, contrary to the assertion of the authors, there is no valid, peerreviewed scientific evidence of any "threat to our health" from optimally fluoridated water. The studies upon which they rely for this assertion have been clearly demonstrated to be invalid, irrelevant, or misrepresented by fluoridation opponents.

13. Authors: "Once fluoride is ingested, teeth, while very important, are relegated to only a minor role in the overall health picture."

Facts:

When infected teeth can, and do, cause the well-documented devastating adverse health effects up to, and including, death, it is infathomable that the authors would claim that they are "relegated to only a minor role in the overall health picture.", while utilizing nothing more than speculation and unsubstantiated claims in attempts to associate fluoridated water with numerous health effects which cannot be supported with any valid evidence.

14. Authors: "Finally, fluoridation is also a social justice concern. Low income and minority populations are more susceptible to kidney disease and diabetes, both of which, according to the NRC Report (pp. 303, 260), can be exacerbated by ingested fluoride"

Facts:

The 2006 NRC Committee on Fluoride in Drinking Water was charged to evaluate the adequacy of the EPA primary and secondary MCLs for fluoride, 4.0 ppm and 2.0 ppm respectively, to protect against adverse effects. The final recommendation of this committee was for the primary MCL to be lowered from 4.0 ppm. The sole reasons cited by the Committee for this recommendation were the risk of severe dental fluorosis, bone fracture, and skeletal fluorosis, with chronic ingestion of water with a fluoride content of 4.0 ppm or greater. Nothing else. Had this committee deemed there to be any concerns with "kidney disease and diabetes" in anyone from fluoride at this level, it would have been responsible for stating so and recommending accordingly. It did not.

Additionally, the NRC Committee made no recommendation to lower the secondary MCL of 2.0 ppm. Water is fluoridated at 0.7 ppm. one third the level which the 2006 NRC Committee on Fluoride in Drinking Water made no recommendation to lower. (17)

In March of 2013, Dr. John Doull, Chair of the 2006 NRC Committee on Fluoride in Drinking Water made the following statement:

"I do not believe there is any valid, scientific reason for fearing adverse health conditions from the consumption of water fluoridated at the optimal level"

---John Doull, MD, PhD, Chair of the National Academy of Sciences, National Research Council 2006 Committee Report on Fluoride in Drinking Water

II. Health Risks

1. Authors: "CADTH relied heavily upon Australia's National Health and Medical Research Council (NHMRC) 2016 report which was an update of NHMRC's 2007 report. NHMRC is part of the Australian government and has endorsed fluoridation since 1958. It cannot be considered balanced and objective regarding health risks."

Facts:

The unsubstantiated opinions of the authors on the quality of the report of the NHMRC of the Australian government are biased and unqualified.

2. Authors: "CADTH omitted the U.S. National Research Council's (NRC) 2006 report "Fluoride in Drinking Water"

Facts:

In regard to the report of the 2006 NRC Committee on Fluoride in Drinking Water, see item #13 in the previous section of this document. There was no need for CADTH to note this report.

3. Authors: "But standard toxicological risk assessment practice, as noted in the reference book A Small Dose of Toxicology (p. 260), always includes a margin of safety factor of at least 10 to account for human variability, protecting more vulnerable sub-populations at higher risk of harm than the average."

Facts:

Purported toxicological margin of safety for drugs has no relevance to optimal level fluoride ions which have always existed in water.

During the entire 74 year history of water fluoridation, hundreds of millions having chronically ingested optimally fluoridated water during this rime, there have been no proven adverse effects. There can be no more definitive demonstration of the adequacy of the "margin of safety factor" than this.

4. Authors: "But this rating [of Broadbent, et al.] is completely unjustified because it fails to account for several major weaknesses (Grandjean/Choi 2015 (2) and Osmunson et al. 2016 (3).

Facts:

The Broadbent study which found no association between optimally fluoridated water and purported IQ reductions was peer-reviewed and published in a highly respected scientific journal. The biased assessment of this study by the antifluoridation authors is of no relevance. Citing Bill Osmunson is of no merit. Osmunson is non-researcher dentist, long-time fluoridation opponent, and former Director of the NY antifluoridationist faction, FAN, who has no qualifications to properly evaluate scientific study.

