

# Studies in Health Care Policy



July 2009

## The Regulation of Health Claims in Advertising for Functional Foods and Natural Health Products in Canada and the United States

by Mark Brosens





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# Introduction

On May 5, 2009, the United States Food and Drug Administration (FDA) issued a letter to General Mills, warning that the food company was illegally marketing its popular breakfast cereal Cheerios® as a “drug” (FDA, 2009a). According to the FDA’s letter, regulators determined that “Cheerios® ... is promoted for conditions that cause it to be a drug because the product is intended for use in the prevention, mitigation, and treatment of disease” (FDA, 2009a: 1). This conclusion was based on advertising printed on Cheerios® cereal boxes, which included claims that “in just 6 weeks Cheerios can reduce bad cholesterol by an average of 4 percent” and that “Cheerios is ... clinically proven to lower cholesterol. A clinical study showed that eating two ½ cup servings daily of Cheerios cereal reduced bad cholesterol when eaten as part of a diet low in saturated fat and cholesterol” (FDA, 2009a: 1). According to the FDA, “these claims indicate that Cheerios® is intended for use in lowering cholesterol, and therefore in preventing, mitigating, and treating the disease hypercholesterolemia ... [and] coronary heart disease through lowering total and ‘bad’ (LDL) cholesterol” (FDA, 2009a: 1). The FDA concluded that, because of these “intended uses,” Cheerios® “is a drug” within the meaning of the US Federal Food, Drug and Cosmetic Act. The FDA went even further and declared Cheerios® to be a “new drug” under the act “because it is not generally recognized as safe and effective for use in preventing or treating hypercholesterolemia or coronary heart disease. Therefore ... it may not be legally marketed with the above claims in the United States without an approved new drug application” (FDA, 2009a: 2).

The Cheerios® “drug” case raises a number of questions about regulatory restrictions on advertising health benefits associated with food products. In Canada, more attention has been focused on the issue of using health claims to advertise the value of nutraceuticals, functional foods, and natural health products (NFFNHPs) because of Bill C-51, which was introduced in Parliament in April 2008. Bill C-51 proposed a regulatory framework governing allowable health claims for NFFNHPs. The purpose of this paper is to determine whether Canadian regulatory standards for advertising health claims associated with NFFNHPs are appropriate, too lax, or too strict. This paper assesses Canadian regulatory standards relative to (1) the scientific research on health benefits linked to diet, and (2) the state of regulation in the United States.

## **What are nutraceuticals, functional foods, and natural health products?**

The use of nutraceuticals, functional foods, and natural health products (NFFNHPs) to derive associated health benefits is common in Canada. Using data from 2005, Health Canada estimates that 71% of Canadians regularly use nutraceuticals, meaning they regularly consume vitamins and minerals, homeopathic medicines, etc. (Health Canada, 2007b). That number might be larger if it included Canadians who have changed their consumption of certain foods or food products because of associated health claims.

According to Agriculture and Agri-Foods Canada (2008), a nutraceutical can be defined as “a product isolated or purified from foods that is generally sold in medicinal forms not usually associated with foods. A nutraceutical is demonstrated to have a physiological benefit or provide protection against chronic disease.”

Functional foods are defined as “similar in appearance to, or may be, a conventional food that is consumed as part of a usual diet, and is demonstrated to have physiological benefits and/or reduce the risk of chronic disease beyond basic nutritional functions, i.e. they contain [a] bioactive compound” (Agriculture and Agri-Foods Canada, 2008).

Natural health products (NHPs) include “homeopathic preparations; substances used in traditional medicines; minerals or trace elements; vitamins; amino acid; essential fatty acids; or other botanical, or animal or micro-organism derived substances. These products are generally sold in medicinal or ‘dosage’ form to diagnose, treat, or prevent disease; restore or correct function; or to maintain or promote health” (Agriculture and Agri-Foods Canada, 2008). As a product group, NHPs include nutraceuticals.

Manufacturers and producers of NFFNHPs often claim that health benefits can be derived from the consumption of their products because of the bioactive compounds those products contain. Bioactive compounds are “the naturally occurring chemical compounds contained in, or derived from, a plant, animal or marine source, that exert the desired health/wellness benefit (e.g., omega-3 fatty acids in flax or fish oils and beta-glucans from oats and barley)” (Agriculture and Agri-Foods Canada, 2008).

# Methodology

This paper briefly examines the state of regulation in Canada and the United States with regard to the commercial advertisement of health claims associated with nutraceuticals, functional foods, and natural health products (NFFNHPs). A literature review was conducted to assess the state of the scientific research on the health benefits of the basic food elements that are essential ingredients in many NFFNHPs, and thus are subject to regulations governing allowable health claims in advertising. The types of health claims allowed to be used in advertising in Canada and the United States were checked for congruence with the scientific research found in the academic literature surveyed.

