# Comments on
# Health Canada's Paper Fluoride in Drinking Water

## Introduction:

This submission is prepared by G.W. Cooper, PEng, MBA in his capacity as Public Policy Advisor, People for Safe Drinking Water. It is a response to Health Canada's draft paper, Fluoride in Drinking Water, of September 2009.

## Purpose of Consultation:

Re page 1 of Health Canada's paper, the attempt to limit the scope of the consultation to the proposed MAC and risk assessment is unacceptable and introduces an untenable bias which impinges on the legitimacy of Health Canada's review and any resulting recommendations or decisions. Whether warranted or not, provincial and municipal governments defer to Health Canada on all matters concerning fluoridated drinking water. Moreover, many of the topics presented in the Health Canada paper go well beyond the MAC and risk assessment. This paper represents a health policy document on fluoridation yet one sees from the very outset serious flaws in the analysis on which the proposed policy is based.

## Part I. Overview and Application:

On page 2, Health Canada further and unduly restricts its risk assessment by setting the "end point" of its concern at moderate fluorosis thereby excluding severe dental fluorosis from its analysis and conclusions. It compounds this mistake by characterising moderate fluorosis as an aesthetic concern. This ignores the fact that moderate fluorosis makes surface enamel porous and more prone to structural damage (e.g. shedding of layers). In turn, this can cause more cavities to develop than otherwise would be the case. Health Canada's approach renders its risk assessment woefully incomplete and misleading to Canadians, especially those children and their families afflicted with dental fluorosis, as well as their elected representatives at all levels of government. For an alternative, multifactor risk assessment, Health Canada should consider the paper entitled The EPA MCLG for Fluoride in Drinking Water: New recommendations, 2007 by Limeback H, Thiessen K, Isaacson R, Hirzy W; Abstract 1531, Poster number 406. A copy of this paper is available at **http://www.oag-bvg.gc.ca/internet/English/pet_221D_e_31257.html**.

On both practical and ethical grounds, this is a major shortfall in the scope and scale of this public health policy review which ought to be corrected in the final version of the Health Canada paper on fluoride. The Minister of Health must fulfill her oversight role by holding departmental staff to account for this egregious error and instructing her staff to correct the shortcomings set out in this response.

On page 3, the Health Canada paper notes that its Chief Dental Officer has concluded that 0.7mg/L is the optimal concentration of fluoride for those communities

adding it to their drinking water. This properly should be made a second recommendation in the Proposed Guideline section on page 1 because the "optimal" level and the MAC are integral elements of the proposed public health guideline and its accompanying risk assessment.

## Part II. Science and Technical Considerations:

On page 8, the Health Canada paper notes the department's recommendations on the use of fluoride toothpaste by infants and children under 6 years old. Yet this paper does not present any recommendations on the use of fluoridated drinking water in preparing infant formula or juices from concentrates for children. For completeness of information and advice provided to Canadians, the latter issues on fluoride use should be addressed here and included in Health Canada's pamphlet "Fluoride and Human Health", July 2008. It is disquieting that Health Canada has not promulgated an advisory on the use of fluoridated drinking water in infant formula and juice concentrates given that this has been done in the USA and other countries in recent years.

On page 24, Health Canada draws no conclusions on the research information it presents on the renal clearance of fluoride. Some 50% of fluoride typically is absorbed into bones and organs of adults and can be significantly higher (~75%-87%, see Whitford, 1994) in infants and people with kidney disease or age-related impairment of kidney function. This is known to lead to skeletal fluorosis with increased risk of bone fractures in the elderly.

Health Canada has a public policy obligation of due diligence to deal fully with these known adverse health effects, weigh them in the balance of good health versus harm, and to reflect them into the paper's risk assessment. Moreover, the risk assessment methodology should be both quantitative and qualitative in nature and embody a rigorous ranking system rather than rely on some vague consensus among staff or members of an expert panel. At the least, for reasons of transparency and objectivity, the draft Health Canada paper should elaborate its risk assessment methodology in an appendix to the paper.