In a peer-reviewed article in the American Journal of Public Health, Broadbent dispelled this assessment by the fluoridation opponents. (18)

In addition, again contrary to the assertion of the authors, Broadbent is not the sole study cited by respected sources as clear evidence of the invalidity of IQ reduction claims. It is but one of several quality studies which have found no such association, not the least of which is the 2018 McPerson, et al. NTP study which was initiated at the request of fluoridation opponents, and promoted heavily by the antifluoridation group, FAN. (40) (42) (43) (44)

Also of note is Li, et al. 2016 which found that while chronic exposure to high fluoride levels may provide a potential risk to cognitive development, low dose fluoride "may play a potential protective rather than harmful role in cognitive functions."(41)

Water is fluoridated at the minuscule level of 0.7 mg/liter.

5. Authors: "CADTH also misrepresented the findings of at least one neurotoxicity study, Choi et al. 2014 (5), which found a statistically significant correlation between dental fluorosis, a biomarker of excess fluoride ingestion, and impaired cognitive function."

Facts:

The 2014 Choi study cited by the authors as having been "misrepresented" by CADTH was of the effects of "exposure to elevated concentrations of fluoride in water" conducted in Sichuan, China, one of the most environmentally fluoride polluted areas in the world. It measured effects of exposure to high, uncontrolled levels of fluoride from well-water sources of this region, not from the minuscule, highly controlled levels of optimally fluoridated water as in Canada and the US. The effect it found was correlated with moderate and severe dental fluorosis, levels which do not occur in association with optimally fluoridated water. (45)

In regard to claimed associations of dental fluorosis, from the EPA:

"With regard to fluorosis, the degree of dental fluorosis is dependent not only on the total fluoride dose but also on the timing and duration of fluoride exposure. A person's individual response to fluoride exposure depends on factors such as body weight, activity level, nutritional factors, and the rate of skeletal growth and remodeling. These variables, along with inter-individual variability in response to similar doses of fluoride, indicate that enamel fluorosis cannot be used as a biological marker of the level of fluoride exposure for an individual (Ref. 28). Hence, the petitioner's use of fluorosis levels as a surrogate for evidence of neurotoxic harm to the U.S. population is inappropriate evidence to support an assertion of unreasonable risk to humans from fluoridation of drinking water." (21)

6. Authors: CADTH's most striking bias is its omission of numerous strong, qualifying studies that showed significant neurotoxicity, including several conducted by Canadian researchers:

Facts:

The plethora of neurotoxicity studies claimed by the authors to demonstrate cognitive development were cited by FAN in its most recent petition to the EPA for an end to fluoridation. In the 40 page rejection of this petition, EPA reviewers cited facts and evidence to dismantle the arguments of petitioners, including detailed explanations of the invalidity, irrelevance, and misrepresentation by petitioners of these studies. (21)

In regard to other studies cited by the authors:

A. 2006 NRC review: see item #13 in previous section

B. Xiang 2003: a study published in the antifluoridation journal, *Fluoride*. In an article addressing the misleading misuse of Xiang data by fluoridation opponents, New Zealand chemist, Ken Perrott PhD, explains:

"The Sydney audience could have been excused for thinking that Xiang's data showed a very strong connection between IQ and drinking water fluoride – a relationship explaining almost all

the variance. Completely misleading as this relationship probably only explains only about 3% of the variance in the original data." (24)

C. Choi, et al: The "reduced IQ studies" are a reference to a 2011 review of 27 Chinese studies from obscure Chinese journals by researchers Phillippe Grandjean and Anna Choi. These studies were of the effects of high levels of fluoride (as high as 11.5 ppm) in the well-water of various Chinese, Mongolian, and Iranian villages.

By the admission of Grandjean and Choi, themselves, these studies had key information missing, inadequate control for confounders, and questionable methodologies. These 27 studies were so seriously flawed that Grandjean and Choi were led to issue a public statement in March, 2012 that the studies should not be used to judge water fluoridation in the US. This obviously has not stopped antifluoridationists from doing so anyway.

"These results do not allow us to make any judgment regarding possible levels of risk at levels of exposure typical for water fluoridation in the U.S. On the other hand, neither can it be concluded that no risk is present. We therefore recommend further research to clarify what role fluoride exposure levels may play in possible adverse effects on brain development, so that future risk assessments can properly take into regard this possible hazard."