For the literature review, the keywords “diet” and “health” were used to search for studies focused on the health effects associated with diet. The following databases were searched: PubMed, Medline, the Health Canada website, and the United States Food and Drug Administration (FDA) website. These searches returned just over 6,200 articles (not including roughly 16,200 articles from the FDA website, most of which were quickly eliminated by the FDA’s redundancy filter). The author selected a sample of 416 articles, which included randomized control studies, crossover studies, meta-analyses, and literature reviews. The main criteria used to select an article for inclusion in the sample were as follows:

- ❧ The article was of scholarly quality; i.e., it was published in a peer reviewed journal and was not a letter or an opinion piece;
- ❧ The article focused on human health outcomes derived from studies of human test subjects; and,
- ❧ The article specifically studied the link between diet and health.

Generally, reading the abstract of a returned article was sufficient to exclude it from the sample based on the above criteria. However, if an abstract was not sufficient to determine whether an article should be included in the sample, the text of the article was examined in greater detail.

All of the sample articles were examined and their conclusions on individual food elements were coded as either:

- ❧ pro: the food element was beneficial to one’s health;
- ❧ con: the food element was detrimental to one’s health;

- ❧ mixed effect: the food element either had different effects when consumed in different amounts or had different effects on different demographic groups; or,
- ❧ no effect: the food element produced no statistically significant outcome.

When an article studied more than one food element, that article was recorded once for every food element on which it came to a conclusion. All of these coded conclusions and the diseases that the articles studied were recorded on a spreadsheet.

The studies in the sample examined the links between the consumption of various kinds of foods, food products, and bioactive compounds and various diseases or health conditions. The six most frequently studied health conditions found in the sample were: cancer (188 conclusions); general cardiovascular disease (71); coronary heart disease (53); blood pressure (47); diabetes (36); and bone health (28). These diseases are also common illnesses among the Canadian population. For instance, in 2003, there were 152,257 incidents of cancer (Statistics Canada, 2009a); in 2005, 71,338 people died of major cardiovascular diseases (Statistics Canada, 2009b); in 2005, 1,325,120 Canadians had diabetes (Statistics Canada, 2007); and in 2006, about one million Canadians were living with osteoporosis (Statistics Canada, 2006).

## **General state of research on health benefits and diet**

From the sample, 661 conclusions were identified. Of these conclusions, 59% determined that the food, food product, or bioactive compound studied was beneficial to human health; 24% concluded that the food, food product, or bioactive compound studied was detrimental to human health [1]; 4% found mixed effects; and 13% found no effect. Many of the studies in the 13% of the sample that showed no link between diet and health outcomes speculated that there was an interaction between diet and health, but that it could not be identified using the study's methodology.

## **Regulatory allowances in Canada and the United States**

If a particular food element has a beneficial impact on health, it is conceivable that public health could be improved if more people consumed that food element, or substituted healthy food elements for unhealthy food elements.

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1 Due to the nature of the search terms, this group included food elements such as saturated fat, trans fat, sodium, and so on.

Theoretically, changes in aggregate demand for healthy food elements could be influenced by advertising—that is, by providing consumers with information about food products and food choices. The regulation of health claims is based on the rationale that in order to ensure that claims about the effects of consuming a food product are accurate and safe, the government should regulate what food producers are able to say in their advertisements with regard to health outcomes. Health Canada defines a health claim as “any representation in labelling and advertising that states, suggests, or implies that a relationship exists between the consumption of foods or food constituents and health” (Health Canada, 2007a: 23). In Canada, health claims are divided into three categories:

- ⌘ biological role: e.g., vitamin A aids in the maintenance of night vision;
- ⌘ general health claims: e.g., eat fibre as part of a healthy diet; and,
- ⌘ disease reduction claims: e.g., a healthy diet with adequate calcium and vitamin D reduces one’s risk of developing osteoporosis.

Health claims regarding the reduction of disease risk have only been permitted in Canada since 2003, when Health Canada approved five such advertising claims (table 1) (Health Canada, 2007a). Prior to 2003, nutraceuticals, functional foods, and natural health products were regulated as either food products or drugs according to the Canadian Food and Drug Act. This meant that a food product could be advertised as a drug, meaning that the product had to pass clinical trials, or it had to be regulated as a food product, meaning that the product could not be advertised as producing any health benefits (Martyres et al., 2008). By contrast, in 1996, the FDA approved 10 advertising claims regarding the reduction of disease risk, and has gradually expanded the number of claims since that time. Presently, there are 27 permissible health claims in the United States (table 2).

**Table 1: Permissible health claims in Canada**

Food element	Reduced risk of:
Low sodium and high potassium	High blood pressure
Adequate calcium and vitamin d	Osteoporosis
Low saturated and trans fat	Heart disease
Consumption of fruits and vegetables	Certain cancers
Reduced dietary sugar alcohols	Dental caries (tooth decay)

Source: Health Canada, 2007c.



