

# **Unregulated, Uncontrolled, Unsafe Fluoridation Products**

## **Sale and Promotion is Illegal and Must Cease Immediately**

by

Carole Clinch B.A., B.P.H.E.

Gilles Parent ND.A

Pierre Morin Ph.D.

Submission to the Auditor General of Canada and the Attorney General and  
Justice Minister of Canada

May 28, 2011

## EXECUTIVE SUMMARY

The purpose of this document is to set out the main legal issues concerning the products and policies involved with artificial drinking water fluoridation. The goal is to prompt an assessment by the Auditor General of Canada and the Minister of Justice and Attorney General of Canada into the conduct of Health Canada, the Public Health Agency of Canada and all other associated agencies in discharging their responsibilities for regulation of fluoridation products and the policy implementation of artificial water fluoridation in Canada.

For the specific health purposes of prevention or treatment of dental caries, Health Canada, the Public Health Agency of Canada and other associated government agencies have recommended that municipal drinking water be infused with fluoride products that are not tested, not regulated and not controlled by any government agency. While making these recommendations, the same government agencies have explicitly stated that they accept no responsibility for determining the safety of drinking water fluoridation products through the use of scientific methods such as toxicological testing (animal safety), clinical trials (human safety), and standard risk assessments.

Currently, fluoridation products are correctly classified and regulated as a “hazardous waste” when handled in bulk. When this identical material is added to drinking water, it is completely unregulated, and untested for human consumption. Drinking water fluoridation products do not satisfy the legal requirements for safety as defined by the *Food and Drugs Act* and associated Regulations, and various provincial laws. Despite such inconsistencies and violations of Canadian law, government agencies have turned a blind eye to the enforcement of these existing legal requirements. Numerous petitions and Freedom of Information requests should have alerted many health agencies in Canada to the scientifically valid risks that uncontrolled and unregulated fluoridation products pose to the Canadian public, and to the serious concerns raised about the lack of compliance of these products to National Sanitation Foundation (NSF) Standard 60 certification procedures which are “prescribed standards” according to both federal and provincial laws. These government agencies have a jurisdictional duty to ensure the protection of public health, yet these expressed concerns have been dismissed or ignored.

Health Canada is violating Canadian laws. The practice of artificial water fluoridation must cease immediately until the legal requirements are met. In essence, fluoridation has effectively been permitted by the government's failure to uphold its own laws, and by government's willingness to operate outside the bounds of law. If the goal of Health Canada is to protect the water fluoridation program at all costs, this is an abject betrayal of the trust the Canadian public has placed in our national health agency whose fundamental duty is to ensure public health protection.

The following summarizes how Health Canada's policy recommendations are scientifically invalid and in violation of Canadian laws:

### **Fluoride products misrepresented**

The fluoride compounds found in source water ( $\text{CaF}_2$ ) differ from the fluoride compounds added intentionally to drinking water ( $\text{H}_2\text{SiF}_6$ ,  $\text{Na}_2\text{SiF}_6$ ), and yet Health Canada makes no distinction between them. Health Canada risk assessments are not acceptable because they are based on the fluoride compounds found naturally in source water, not on the actual fluoride products used in artificial water fluoridation. Dissociation of these fluoride compounds into their constituent ions in water does not

obviate the need to characterize the human toxicity of all products utilized for artificial water fluoridation.

### **Health claims illegal**

The fluoride products used in artificial water fluoridation are commonly known to be used in the prevention, treatment or mitigation of dental disease. The Supreme Court of Canada defines fluoridation as “compulsory preventive medication” used for “special health purposes”(1). Health Canada and the Public Health Agency(2) of Canada have also explicitly stated that fluoride products used in artificial water fluoridation are used for specific health purposes in the prevention, mitigation or treatment of cavities. These definitions are consistent with the definition of drugs or natural health products, as defined in the *Food and Drugs Act* and associated regulations. Despite these health claims and the legal requirements for making such health claims, Health Canada has not defined water fluoridation products as drugs or health products and continues to make health claims that are not legally permissible without such classification.

### **Fluoride guidelines misrepresented**

The Health Canada guidelines for fluoride concentrations found in source water (MAC of 1.5 mg/L) and for fluoride concentrations created by artificial water fluoridation (.7 mg/L) are frequently confused and not correctly described by Health Canada and other government agencies. These levels may be exceeded without legal consequences because neither of these Health Canada guidelines are legal requirements in most of Canada.