Health Canada also should recognize that this is but one of a number of dimensions of the issue on fluoride in drinking water which militate against a one-solution-fits-all approach to risk assessments forming the basis of fluoride concentration levels, margins of safety, and the MAC. In this regard, Page 24 ends by citing the work of Whitford (1996) that concluded an acute fluoride dose of 5mg/kg body weight might lead to adverse health effects. Table A herein applies this acute dose threshold to data based on Table B-11 of the NRC Review (2006) to estimate how long it can take for that acute dose to be reached by various age groups in the population for a range of fluoride concentrations. Key points are:

- there is a considerable variation in time to reach the acute toxic point as a function of age group and F concentration level, with the mean intake ranging from three months for a newborn to 3.2 years for the 20-24 age cohort;
- there is an inflection point at the 25-54 age cohort where the time to reach the acute toxic level begins to decline;

- the higher the fluoride concentration, the shorter the time to the acute toxic point will be; and,
- for those who are above average consumers of tap water, the time to the acute toxic point will also be significantly less, regardless of age group. As Table B-11 of the NRC Review, 2006 shows, the range of consumption is four times greater for the 99$^{th}$ percentile group than the average group. Above average consumption, which can be two to ten times higher than the mean, is especially prevalent for diabetics, athletes, construction workers, police, firefighters, and the military.

This further underscores that a one size approach (i.e., a constant fluoride concentration level for all consumers regardless of individual circumstances) to mass medication of fluoride in drinking water does not fit all groups and their different circumstances in the population. The risk of developing dental fluorosis will vary by age group, body weight, consumption rates, and underlying medical conditions. Neither public health officials nor water treatment officials can manage these different risks or control these variables or outcomes that are inherent in adding fluoride to community drinking water. As such, this modality of delivering fluoride is not the best one available.

It is also significant that the Health Canada paper states that it '…recommends that fluoride requirements should "only be based on the beneficial effect on dental caries". ' First this position does not recognize the inherent trade-off between lowering the prevalence of caries while avoiding the prevalence and severity of dental fluorosis. Secondly, as will be demonstrated later in this response, a number of research studies, WHO data comparisons and CDC's 2001 statement reveal the main dental health benefit of fluoride comes from its topical application and not ingestion of fluoridated drinking water. Yet again the Health Canada paper ignores these evidence-based references and clings to an outdated orthodoxy which relies more on doctrine than science. Simply put, this is not a sound basis for the federal government's policy advice on fluoridation and dental health.

## Table A: Days to Reach Acute Fluoride Intake Threshold of 5mg/kg

| Age Group | Mean Water Intake mL/kg/day Table B-11 | Mean Fluoride intake = mg/kg/day x BioA F Table B-11 NRC 2006 | | | |
|---|---|---|---|---|---|
| | | Level 1 F = 0.7mg/L | Level 2 F = 1mg/L | Level 3 F = 1.2mg/L | Level 4 F = 1.5mg/L |
| **All Ages** | 17 | | | | |
| BioA F 50% | | 0.006 | 0.009 | 0.010 | 0.013 |
| Days to Acute F | | **840 days/~2.3yrs** | **588 days** | **490 days** | **392 days** |
| **< 0.5 years** | 88 | | | | |
| BioaA F 75% | | 0.046 | 0.066 | 0.079 | 0.099 |
| Days to Acute F | | **108 days/~0.3yrs** | **76 days** | **63 days** | **51 days** |
| **0.5 – 0.9 yrs** | 56 | | | | |
| BioA F 75% | | 0.029 | 0.042 | 0.050 | 0.063 |
| Days to Acute F | | **170 days/~0.5yrs** | **119 days** | **99 days** | **79 days** |
| **1-3 years** | 26 | | | | |
| BioA F 50% | | 0.009 | 0.013 | 0.016 | 0.020 |
| Days to Acute F | | **549 days/~1.5yrs** | **385 days** | **321 days** | **256 days** |
| **4-6 years** | 23 | | | | |
| BioA F 50% | | 0.008 | 0.012 | 0.014 | 0.017 |
| Days to Acute F | | **621 days/~1.7yrs** | **435 days** | **362 days** | **290 days** |
| **7-10 years** | 16 | | | | |
| BioA F 50% | | 0.006 | 0.008 | 0.010 | 0.012 |
| Days to Acute F | | **893days/~2.4yrs** | **625 days** | **521 days** | **417 days** |
| **11-14 years** | 13 | | | | |
| BioA F 50% | | 0.005 | 0.007 | 0.008 | 0.010 |
| Days to Acute F | | **1099 days/~3yrs** | **769 days** | **641 days** | **513 days** |
| **15-19 years** | 12 | | | | |
| BioA F 50% | | 0.004 | 0.006 | 0.007 | 0.009 |
| Days to Acute F | | **1190 days/~3.2yrs** | **833 days** | **694 days** | **556 days** |
| **20-24 years** | 15 | | | | |
| BioA F 50% | | 0.005 | 0.008 | 0.009 | 0.011 |
| Days to Acute F | | **952 days/~2.6yrs** | **667 days** | **556 days** | **444 days** |
| **25-54 years** | 16 | | | | |
| BioA F 50% | | 0.006 | 0.008 | 0.010 | 0.012 |
| Days to Acute F | | **893 days/~2.4yrs** | **625 days** | **521 days** | **417 days** |
| **55-64 years** | 17 | | | | |
| BioA F 50% | | 0.006 | 0.009 | 0.010 | 0.013 |
| Days to Acute F | | **840 days/~2.3yrs** | **588 days** | **490 days** | **392 days** |
| **>65 years** | 18 | | | | |
| BioA F 50% | | 0.006 | 0.009 | 0.011 | 0.014 |
| Days to Acute F | | **794 days/~2.2yrs** | **556 days** | **463 days** | **370 days** |