--Anna Choi, research scientist in the Department of Environmental Health at HSPH, lead author, and Philippe Grandjean, adjunct professor of environmental health at HSPH, senior author. (9)

Regarding the meta-analysis:

"EPA agrees with the conclusions by Choi et al. (Ref. 11) that the studies included in Table 1 of the petition are unsuitable for evaluating levels of fluoride associated with neurotoxic effects and for deriving dose-response relationships necessary for risk assessment. (21)

D. Malin/Till 2015: this study concluding a correlation between fluoridated water and ADHD has been widely discredited in the peer-reviewed literature for its inadequate control for confounders, poor methodology, and reaching a conclusion not supported by the peer-reviewed science.

From Fluoride Science of the American Association of Public Health Dentistry:

"It's an ecological study design with 51 observations (50 states & DC), and is not appropriate to test a hypothesis. ADHD prevalence was based on self-reported data, and hence had a potential of misclassification of disorder status. State-wide fluoridation measures were used. Individuals' exposure to fluoridation were not measured. Due to ecological assessment of exposure to fluoride in drinking water and the use of prevalence data of self-reported ADHD and water fluoridation from different years, the findings are at high risk for ecological fallacy. Authors did not adjust for important confounders (smoking, low birth weight, age, sex etc.). Moreover, authors' poor literature review and skewed interpretation of literature concerning fluoride and neurodevelopmental defects may have introduced bias." (8)

Clear evidence of the inadequate for confounders was demonstrated in the Huber, et al study which, utilizing the same data as did Malin/Till, concluded the reported instances of ADHD to be due to elevation levels at which the children resided, not water fluoridation. (19)

E. Bashash, et al. 2017: This study used data from a study of lead impact on pregnant women residing in non-fluoridated Mexico in an attempt to extrapolate impact of the urine fluoride level of these women on the IQ of their offspring. As clearly noted by the limitations expressed in this study itself, it has limited, if any, applicability to optimally fluoridated water in the US. Among other problems, the study was unable to adequately control for the impact of arsenic and other contaminants which were far more likely to have been the cause of any adverse effects on cognitive development than was fluoride.

As noted in an evaluation of this study by an expert panel of noted researchers

"This [Bashash, et al.] is an observational study that by definition can only show a possible association between fluoride exposure and IQ – not cause and effect. The association between fluoride and cognitive abilities observed as the result of this analysis should not be interpreted to mean that drinking fluoridated water during pregnancy causes IQ deficits in children.

Because not all potential confounders were adequately addressed in the study, there are other factors that might explain the association. There are many factors such as genetics, family, peer group, education, training and interventions, environmental enrichment, prenatal and postnatal nutrition, breast feeding, stress, maternal age, gestational age, birth weight, and exposure to lead, mercury, arsenic, iodine, alcohol, and drugs that affect IQ and other measures of cognitive ability." (20)

In a September 2017 statement, Dr. Angeles Martinez-Mier a lead researcher in the 2017 Bashash, et al. Mexican study, relayed:

a) "While I stand fully behind our study's conclusions, as an individual, I am happy to go on the record to say that I continue to support water fluoridation"

b) "If I were pregnant today I would limit my fluoride intake. I would continue to consume fluoridated water, but would avoid other sources that could increase my fluoride intake, for example if I lived in Mexico I would limit my salt intake."

c) "I am involved in this research because I am committed to contribute to the science to ensure fluoridation is safe for all. Our study is rigorous, our team of researchers does not have an agenda, and will go where the data take us."

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F. Petition to the EPA 2017: This petition filed by the NY antifluoridationist group, FAN and other antifluoridationist groups was soundly rejected by the EPA. In a 40 page document, EPA reviewers cited facts and evidence to dismantle the arguments of petitioners, including detailed explanations of the irrelevance, invalidity, and misrepresentation by petitioners of the studies presented as their support. (21)

The lawsuit to which the authors refer is simply an appeal of the petition rejection by the antifluoridationist groups. Such appeals are routinely offered as a matter of policy by the EPA for rejections of any such petitions. As the facts and evidence have not changed in any significant manner since the petition was rejected, there is no reason to expect a different outcome with this appeal.

G. Till, et al. 2018: This study simply confirmed what is expected with, and is the intent of, fluoridation.... the fluoride level in those residing in fluoridated areas is higher than that of those living in non-fluoridated areas. The study did not demonstrate fluoride level in any of the subjects to exceed safe levels, or to be within the range of adverse effects. As the Bashash 2017 study has no applicability to optimally fluoridated water, any comparison of the fluoride levels within these subjects to those within the Bashash subjects is moot.