### **Safety studies do not exist**

There is no scientific evidence (animal studies or human studies of safety) demonstrating that all Canadians are safe from harm from the actual products used in artificial water fluoridation at the recommended fluoride levels, for a lifetime of ingestion. On the contrary, there is irrefutable scientific evidence from Health Canada(3) and many international sources that health harm is occurring to susceptible populations from the use of fluoride products used in artificial water fluoridation. For most individuals, drinking water is their largest source of fluoride.(4) Health Canada and other government agencies rely on the private consortium called National Sanitation Foundation (NSF) for safety studies, but this company has no animal safety studies (toxicology studies) as required by their own standard. NSF Standard 60 is a “prescribed standard” for products added to drinking water according to federal and provincial laws, and yet the fluoride products used in artificial water fluoridation are not in compliance with this “prescribed standard”.

### **Environmental laws ignored**

Safe drinking water is a basic human need. Safe drinking water is a basic human right according to the 2010 UN resolution. Safe drinking water is a finite and diminishing resource. Health Canada fails to inform Canadians that the fluoride products used in artificial water fluoridation (fluorosilicates) are defined as “toxic substances” recommended for “virtual elimination” by various laws and treaties and that they are also defined as “hazardous waste” according to a wide range of international, federal and provincial laws. The requirements of these environmental laws are in conflict with the policy of artificial water fluoridation promoted by Health Canada and the Public Health Agency of Canada. The use of drinking water to deliver medications is environmentally unsustainable, economically wasteful of taxpayers money and an inefficient delivery method because less than 1% of treated drinking water is actually ingested. Because municipal water systems are unable to remove fluoride, treated sewage

contains fluoride levels which are 10 times higher than the Canadian Water Quality Guideline (CWQG) for Aquatic Species. In effect, our municipal drinking water systems are being used as conduits for disposal of industrial fluoride by-products. Municipal effluent, for example, is a major contributor to Great Lakes background fluoride concentrations exceeding the CWQG for Aquatic Species.

### **Human rights and freedoms ignored**

A fundamental question is whether drinking water should be used for the delivery of products used for specific health purposes when basic rights and freedoms such as the following are violated:

- a) the right to informed consent before being medicated (many Canadians are unaware that fluoride products are in drinking water);
- b) the right to avoid harmful substances when the potential for health harm is certain;(5)
- c) the ability to control the daily intake of a substance used for medical purposes;(6)
- d) the ability to avoid skin exposure which has the potential to cause harm;(7)
- e) the right to avoid substances for religious or cultural reasons;(8)

Because fluoride products used in artificial water fluoridation do not satisfy ethical and legal requirements for products used for specific health purposes, the promotion of artificial water fluoridation by Health Canada and the Public Health Agency of Canada violates fundamental rights and freedoms as enshrined in the Canadian Charter of Rights and Freedoms. For many citizens, there is no alternative to the consumption of municipal drinking water straight out of the tap. In contrast to any other public health measure or use of medication, artificial water fluoridation effectively denies Canadians the right to refuse medication and the right to informed consent.

### **False and misleading statements**

Government agencies such as Health Canada have made claims regarding the safety of fluoride products used in artificial water fluoridation which are not supported by research. Any individual(s) who distort(s) or misrepresent(s) scientific evidence and known facts for reasons of ignorance, political expedience, financial gain, or self-interest imperil(s) the integrity of scientific discourse and leads to an erosion of public trust in our government institutions where policy decisions regarding public health are deemed to be made, based on scientific evidence. Health Canada has misrepresented the NRC 2006 Review,(9) the York 2000 Review,(10) and the WHO.(11)

### **Health harm**

The scope of health problems associated with the lack of regulation, lack of informed consent, the inability to protect susceptible populations from exposure, and the inability to control daily intakes of fluoride from drinking water and all other sources, has never been adequately addressed by Health Canada and the Public Health Agency of Canada. The prevalence and costs to society for dental harm, neurotoxic damage, cardiovascular disease,(12) arthritic-like symptoms and bone fractures,(13) Alzheimer's disease,(14) premature births,(15) cancer,(16) and renal disease(17) due to fluoride over-exposure is difficult to calculate, but recent estimates done in the USA suggest that the health costs due to artificial water fluoridation exceed one trillion dollars.(18) The half life of fluoride in the body is about 20 years. A cessation of fluoridation will take at least 20 years to reduce the economic impact.