## National Research Council Review 2006 data used

Table B-11 shows source of daily water intake by age group and acute dose threshold data. This is an estimate for how long it can take for that acute dose to be reached by various age groups in the population for a range of fluoride concentrations

Table B-14 shows that the range of consumption is four times greater for the 99th percentile group than the average group;

Table 2-4 shows that susceptible groups consume up to ten times more than the mean; e.g., diabetics, lactating mothers, athletes, construction workers, police, firefighters, and military.

**Acute F threshold** is the amount of F that causes adverse health effects. Highest estimate of 5 mg/kg/day is used in these calculations:

- per Whitford (1996), the threshold for acute F dosage is 5 mg/kg/day. Source: p24 HC Review 2009;
- per Akiniwa (1997), the threshold for acute F dosage is 0.1 to 0.8 mgF/kg. Source: Tardif 2006 (internal submission to HC review 2009).

**Bioaccumulation factor (BioA F)** is the amount of F that accumulates in the body over time:

- 50% of ingested F bioaccumulates in a healthy adult body;
- 75-87% of ingested F bioaccumulates in young children (Whitford 1994);
- Those with impaired kidney function will bioaccumulate more than healthy adults.

**Water and Fluoride Intake per day:**

- millilitre per kilogram per day (mL/kg/day) for estimated water intake;
- milligrams per kilogram per day (mg/kg/day) for estimated fluoride intake;
- F intake per day estimates do not include F from other sources (foods, beverages using fluoridated water, dental products, air, drugs, salt; Windsor & Sifto salt is 200 ppm – Gingerich 2006).

## Time to acute F intake is significantly less:

- when all sources of F exposure are included.
- when fluoride concentrations are higher. Many communities in Ontario exceed the MAC of 1.5 mg/L, including Stratford, Ingersoll, Sebringville, Mitchell, Chepstow, St. Paul's.
- for children under the age of 1.
- for those who are above average consumers of tap water, regardless of age group
- for those with kidney impairment, regardless of age group.
- for those who consume significant F from other sources, regardless of age group.

Again, on page 27 of the paper, it states that both epidemiological and clinical studies show a clear causative association between long term ingestion of fluoride and skeletal fluorosis which is known to increase the incidence of bone fractures among the elderly. On page 37, the paper cites research that shows kidney stones were some 4.6 times greater in a fluoridated area than in a non-fluoridated area. It adds that increased serum parathyroid levels correlate well with increased fluoride ingestion. These research findings should be sufficient for Health Canada to apply the medical principle of caution and thereby recommend the cessation of fluoridated drinking water in all federal institutions across Canada. This would serve as a clear signal to provinces and municipalities to follow suit. To do otherwise, such as endorsing the status quo, could Health Canada be exposing itself to charges of medical malpractice?

It is these and other non-dental yet systemic adverse health effects that render meaningless ongoing attempts by Health Canada to set guidelines for fluoride levels in drinking water. These draft guidelines are an ineffective and counterproductive strategy that is causing more health harm than good for Canadians. Applying a more holistic approach to public dental health policy is essential to achieving Health Canada's overarching priority of promoting and protecting the general health and well-being of Canadians.

On page 52 of the paper, Health Canada states that a Limeback, 2007 article refers to a case study of a set of twins that "… demonstrated swallowing toothpaste at a young age was the main factor contributing to dental fluorosis." This characterization is not born out by the actual article which reads: "Fraternal twins, 12 years of age, were exposed from birth to 1 ppm fluoride in drinking water. Regular use of fluoridated toothpaste from an early age resulted in extra fluoride ingestion in the girl (top left) because she was less efficient at expectorating the toothpaste than her brother, who had mild fluorosis." It is not evident from this full quote that Dr. Limeback attributed swallowing toothpaste as being the main factor. At best, it would appear to have been a contributing factor. Health Canada's paper has overstated and distorted what was presented in Dr. Limeback's article. This too ought to be corrected.