H. Bashash, et al 2018: A review of this study demonstrating its flaws and limitations has been prepared by Public Health Ontario. (22)

III. Hypothyroidism

1. Authors: "Based on studies done from 1960 to 2005, the NRC report conclusively determined fluoride was an endocrine disruptor and "The chief endocrine effects of fluoride . . . include decreased thyroid function."

Facts:

As noted on page 352 of the 2006 NRC report, contrary to the implication of the authors, hypothyroidism was not cited in the final recommendation of the report as being of concern with fluoride at the level of 4.0 ppm or below in water. Had this committee viewed this to be of concern at this level, it would have been responsible for so noting and recommending accordingly. (17)

2. Authors: "Numerous human, animal and epidemiological studies have found fluoride decreases thyroid function. In the 1940's and 1950's, fluoride was used as a treatment for hyperthyroidism (over-active thyroid)."

Facts:

Outdated medical practices utilized 80 years ago, as cited by the authors, are of no relevance to community water fluoridation.

3. Authors: "But even though scientific data linking fluoride ingestion with hypothyroidism is extensive, CADTH's summary on the subject was inconclusive: "Overall, there was insufficient evidence for an association between water fluoridation at the current Canadian levels and thyroid function." Unfortunately, CADTH's errors and omissions, which led to this statement, were especially glaring for this subject."

Facts:

Contrary to the assertion of the authors, the statement by CADTH that "Overall, there was insufficient evidence for an association between water fluoridation at the current Canadian levels and thyroid function." is entirely accurate. As demonstrated in this response document, these authors have provided no credible evidence to dispute this statement. In tegard to the studies cited by the authors:

a. The Malin 2018 study was of the effects of iodine deficiency on the thyroid, not of fluoride on the thyroid. The logical answer to this problem is to address dietary iodine deficiencies, not cease water fluoridation. While Malin, and anyone else, are certainly welcome to their personal opinions, there has been no valid scientific evidence of adverse effect on the thyroid from optimally fluoridated water in conjunction with that from all other normal sources of fluoride exposure.

b. As stated by the authors, the 2018 Indian review suggested a positive correlation between excess fluoride and hypothyroidism. Yes, there are adverse effects associated with excessive amounts of any substance, including plain water. (23) This is why concentration levels are closely monitored for the substances we consume. Water is fluoridated at 0.7 mg/ liter, a minuscule level for which there is no valid scientific evidence of adverse effect on the thyroid.

c. The 2018 Kheradpisheh et al. study was performed in Iran, one of the areas with the highest levels of environmental fluoride pollution in the world. As stated in the study: "The main source of drinking water in Yazd city is surface water and well resources in different seasons; thus, differences in fluoride concentration are bound to exist."

As stated in the study, it was of the impact of exposure to excessive amounts of environmental fluoride, not of the minuscule amount of fluoride in highly controlled optimally fluoridated water systems.

"In areas that experience excess fluoride, especially from water, low iodine levels in the body can cause fluoride uptake into the thyroid gland."

Water is fluoridated at 0.7 mg/liter.

d. Singh, et al. 2014: A study of the effects of exposure to excessive levels of fluoride in India, another area with the highest level of environmental fluoridation in the world. The water fluoride levels of this study ranged from 2.6 mg/liter - 5.1 mg/liter, levels of no relevance to the 0.7 mg/liter at which water is fluoridated.

e. 2015 Peckham: This study has been widely discredited within the scientific literature for its inadequate control for confounders, poor methodology, and reaching a conclusion not supported by the scientific literature.

As concluded by Warren and Saraiva:

"In summary, this study is an ecologic one that has several significant flaws, making it almost meaningless with regard to assessing any possible association between water fluoridation and hypothyroidism. As such, this study provides no evidence of a causal relationship between water fluoride concentration and hypothyroidism." (25)

IV. Dental Fluorosis

Authors: Dental fluorosis is damaged tooth enamel, a visible sign of overexposure and toxicity, caused by an excess of swallowed fluoride by children up to 8 years of age. It comes from fluoridated water, food and drinks processed with it (including infant formula), food grown with fluoride pesticides, swallowed fluoridated toothpaste, fluoride tablets and other sources.