## **Not effective**

Health Canada's conclusions of efficacy for artificial water fluoridation ignores the current scientific consensus that fluoride works not by swallowing but by direct application on the tooth surface, in high concentrations. The Health Canada review panel ignored the growing body of epidemiological evidence from Canada and abroad,(19,20) written by some of the Health Canada review panel members themselves,(21) which failed to demonstrate any benefit from artificial water fluoridation on cavity rates. Health Canada's conclusions that artificial water fluoridation works “topically” fails to consider that the level of fluoride in the saliva of someone who drinks fluoridated water “is not likely to affect cariogenic activity” according to the US Centers for Disease Control.(22) Health Canada ignored the following evidence from the York Review: “The review team was surprised that in spite of the large number of studies carried out over several decades there is a dearth of 'reliable' evidence with which to inform policy.”(23) The incorrect assumptions made by Health Canada do not create a sound basis on which to base policy decisions.

## **Not logical**

Health Canada appears to be using a double standard by stating clearly that they do not regulate the fluoride products used in artificial water fluoridation which are ingested, but they do regulate similar fluoride products used for dental care which are not recommended for ingestion (e.g., toothpaste, mouthwashes). Health Canada also does not recommend the ingestion of fluoride in any other format.(24) Health Canada and the Canadian Public Health Agency have acted in bad faith by not proposing any scientific or logical explanation as to how they moved from the evidence of all the actual and potential harms fluoride can cause, to their apparent conclusion that 0.7 mg/L fluoride concentration in drinking water is safe for everyone, for an entire lifetime, when the scientific and legal requirements for animal and human safety studies of these products have not been met. These government agencies seem to have used some form of absurd logic to convince themselves that unregulated, uncontrolled fluoride products, which lack safety studies, go selectively to the teeth upon ingestion and have no impact on the rest of the body.

## **Conclusion**

Artificial water fluoridation in Canada is permitted by Health Canada through a litany of transgressions that includes mis-representation of scientific evidence, mis-classification of fluoridation products, non-regulation of fluoridation products used for specific health purposes, dismissal of ethical and human rights violations, ignoring violations of environmental laws, ignoring legal requirements for safety, ignoring the evidence of health harm, and ignoring evidence that fluoridation of drinking water is ineffective in dental cavity prevention. This collection of misdeeds by Health Canada has created a situation whereby it is impossible to monitor Canadians' fluoride exposures because of its ubiquitous presence in our entire food chain. All Canadian citizens consume beverages or foods prepared with fluoridated drinking water, whether they know it or not. Because fluoride is promulgated as a therapeutic agent, it would represent the most widely used medication in use in Canada. For this reason, government regulation of these ubiquitous fluoride products must no longer be ignored.

The government policy of artificial water fluoridation puts an unregulated fluoride product into public water supplies, which has not undergone standard toxicological tests or clinical trials for safety. These fluoride products must cease to be used in drinking water because they do not satisfy the scientific and legal requirements for safety. Canadians deserve nothing less than the safest drinking water possible.

With regard to regulation of water fluoridation products and policies for artificial water fluoridation, it is imperative that the conduct of Health Canada be investigated by the Auditor General and the Attorney General of Canada.

## Citations

- 1 SCC Toronto v Forest Hill 1957 <http://csc.lexum.org/en/1957/1957scr0-569/1957scr0-569.html>
- 2 “Municipal water fluoridation programs were also introduced and recognized as beneficial in tooth decay prevention.” <http://www.phac-aspc.gc.ca/cphorsphc-respcacsp/2009/fr-rc/cphorsphc-respcacsp05-eng.php>
- 3 Health Canada National Health Measures Survey 2007-2009 shows that only 60% of Canadian children in mostly unfluoridated communities (10 of 15 communities surveyed were unfluoridated) have “normal” teeth undamaged by fluoride over-exposure. These rates would be much lower in a survey of only fluoridated communities.
- 4 “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.” p24, 2006 National Research Council Review  
  