As well, Health Canada should not base or defend its position on causes of dental fluorosis on just one case study, the details of which, including confounding variables, are not included in the article. To do so falls far short of taking an objective, balanced and scientific approach to this issue.

It is well established that fluoride exposure from fluoridated drinking water is the single largest exposure for most individuals. Two significant references on this are: "Water and processed beverages (e.g., soft drinks, fruit juices) can provide approximately 75% of a person's fluoride intake," per CDC's web site at www.cdc.gov/FLUORIDATION/safety/enamel_fluorosis.htm; and,

"The major dietary source of fluoride for most people in the United States is fluoridated municipal (community) drinking water, including water consumed directly, food and beverages prepared at home or in restaurants from municipal drinking water, and

commercial beverages and processed foods originating from fluoridated municipalities." per page 24, NRC 2006 review.

On page 53 of the paper, Health Canada fails to quantify the increase in dental fluorosis (DF) over the past 55 years. Perhaps this is due to the overall thrust of the discussion in the paper that appears to cast doubt on and even discount concern over the prevalence of dental fluorosis. By contrast, over the past ten years, Heller (1997), McDonagh (2000) and Levy (2006) have independently produced similar results on the prevalence of DF.

**Table B - Prevalence of Dental Fluorosis**

| | **<0.3ppm** | **0.3<0.7ppm** | **0.7-1.2ppm** | **>1.2ppm** |
|---|---|---|---|---|
| Heller (1997) | 13.5% | 21.7% | 29.9% | 41.4% |
| Levy (2006) | N/A | 21% | 41.1% | 46.3% |
| McDonagh (2000) | | | 48% (@ 1ppm) | |

Table B shows, among other things, that a MAC of 1.5 ppm does not protect against toxic effects of fluoride. And Levy (2006) further shows that the prevalence of caries does not decline significantly with decreasing concentrations of fluoride below a certain level but definitely does increase with increasing fluoride concentrations.

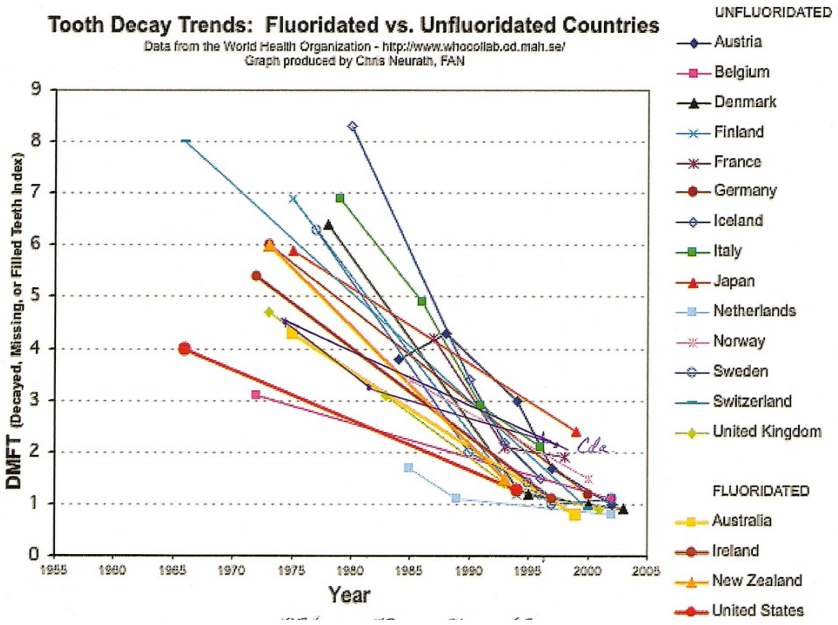
Table B is reinforced by CDC longitudinal surveys which found a marked increase in the prevalence of dental fluorosis among American youth. It virtually doubled over 20 years from 23% in 1987 to 32% in 2003 and then to 41% in 2007.

It also shows that Health Canada's proposal to risk manage the MAC to 1.5 ppm is unacceptable as it is inconsistent and incompatible with the above results obtained by Heller, McDonagh, and Levy. It would appear that Health Canada's expert panel either was unaware of Levy's work (even though he was a member) or ignored it. In either case, this evidence reveals even more starkly, the pro-fluoride bias of the panel and Health Canada staff.