Facts:

Dental fluorosis is an effect of the teeth which is merely cosmetic in all but the severe level. Severe is the only level considered an adverse effect by the 2006 NRC Committee on Fluoride in Drinking Water, and as clearly noted on page 114 of that report, does not occur in communities with a water fluoride level below 2.0 mg/liter. Water is fluoridated at one third this level. (17)

Mild to very mild dental fluorosis, the level which may be associated with optimally fluoridated water, is a benign, barely detectable effect which causes no adverse effect on cosmetics, form, function, or health of teeth. The following images from the American Dental Association depict mild dental fluorosis.



Contrary to the claim of the authors, as can be seen, there is no "damage" to the teeth, with the faint white

streaks being barely detectable except under close examination. As peer-reviewed science has demonstrated mildly fluorosed to be more decay resistant, many consider this effect to not even be undesirable, much less adverse. (26) (27)

To gain proper perspective on dental fluorosis, while this effect has been demonstrated by peer-reviewed science to have no negative impact on oral health-related quality of life (OHRQoL), dental decay (caries) which can be, and is, prevented by water fluoridation does have such an impact.

As reported by Onoriobe, Rozier, et al. In 2014:

"Using a population- and person-centered perspective, we conclude that dental caries in school-aged children in North Carolina is a much bigger public health concern than enamel fluorosis. The prevalence of fluorosis is less than caries, and it had no impact on the OHRQoL of children or their families. Dental caries had a negative impact on OHRQoL for the majority of students and their families." (28)

From a 2016 study reported in the Medical Journal of Australia:

"Conclusion: Very mild and mild dental fluorosis diminished with time. Dental fluorosis did not have a negative impact on perceptions of oral health." (29)

Clearly, dental fluorosis is not an issue of concern in association with the minuscule amount of fluoride in optimally fluoridated water, even in conjunction with fluoride intake from all other normal sources. Efforts by these authors and other fluoridation opponents to combine and confuse the various levels of this effect do not change the findings of the 2006 NRC Committee and other peer-reviewed science which have determined that the only adverse level of this fluorosis is not associated with water fluoridation.

In regard to the cost-estimates cited by the authors to treat dental fluorosis, as can be noted in the above images, the mild dental fluorosis which may be associated with optimally fluoridated water requires no treatment. Implying that such teeth require expensive veneers and/or other treatment is an egregious breech of responsibility and intentional effort to mislead the public in regard to this effect.

V. Chemical Sensitivities/Immune and Inflammatory Responses

In this section, the authors cite half-century old, long since discredited studies, and unsubstantiated opinions of George Waldbott, a medical practitioner educated in the 1920s, leading activist against water fluoridation in the 1950s, and founder of an antifluoridation group which provides biased information against the initiative to this day.

As will be demonstrated in the following, this section provides an excellent example of the faulty "science" and dubious sources upon which fluoridation opponents rely for the misleading misinformation they disseminate.

1. Authors: "Fluoridated water is no different than other drugs, chemicals, or various foods, such as peanuts or shell fish. There is a subset of the population that will have adverse reactions upon swallowing them. In some cases, even being exposed topically, such as in fluoridated toothpaste or mouthwash, will produce harmful effects."

Facts:

The authors attempt to associate fluoride with drugs which have documented side effects. Fluoride in water supplies is not a drug. It is simply an ion that has always existed in water. The outdated, discredited studies presented by the authors notwithstanding, there is no valid, peer-reviewed scientific evidence of any "harmful effects" to anyone from ingestion of fluoride at the optimal level at which water is fluoridated. There is no such evidence of any "allergy" or "intolerance" to fluoride, nor is there any such evidence to support the "variety of symptoms" the authors attempt to associate with such "allergies".

2. In regard to the claims of Waldbott, the following is from a 1979 review of his book:

"Symptoms described by R. Finn and H.N. Cohen last year in a few tea drinkers are stated by Dr. Waldbott to be "probably due to fluoride". He does not mention that similar symptoms occurred in some people after drinking coffee which contains no fluoride".

"This book has already been widely publicised by the antifluoridation movement in Britain and is likely to have great influence in furthering their cause. Its tone is low-key, completely free from emotional outbursts and presents evidence on both sides of the argument with apparent impartiality. Laymen, including those concerned with decisions on fluoridation, will be impressed by what seems to be the reasonableness of the case, oblivious of the omissions and obsolete presuppositions upon which much of it is based." (30)

3. Feltman's 60 year old study was completely refuted by the American Academy of Allergies in 1971:

"The reports of fluoride allergy reviewed (3, 4, 5, 6, 7) listed a wide variety of symptoms including vomiting, abdominal pain, headaches, scotomata, personality change, muscular weakness, painful numbness in extremities, joint pain, migraine headaches, dryness in the mouth, oral ulcers, convulsions, mental deterioration, colitis, pelvic hemorrhages, urticaria, nasal congestion, skin rashes, epigastric distress and hematemesis."