**Table 2: Permissible health claims in the United States**

<b>Food element</b>	<b>Reduced risk of:</b>
Low sodium	Hypertension
Calcium	Osteoporosis
Low dietary saturated fat and cholesterol	Coronary heart disease
Consumption of fruits and vegetables	Cancer
Reduced dietary sugar alcohols	Dental caries (tooth decay)
Fruits, vegetables and grain products that contain fibre (particularly soluble fibre)	Coronary heart disease
Folate	Neural tube defects
Soy protein	Heart disease
Dietary soluble fibre (from certain foods)	Coronary heart disease
Fibre containing grain products, fruit and vegetables	Cancer
Plant sterols and plant stanol esters	Coronary heart disease
Decreased consumption of dietary fat	Cancer
Tomatoes and/or tomato sauce	Prostate, ovarian, gastric, and pancreatic cancers
Calcium	Colon/rectal cancer and recurrent colon/rectal polyps
Green tea	Cancer
Selenium	Cancer
Antioxidant vitamins	Cancer
Nuts	Heart disease
Walnuts	Heart disease
Omega-3 fatty acids	Coronary heart disease
B vitamins	Vascular disease
Monounsaturated fatty acids from olive oil	Coronary heart disease
Unsaturated fatty acids from canola oil	Coronary heart disease
Phosphatidylserine	Cognitive dysfunction and dementia
Chromium picolinate	Diabetes
Calcium	Hypertension, pregnancy-induced hypertension, and preeclampsia
Folic acid	Neural tube birth defects

Sources: Agriculture and Agri-Foods Canada, 2006; FDA, 2009b.

## Regulatory congruence with the scientific research on health claims

For the most part, Canadian and American regulatory permissions regarding health claims were congruent with scientific research. Seventy-eight percent of the conclusions found in the sample of articles selected for this paper were in agreement with the five Canadian health claims, while 22% disagreed with the approved claims. In comparison, 64% of the sample's entries were in agreement with the 27 American health claims, while 36% disagreed with the approved claims. [2]

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- 2 It is important to note that these comparisons tell us little about the broader effects of these food elements on human health (i.e., whether a food element increases or decreases the risk of contracting a disease or illness beyond those listed in the approved health claims). For instance, as a strictly theoretical example, regularly consuming a particular substance may decrease your risk of developing diabetes, but may also increase your chance of developing hypertension. Thus, a simple examination of the research on the predicted outcomes associated with certain food elements cannot determine the broader implications of a health claim beyond the specific benefit identified.

## Recent legislation in Canada

On April 8, 2008, the Conservative government introduced Bill C-51, “An Act to amend the *Food and Drug Act* and make consequential amendments to other Acts,” in the House of Commons. The government argued that this legislation—which expanded the powers of Health Canada inspectors, dramatically increased penalties for non-compliance with advertising regulations, and gave the health minister the power to recall products—was necessary to protect Canadians.

Concern was raised when the bill proposed changing the term “drug” to “therapeutic products” throughout the Food and Drug Act. Although the definition of a therapeutic product found in the bill seemed to exclude nutraceuticals, functional foods, and natural health products (NFFNHPs), some worried that Bill C-51 would broaden the scope of the relatively stricter regulations applied to bio-pharmaceuticals by way of the Food and Drug Act to include NFFNHPs. In response, the government and Health Canada issued a document stating that “Bill C-51 will not affect the way that natural health products are regulated in Canada” (Canada, 2008b).

Despite the government’s assurances, the legislation did raise questions about the regulation of NFFNHPs. For example, section 19 of the bill, which addressed the clinical trials necessary for licensing a product, seemed to group drugs and natural health products together. During its second reading, amendments to Bill C-51 were introduced by the government to address these concerns. The amended bill included a preamble stating that “the Parliament of Canada recognizes the value of traditional knowledge and of the history of use of natural health products in the assessment of their benefits and risks” (Canada, 2008a). Bill C-51 expired when the 39th Parliament was dissolved in September 2008.

## Conclusion

Canadian policy makers should study the merits of adopting a less rigid standard for health claims associated with food products. It can be difficult to definitively prove that a particular food element reduces the risk of developing a disease, but the bulk of the research reviewed for this paper seems to suggest that a number of food elements are associated with health benefits.

For a model of reform, Canada could look to the United States, which uses a tiered “qualified health claims” system. Under the American system, the scientific evidence regarding a particular food product is used to rank its medical effectiveness against qualified health claims. This rank then dictates the language that an advertiser can use to make a health claim. The type of language that must be used in the United States includes, for example, the following:

- ⌘ “although there is scientific evidence supporting the claim, the evidence is not conclusive”;
- ⌘ “very limited and preliminary scientific research suggests”; and,
- ⌘ “the FDA concludes that there is little scientific evidence supporting this claim” (Agriculture and Agri-Foods Canada, 2006: 114; FDA, 2009c).

Considering that this paper shows that the 27 permissible health claims in the United States are largely congruent with the scientific research, Canada should harmonize its regulations with those in the US. If anything, a wider array of permissible health claims in Canada would give advertisers further opportunity to bring the interaction between diet and health to the public’s attention. This would help individuals make informed health care decisions, and would advance the discussion of preventive medicine and market dynamics, while acknowledging legitimate worries about public safety and consumer protection.

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