It also suggests that public health officials cannot achieve a workable or "optimal" trade-off between the prevalence of caries and the prevalence of dental fluorosis by mass medicating the public with fluoridated drinking water. What is needed is an entirely new strategy that relies on the personalized, age-sensitive topical application of fluoride, supported by public education on tooth-friendly diets, with the twin goals of achieving 0-0 prevalence of both caries and dental fluorosis. This is where funds for research, for education, for Canada-wide adoption of best dental hygiene practices, and for dental insurance coverage of all SES levels ought to become the hallmarks of a 21st century national dental health care program in Canada.

On page 54, the paper states that "…the caries preventative effects of fluoridated drinking water are still evident in modern studies of fluoridated versus non-fluoridated

communities." But it fails to reference these studies. This is one more example of poor science protocol being practiced by Health Canada staff. One has to wonder why, especially in light of data from the World Health Organization reproduced below which refutes the foregoing quote.




On August 17, 2001 the US Centres For Disease Control and Prevention issued a report entitled Recommendations for Using Fluoride to Prevent and Control Dental Caries in the United States. The Health Canada paper, 2009 omits this report from its references and its discussion on page 55, even though the CDC's declared purpose was to focus "… on critical analysis of the scientific evidence regarding the efficacy and effectiveness of each fluoride modality in preventing and controlling dental caries and on the use of multiple sources of fluoride." On the topic of fluoride's role in the prevention of caries the CDC report goes on to state: "The laboratory and epidemiologic research that has led to the better understanding of how fluoride prevents dental caries indicates that fluoride's predominant effect is posteruptive and topical and that the effect depends on fluoride being in the right amount in the right place at the right time." This further undermines any rationale Health Canada's paper offers for Fluoridated drinking water being the primary modality for reducing dental caries. The draft paper and its recommendations should be amended accordingly.

Taken together, the foregoing CDC finding on topical application of fluoride as the main modality for caries reduction, the WHO data on dental caries rates in fluoridated and unfluoridated countries being virtually the same, and the research findings by Heller, McDonagh, and Levy on the increasing prevalence of dental fluorosis lead to the undeniable conclusion that fluoridated drinking water is neither effective nor safe. In Canada, this conclusion is further supported by the community level work of Clark, Levy et

al (2006) and Ito (2007) in British Columbia and Ontario. It is clear then that fluoridating drinking water should, as a matter of dental health policy, now be discontinued.

On page 59, the paper provides a risk assessment derived from a health-based value (HBV) for fluoride concentration as a means of assuring protection of the public from any adverse health effects. Given the foregoing science-based conclusion about ingested fluoride, this assessment may be best considered irrelevant. But the HBV methodology warrants a few additional comments.

First, in its construct, the Health Canada paper assigns to fluoridated drinking water a 50% contributing factor, the single highest of the main sources of daily fluoride intake in our diets. That is tantamount to agreeing that fluoride toothpaste is but a secondary contributor to dental fluorosis, notwithstanding its misleading reference on page 51 to Limeback's 2007 article. As Health Canada can't have it both ways, which one should the Canadian public believe and why? Secondly, the paper states that moderate dental fluorosis is the end point of its concern for adverse dental health effects, given the aesthetic concerns it creates. Yet as noted in Limeback (2007) "…moderate fluorosis may be associated with some structural loss of the surface enamel in thin layers, …" Health Canada staff conveniently but wrongly exclude from the risk assessment severe dental fluorosis and the non-dental adverse effects fluoride causes, including skeletal fluorosis, bone fractures, kidney stones and impairment, disruptions of the endocrine system which were not evaluated (thyroid, pineal gland), neurotoxic effects, and lead poisoning due to fluoride-induced leaching. While the Chief Dental Officer may feel professionally constrained from dealing with non-dental effects, Health Canada should bring to bear its other in-house medical resources to make this risk assessment more relevant and realistic.

It is also bizarre that the paper walks away from the NBV of 0.9 mg/L of fluoride as a new MAC and proposes to stay with the current MAC of 1.5 mg/L. It also points out that the "optimal" level will be 0.7 mg/L which is 46.66% of the MAC. If the MAC were to be reduced to the HBV, then presumably the "optimal" level should be no more than 46.66% of that new MAC to maintain the same margin of safety. That would be 0.42 mg/L. But with no science–based explanation provided for staying with the current MAC, the draft paper amazingly states it will risk manage the gap between the NBV and the current MAC. In adopting a wait-and-see posture and failing to offer a control strategy for managing this gap, isn't Health Canada passing the health risks of ingesting fluoride onto the Canadian public? Is this right? Is this fair? Is this ethical? The answer to all of these questions is a resounding no.