"The review of the reported allergic reactions showed no evidence that immunologically mediated reaction of the Types I-IV had been presented. Secondly, the review of the cases reported demonstrated that there was insufficient clinical and laboratory evidence to state that true syndromes of fluoride allergy or intolerance exist."

"As a result of this review, the members of the Executive Committee of the American Academy of Allergy have adopted unanimously the following statement:"

'There is no evidence of allergy or intolerance to fluorides as used in the fluoridation of community water supplies.' " (31)

Feltman and Kosel were #'s 4 and 5 of the reports reviewed by the AAA.

4. Grimbergen was a 40 year old study from an antifluoridation publication. Moolenburgh upon whose works Grimbergen relied, was an antifluoridation, anti-vaccination activist involved with a pseudo-science "healing sound movement." which claims that people can heal their health problems by listening to digital recordings of "ancient chants and cosmic sounds".

5. The Gutowska abstract provided by the authors theorizes an inflammatory response at some uncited level of fluoride.

6. The Follin-Arbelet abstract provided by the authors theorizes an association of chronic exposure to some uncited amount of fluoride with irritable bowel syndrome.

7. Ma, et al. assessed the impact of exposure of human endothelial cells to 1 mM of sodium fluoride, an equivalence of 19 ppm fluoride. This obviously has no relevance to water fluoridated at 0.7 ppm.

8. The 2006 NRC Committee reviewed a plethora of fluoride studies including those from sources of questionable quality, diligently reported what was in those studies, then made its final recommendation based on what it deemed to be of any concern with fluoride at the level of 4.0 mg/liter in drinking water. There was no mention of concern with adverse effects on the immune system in the final recommendation. Had the committee any such concern, it would have been responsible for so noting and recommending accordingly. It did not. (17)

9. The authors have presented no valid evidence to support their claim that optimally fluoridated water "will adversely affect 1% of Calgary's population"nor is there any such evidence to support this claim for any optimally fluoridated area.

VII. Effectiveness

1. Authors: "There was insufficient evidence from studies on changes in cavity rates after a city had stopped fluoridating and no firm conclusions could be drawn."

Facts:

This is false. Both of McLaren's Calgary studies demonstrated definitive evidence of adverse effect of cessation of fluoridation in that city, as did Myer, et al. in Juneau. (32) (33) (34)

The criticisms of the McLaren study expressed by the authors demonstrates a profound lack of understanding of this study, and raises legitimate questions as to whether they have even read the study as well as to their understanding of scientific study in general.

Authors: "McLaren's study only used data from two dental surveys in Calgary and Edmonton, one in 2004/2005, many years before Calgary stopped fluoridating in 2011, and the other from about 3 years after cessation. However, the study omitted a survey in Calgary from 2009/2010, just 1.5 years before cessation. When the cavity rate for primary teeth from this omitted survey is combined with the data used by McLaren, it is clear that decay had been increasing in Calgary at virtually the same rate before cessation as after cessation:"

Facts:

First of all, the 2009/2010 "critical data" claimed by to have been "omitted" from McLaren's study of Calgary and Edmonton was not applicable for the following reasons:

a. The 2009/2010 data was "apples to oranges" in regard to the data utilized by McLaren. McLaren utilized reported findings in units of decayed, missing, and filled *surfaces* of teeth. The 2009/2010 "critical data" was in the less sensitive units of decayed, missing and filled *teeth.* There is no reliable way to equate data per tooth surface of decay with that of reported per teeth decayed with no regard to the number of surfaces of those teeth which may be decayed. As standard studies evaluate 4 tooth surfaces, attempting such a comparison would mean one unit of the 2009/2010 data would be equivalent to as many as 4 units of the data utilized by McLaren....apples to oranges.

b. The critical aspect of McLaren's study was comparison of decay trend data in Calgary which had ceased fluoridation, to that data from the similar city of Edmonton which had not. Having Edmonton provided the advantage of significantly improving control over variables involved in such trends. The 2009/2010 data was only for Calgary, with none for Edmonton. Obviously, without any Edmonton data, there could be no such comparison.