“Water and processed beverages (e.g. soft drinks and fruit juices) can provide approximately 75% of a person's fluoride intake” US Centers for Disease Control available from: [http://www.cdc.gov/fluoridation/safety/dental\\_fluorosis.htm](http://www.cdc.gov/fluoridation/safety/dental_fluorosis.htm)
- 5 Health Canada's 2007-2009 National Health Measures survey of 15 communities where the majority (10 out of 15) of the communities surveyed were UNFLUORIDATED showed that only 60% of children had “normal” teeth and 40% of children had dental fluorosis. The incidence of dental fluorosis would be much higher in fluoridated communities according to the 1999 Review by the Ontario Ministry of Health which stated that 20-75% of citizens have dental fluorosis in fluoridated communities.
- 6 [http://www.newmediaexplorer.org/chris/Clinch\\_2011\\_Dose\\_Concentration.pdf](http://www.newmediaexplorer.org/chris/Clinch_2011_Dose_Concentration.pdf)
- 7 "In hypersensitive individuals, fluorides occasionally cause skin eruptions such as atopic dermatitis, eczema or urticaria. Gastric distress, headache and weakness have also been reported. These hypersensitivity reactions usually disappear promptly after discontinuation of the fluoride." PHYSICIANS' DESK REFERENCE, 1994, 48th Edition, p. 2335-6. <http://www.fluoridealert.org/health/allergy/pdr.html>
- 8 Muslim concepts not consistent with forced medication: 1) Tahoor: Do not adulterate drinking water; 2) Shabuha: Anything controversial should be prohibited (Precautionary Principle: When in doubt, leave it out); 3) Haram: Anything harmful should be prohibited.
- 9 Look under Health Canada: [http://www.newmediaexplorer.org/chris/2009/10/26/people\\_for\\_safe\\_drinking\\_water.htm](http://www.newmediaexplorer.org/chris/2009/10/26/people_for_safe_drinking_water.htm)
- 10 Chairman of the York Review letter available from: <http://www.fluoridealert.org/sheldon.htm>
- 11 <http://fluoridealert.org/re/canada.report.response.clinch.pdf>
- 12 [http://www.newmediaexplorer.org/chris/Clinch\\_2010\\_Fluoride\\_and\\_Cardiovascular\\_System.pdf](http://www.newmediaexplorer.org/chris/Clinch_2010_Fluoride_and_Cardiovascular_System.pdf)
- 13 [http://www.newmediaexplorer.org/chris/Clinch\\_2009\\_Fluoride\\_and\\_Skeletal\\_Fluorosis2.pdf](http://www.newmediaexplorer.org/chris/Clinch_2009_Fluoride_and_Skeletal_Fluorosis2.pdf)
- 14 NRC Review: “These changes have a bearing on the possibility that fluorides act to increase the risk of developing Alzheimer’s disease.” NRC p186
- 15 [http://www.newmediaexplorer.org/chris/Clinch\\_2009\\_Fluoride\\_and\\_Premature\\_Births.pdf](http://www.newmediaexplorer.org/chris/Clinch_2009_Fluoride_and_Premature_Births.pdf)
- 16 “Fluoride appears to have the potential to initiate or promote cancers, particularly of the bone” NRC p286
- 17 “Human kidneys... concentrate fluoride as much as 50-fold from plasma to urine. Portions of the renal system may therefore be at higher risk of fluoride toxicity than most soft tissues.” NRC p236  
  
“future studies should be directed toward determining whether kidney stone formation is the most sensitive end point on which to base the MCLG.” NRC p247
- 18 Dr. Bill Osmunson, DDS, MPH, petition to US FDA Nov 2010.

[19 http://www.newmediaexplorer.org/chris/Clinch\\_2009\\_Swallow\\_F\\_Does\\_Not\\_Prevent\\_Cavities.pdf](http://www.newmediaexplorer.org/chris/Clinch_2009_Swallow_F_Does_Not_Prevent_Cavities.pdf)

[20 http://www.newmediaexplorer.org/chris/Clinch\\_2010\\_40-50\\_Years\\_Later-Kingston-Newburgh\\_Trial.pdf](http://www.newmediaexplorer.org/chris/Clinch_2010_40-50_Years_Later-Kingston-Newburgh_Trial.pdf)

[21](http://www.newmediaexplorer.org/chris/Clinch_2009_No_Benefit_Definite_Harm2.pdf) Kumar and Clark were both members of the recent Health Canada panel. Why did they never mention their own published research? [http://www.newmediaexplorer.org/chris/Clinch\\_2009\\_No\\_Benefit\\_Definite\\_Harm2.pdf](http://www.newmediaexplorer.org/chris/Clinch_2009_No_Benefit_Definite_Harm2.pdf)

[22](http://www.cdc.gov/mmwr/rr/rr14.htm) Centers for Disease Control and Prevention, August 17, 2001. Recommendations for using fluoride to prevent and control dental caries in the United States. Fluoride Recommendations Work group. MMWR 50 (RR14); 1-42. "Saliva is a major carrier of topical fluoride. The concentration of fluoride in ductal saliva, as it is secreted from salivary glands, is low...approximately 0.016 parts per million in areas where drinking water is fluoridated and 0.006ppm in non-fluoridated areas. This concentration of fluoride is not likely to affect cariogenic activity."