# Other Considerations:

Neither the medical principle of exercising caution nor the medical ethics of obtaining and maintaining informed consent are addressed in the draft paper. On the former, the draft paper presents sufficient and significant evidence of harm to health to require Health Canada to adopt a much higher level of caution in its approach to and policy on fluoride in drinking water.

On the latter, as the current uproar in the USA over the H1N1 flu vaccine amply demonstrates, people do not want to be forced to take medicine against their will and better judgement. Recent public opinion polls show that less than half of Canadians, including health care professionals, intend to take this flu shot. The most recent poll, released on October 20, 2009, reveals that fewer that 40% of Quebecers intend to be inoculated with the vaccine against H1N1! They are increasingly sceptical and mistrusting of public health authorities. Health Canada would do well to take into account this public mood and mind set as it grapples with the controversial fluoridation issue.

We should only consume medicines or undergo medical procedures after giving our informed consent. Yet forced and massive medication without such consent and without active monitoring for adverse effects is precisely what public health officials are doing by supporting and promoting the widespread ingestion of fluoridated drinking water. This violation of a generally accepted medical care principle is intolerable in the 21st century. It is a failure to exercise duty of care. It destroys the respect and trust that underpin the legitimacy of the provision of advice and the exercise of authority by public health officials.

Water fluoridation, while being a drug similar to a flu vaccine in its attempts to protect against caries disease, remains the only mass medication where patients:

1. don't know they are being medicated;

2. are told by public health officials, dental practice regulators, without informed consent, to ingest the medication;

3. are not warned about the effects of large doses; and,

4. are not given instructions on appropriate doses for age/weight or need for treatment.

This dental public health approach to fluoride in drinking water is inconsistent with RCDSO-endorsed guidelines of June 2001 on informed consent, authored by Elizabeth Cronk. The following summarizes many of the operating principles therein that are applicable to all health-care practitioners, including dentists:

- dentists have both an ethical and legal duty to ensure that the informed consent of patients is obtained prior to the commencement of heath-care treatments or procedures. Informed consent is an ongoing exchange of information between the health-care practitioner and patient, beginning with a detailed medical history and continuing the dialogue throughout the course of treatment;

- that information exchange must be full and complete including a two-way examination of the proposed treatment and its expected benefits; as a

precondition to obtaining informed consent, disclosure by the health-care practitioner of all material, special or unusual risks associated with the proposed treatment or procedure; discussion of all alternative courses of action; consideration of likely consequences of not proceeding with the proposed treatment; and must entail verification that the patient understands the nature of the information provided by the health-care practitioner and his/her staff.

- the requirements of disclosure, known as the objective, patient-focussed standard of disclosure, were put in place by the Supreme Court of Canada based on cases adjudicated by the Court. More generally, the health-care practitioner must meet the requirements set out in the Health Care Consent Act, 1996 (Ontario) or comparable legislation in other provinces;

- *a fundamental principle is that the advice provided to the patient regarding risks of treatment must relate to the condition and circumstances of the particular patient* (emphasis added); and,

- the health-practitioner has an affirmative duty to respond truthfully to a patient's questions with reasonable answers and the most recent information relevant to the patient's circumstances and to exercise due care in explaining the consequences of declining treatment.

Dentists and physicians, be they in private practice or public health organizations, are bound by ethics, law and regulations such as the foregoing on informed consent. Yet it appears that public health officials may be putting themselves above this code of conduct with regards to their advice and behaviour regarding the water fluoridation issue. The draft Health Canada paper certainly warrants close examination as to its compliance or lack thereof with the ethics of informed consent. The paper, in fact, ought to include a final section on medical ethics, including the precepts of caution and informed consent.

To sum up, it appears that historical orthodoxy and close-minded dogma have prevailed in the draft Health Canada paper to the detriment of important values of open-mindedness, objectivity, and a science-based dental public health policy. This is an unacceptable basis for promoting and protecting dental health and, for that matter, general health in Canada. It is a self-inflicted disservice to the need for Health Canada to earn and sustain the respect and trust of Canadians so essential to the legitimacy of its authority to conduct public health policy and programs.

The policy option still open to Health Canada is to explore objectively and, on its merits, embrace wholeheartedly the withdrawal of its support for fluoridated drinking water. It is not too late to do this.