Unfortunately, fluoridation opponents still continue to make the claim of "omitted data" in spite of the inapplicability of this data to McLaren's study.

The claim that Edmonton "also experienced an increase in decay over the study period" is a superficial oversimplification that fails to understand the central point of difference in dental decay trends between the two cities, as demonstrated by McLaren.

As explained by McLaren, that while there was indeed an increase in decay in both cities during the examined time frame, the increase in Calgary was significantly greater in magnitude than that in Edmonton.

"This line of thinking was borne out in our results. In primary teeth, an increase in caries experience was observed in Calgary (where cessation occurred in 2011). A similar observation, which was smaller in magnitude, was noted in Edmonton (where fluoridation remained in place). Thus, for primary teeth, our results presented here and elsewhere (L. McLaren, S. Patterson, S. Thawer, P. Faris, D. McNeil, M. Potestio et al., unpublished results) provide consistent indication of an adverse short-term effect of cessation." (32)

2. Authors: "As CADTH reported, a number of studies have shown decreased cavity rates in fluoridated water areas. They have typically been expressed by percentage, but almost always omit actual number of cavities. When these figures are reported, fluoridation's minimal effectiveness becomes clearer."

Facts:

The attempt to trivialize the impact of a broad population-based initiative by utilizing averages of decay on an individual tooth level is naïve, misleading, and deceptive. Contrary to the

assertion of the authors, assessing effectiveness of a broad, population-based public initiative such as water fluoridation based on percentage impact on the entire population is far more informational than is use of averages for individuals.

As noted by Slade, et al, 2018:

"When considered at the level of an individual, these effect estimates represent clinical benefits that are either small (1.3 fewer dfs per child) or negligible (0.3 fewer DMFS per child). However, caries experience indices are more meaningfully interpreted for groups, just as clinical trials report number needed to treat. For example, effect estimates from this study translate as 13 fewer primary tooth surfaces and 3 fewer permanent tooth surfaces developing caries for every 10 children who gain access to CWF. The potential public health benefit is substantial in the United States, where 115 million people currently do not have fluoridated tap water. The Healthy People 2020 objective OH-13, if met, would extend CWF to 20 million more (Healthy People 2020 2018), and 24% of them would be children and adolescents based on the national age distribution. Hence, if CWF were extended to 4.8 million children, and they experienced the prevented fractions found here, it would translate to 6.2 million fewer primary tooth surfaces developing caries."(35)

As Slade has also stated:

"In summary, while Dr. Limeback is using the correct math for permanent teeth, he's disregarding the primary teeth, and he's disregarding the more important point that it's the water supply that's fluoridated, not a single child's water bottle, which means that the benefits are relevant for groups, moreso than for individuals."

3. Authors: "The Cochrane Collaboration is considered the gold standard of evaluating effectiveness. Its 2015 analysis found a 26% DMFT (decayed, missing, filled permanent teeth) reduction in fluoridated areas. The U.S. CDC cites a similar 25% reduction. Cochrane also cited 'insufficient evidence' that 'fluoridation results in a change of disparities in caries levels across socio-economic status.' "

Facts:

While the opinions of the Cochrane Collaboration are widely respected, there is no evidence to suggest that they are the "gold standard of evaluating effectiveness". Cochrane is simply one of numerous credible organizations which provides differing opinions on the scientific literature, subject to the same biases, inaccuracies, and limitations as is any other such group.

The outdated Cochrane claim cited by the authors that there is "insufficient evidence that fluoridation results in a change of disparities in caries levels across socio-economic status." is belied by recent findings of Slade, et al. and Han-Na, et al. which have, indeed, demonstrated such a change. (36) (37).

4. Authors: "The most recent relevant study from IFS, Curtis et al. 2018 (5) found no significant correlation between ingested fluoride and cavity reduction, further validating a 2009 study from IFS, Warren et al. that stated: 'Achieving a caries-free status may have relatively little to do with fluoride intake (emphasis in the original) . . . recommending an 'optimal' fluoride intake is problematic.' "

Facts:

In regard to the misrepresentative out-of-context quote from Warren, Levy, provided by the authors, as have many other fluoridation opponents through the years, co-author Stephen Levy provided the following statement:

 "We looked at total F intake from almost all sources (water, beverages, selected foods that absorb water, dietary F supplements, dentifrice they acknowledge this ok in their point #3)
 But we did not say that we "found no relation between tooth decay and the amount of fluoride swallowed", but that it is very complicated--e.g., those with caries but not mild dental fluorosis tended to have lower F intake than the other 3 sub-groups

3) And in many other published articles and abstracts as well as unpublished data, we consistently see ~14-20% less decay among those in F areas, across exams at several ages (for prevalence at 5, 9, 13 and 17 years and incidence across 4-year intervals) --even after adjusting for all that we can (brushing with F dentifrice, SES, dietary exposures, F supplements, etc.)