[23 http://www.fluoridealert.org/sheldon.htm](http://www.fluoridealert.org/sheldon.htm)

[24](http://www.hc-sc.gc.ca/iyh-vsv/environ/fluor_e.html) "Health Canada does not recommend the use of fluoride supplements (drops or tablets). This guideline is consistent with recommendations made by Health Canada's First Nations and Inuit Health Branch (FNIHB) and the Canadian Association of Public Health Dentistry (CAPHD)." [http://www.hc-sc.gc.ca/iyh-vsv/environ/fluor\\_e.html](http://www.hc-sc.gc.ca/iyh-vsv/environ/fluor_e.html)

## About the Authors

### Contact Information

Gilles Parent	Tel: 514-747-2259	Email: <a href="mailto:gilles.parent@bellnet.ca">gilles.parent@bellnet.ca</a>
Carole Clinch	Tel: 519-884-8184	Email: <a href="mailto:caclinch@gmail.com">caclinch@gmail.com</a>
Pierre Morin	Tel: 819-292-3045	

**CAROLE CLINCH:** BA, BPHE from Queen's University in Kingston. In the past four years she has written more than 15 reviews on fluoride issues to various government agencies and she has published 4 recent papers on the subject of fluoride, including:

- Clinch CA. Fluoride Interactions with Iodine and Iodide: Implications for Breast Health. Fluoride April-June 2009;42(2):75-87.
- Long H, Jin Y, Lin M, Sun Y, Zhang L, Clinch C. Fluoride Toxicity in the Male Reproductive System. Fluoride Oct-Dec 2009;42(4):275-291.
- Clinch CA. Does Dental Fluoride Use have Clinically Significant Effects on Oral Bacteria? Fluoride Oct-Dec 2010;43(4):213-22.
- Clinch CA. Excess Fluoride Interference with Cystic Fibrosis Transmembrane Conductance Regulator. Fluoride Jan-Mar 2011;44(1):7-8.

**GILLES PARENT:** NDA., has been a clinical practitioner of naturopathy for 38 years in Montreal and Sherbrook. He is now one of the spokespersons for the Association des naturopathes agréés du Québec after serving as vice president. He was editor of "La fluoration en question" from 1977 to 1979. He has written and published several books on questions of human health, and written several papers on water fluoridation, including:

- Parent G. L'inconséquence de la fluoration. Les Grandes Éditions du Québec, 156 p, 1975.
- Parent G. Vaincre l'arthrite. Libre Expression, 175 p. 1987.
- Morin PJ, Graham JR, Parent G. La fluoration: autopsie d'une erreur scientifique. Les Éditions Berger, 315 p. 2005 (French), 2010 Fluoridation: autopsy of a scientific error. (English).

**PIERRE-JEAN MORIN**, Ph.D. in experimental medicine from Laval University, has taught medicine at Laval University in Quebec, and served as director of medical research at Laval University Hospital. Dr. Morin has served as scientific advisor to the environment minister and premier of Quebec. He was an important witness and scientific advisor to counsel for the plaintiffs in the fluoridation trial before Judge Anthony Farris in Houston. He is also listed in Who's Who in the World. He was a member of the board of “La fluoration en question” from 1977 to 1979. Dr. Morin is co-author of more than eighty published articles, reports, books, or monographs in various questions of medical research, including key works on water fluoridation, including:

- Coauthor of the report of the Conseil consultative en environnement du Québec: Les fluorures, la fluoration et l'environnement. 1979.
- Bundock JB, Graham JR, Morin PJ. Fluorides, Water Fluoridation and Environmental Quality. *Journal of Science and Public Policy*. June 1982.
- Morin PJ, Burk D, Bundock JB, Graham JR. Les fluorures. Relations avec les maladies congenitales et le cancer. L'image globale. *Compte rendus de la journée d'information sur la sante environnementale*. Published by the Ministère des Affaires sociales du Québec, le Centre de Toxicologie du Québec et le Département de santé communautaire du CHUL. Nov. 1984.
- Morin PJ, Graham JR, Ziegelbecker R. Tout ce qu'il est interdit de dire au sujet de la fluoration des eaux de consommation. Published by the CLSC Lotbiniere-Ouest. 1985.
- Bundock JB, Burk D, Graham JR, Morin PJ. Fluoride, water fluoridation, cancer and genetic diseases. *Science and Public Policy*. vol.12, p.36-42, 1985.
- Morin PJ, Graham JR, Parent G. La fluoration: autopsie d'une erreur scientifique. Les Éditions Berger, 315 p. 2005 (French), 2010 Fluoridation: autopsy of a scientific error. (English).