-Steven M. Levy, DDS, MPH Wright-Bush-Shreves Endowed Professor of Research Department of Preventive & Community Dentistry University of Iowa College of Dentistry

5. Authors: "Indeed, there is a consensus, including the CDC, NRC, Cochrane Collaboration, lowa Fluoride Study and others that fluoride's effectiveness is mainly topical, not from ingestion."

This claim is misleading and false.

None have stated that fluoride's effectiveness is not from ingestion. What has been stated in a 2001 CDC report is that the effects of fluoride are "predominantly topical". "Predominantly" does not mean "only", and this statement includes the topical effect provided by fluoride incorporated into saliva through ingestion of that fluoride. (10)

6. Authors: "There is little robust scientific evidence that swallowing fluoride provides any benefit over and above more appropriate topical applications."

This is false. There is ample "robust scientific evidence that swallowing fluoride provides any benefit over and above more appropriate topical applications."

The effects of fluoride are both topical and systemic. The systemic effects are demonstrated in the mild to very mild dental fluorosis which may be associated with optimally fluoridated water. Mild to very mild dental fluorosis is a barely detectable effect which causes no adverse effect on cosmetics, form, function, or health of teeth. As peer-reviewed science has demonstrated mildly fluorosed teeth to be more decay resistant, many consider this effect to not even be undesirable, much less adverse. Dental fluorosis can only occur systemically. (27)

Saliva with fluoride incorporated into it provides a constant bathing of the teeth in a low concentration of fluoride all throughout the day, a very effective means of dental decay prevention. Incorporation of fluoride into saliva occurs systemically.

From the CDC:

"Fluoride works to control early dental caries in several ways. Fluoride concentrated in plaque and saliva inhibits the demineralization of sound enamel and enhances the remineralization (i.e., recovery) of demineralized enamel. As cariogenic bacteria metabolize carbohydrates and produce acid, fluoride is released from dental plaque in response to lowered pH at the toothplaque interface. The released fluoride and the fluoride present in saliva are then taken up, along with calcium and phosphate, by de-mineralized enamel to establish an improved enamel crystal structure. This improved structure is more acid resistant and contains more fluoride and less carbonate. Fluoride is more readily taken up by demineralized enamel than by sound enamel. Cycles of demineralization and remineralization continue throughout the lifetime of the tooth." (10)

Cho, et al. found in 2014:

"Conclusions: While 6-year-old children who had not ingested fluoridated water showed higher dft in the WF-ceased area than in the non-WF area, 11-year-old children in theWF-ceased area who had ingested fluoridated water for approximately 4 years after birth showed significantly lower DMFT than those in the non-WF area. This suggests that the systemic effect of fluoride intake through water fluoridation could be important for the prevention of dental caries." (5)

VIII. Cost-Effectiveness

The cost-effectiveness of water fluoridation has been well established within the peer-reviewed scientific literature.

Examples:

a. O'Connell J, et al. 2016:

"Savings associated with dental caries averted in 2013 as a result of fluoridation were estimated to be \$32.19 per capita for this population. Based on 2013 estimated costs (\$324 million), net savings (savings minus costs) from fluoridation systems were estimated to be \$6,469 million and the estimated return on investment, 20.0." (4)

b. Ran, et al 2016:

"Recent evidence continues to indicate that the economic benefit of community water fluoridation exceeds the intervention cost. Further, the benefit–cost ratio increases with the community population size." (13)

c. Elmer, Langford, Morris 2014:

"After ranking by IMD, DSRs of hospital admissions for the extraction of decayed or pulpally/ periapically involved teeth is lower in areas with a fluoridated water supply." (38)

The sole study the authors present to contradict this is Thiessen, et al. which includes the false premise that mild dental fluorosis requires treatment. Aside from that, the rest of their claims are personal opinions and calculations based on false and unsubstantiated claims of adverse effects from water fluoridation.

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