Labelling and Marketing Natural Health Products in Canada:
Regulatory Issues and Class Actions

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Life Sciences Group Seminar
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Introduction

• Canadians are health conscious
• Many Canadians regularly take NHPs
• “Healthy food” initiatives
• Primary reasons:
  • Health maintenance
  • Illness prevention
  • Perception is: better than conventional drug products
Introduction cont.

But at the same time…

- Canadians are concerned about the safety of NHPs
- Perception that health claims by NHP and food manufacturers are unproven
- Preferred method of receiving information about NHPs is through a physician or pharmacist
- Least preferred: information from retailers or manufacturers – seen as lacking credibility

Today’s Presentation

- Issues concerning NHP (and food) labelling and advertising
- Intersection between foods and NHPs
- Regulatory restrictions on consumer advertising of NHPS (and foods
- Advertising preclearance
- Health Canada enforcement
- Emergence of class actions in relation to NHP/food advertising
What is an NHP?

2-part test:

Content: A product whose medicinal ingredient is (1) a plant, algae, bacterium, fungus or non-human animal material, or an extract thereof (2) a vitamin (3) an amino acid (4) an essential fatty acid (5) a synthetic duplicate of any of the above (6) a mineral, (7) a probiotic, or (8) a homeopathic or traditional medicine...

Claim: Represented for use in (1) the diagnosis, treatment mitigation, prevention of disease/disorder, or its symptoms, in humans (2) restoring or correcting organic functions in humans, or (3) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health

Natural Health Products Regulations, SOR/2003-196, Section 1(1)

What is an NHP? cont.

- Definition could catch food products
- In fact, the Natural Health Products Directorate (NHPD) was inundated with applications to approve food format NHPs
- Two reasons for this:
  1. Legal restrictions on fortification of foods (addition of vitamins/minerals)
  2. Legal restrictions on health claims that can be made for foods
What is an NHP? cont.

- NHPD issued a guidance document to assist with classification of products at the food/NHP interface

- Looks at:
  1. Product compositions (does ingredient serve a food or a therapeutic purpose)
  2. Product representations (are there references to dosage, recommended use)
  3. Product format (food/beverage or dosage-like)
  4. Public perception/history of use

Ex. Energy drinks versus energy shots

NHP Regulation

- Regulated as a drugs under the Food & Drug Act (FDA)
- If product is an NHP – product license (PL) must be sought
- PL will define advertising of the NHP
- PL application must include “recommended conditions for use:
  - Purpose
  - Dosage form
  - Route of administration
  - Duration of use
  - Risk information, including cautions, warnings, contraindications and known adverse reactions
NHP Regulation cont.

- Once the PL is issued by Health Canada, the “recommended conditions for use” become the Terms of Market Authorization (TMA)
- The TMA are the measuring stick against which advertising claims will be assessed
- Advertising claims inconsistent with the TMA may be considered to be misleading (i.e. off-label)
- “Recommended conditions for use” submitted with the PL application should be crafted with product claims in mind (to the extent possible)

Food Regulation

- No licenses needed for marketing
- But if food contains additive not approved under Food & Drug Regulations (FDR) (e.g., vitamins, minerals, caffeine) – regulatory amendment required before product can be sold
- Likewise, if label/advertising makes health claim not approved in FDR, Health Canada must evaluate and approve claim before it can be made
Advertising Restrictions

- FDA, Section 3(1):
  "No person shall advertise any food, drug… to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A"

- Schedule A lists 29 conditions, including:
  - Acute anxiety
  - Asthma
  - Cancer
  - Depression
  - Obesity

- However, NHP’s are exempt under the NHP Regs insofar as preventative claims for these conditions are permitted (and supported by evidence)

Advertising Restriction cont.

- FDA, Section 5(1):
  "No person shall label, package, treat, process, sell or advertise any food in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety"

- FDA, Section 9(1):
  "No person shall advertise any […] drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety"
Advertising Restrictions cont.

Other statutes also speak to misleading advertising:

- Competition Act
- Consumer Packaging and Labelling Act (foods)
- Provincial Consumer Protection Acts (food and drugs)

“Likely to create an erroneous impression” is the threshold test
- What does this mean?

Advertising of NHPs

- All advertising claims are measured against the NHP’s TMA
- Use Health Canada Guidance Document: Consumer Advertising Guidelines for Marketed Health Products (for Nonprescription Drugs including Natural Health Products) as your reference
- Sets out Health Canada’s rules relating to over 30 types of product claims and risk disclosures (and provides examples)
- The Guidance is not law, but it is an indication of how Health Canada applies the “erroneous impression” test
Advertising of NHPs cont.

Key rules for NHP advertising:

- An advertisement must not create an erroneous impression as to the product category under which it received its TMA (e.g. don’t represent an NHP as a food or cosmetic)
- An advertisement must always include the product’s therapeutic purpose
- An advertisement must not create an erroneous impression as to directions for use, dosage or administration (depictions of ingestion must be consistent with the product’s TMA), duration of action and duration of use

Advertising of NHPs cont.

Key rules for NHP advertising (cont’d):

- An advertisement must not directly or indirectly exaggerate the degree of relief/benefit (superlative language must not be used unless supported by the TMA)
- An advertisement must not include an absence of ingredient claim that creates an erroneous impression about the NHP or competing product
- “Clinically tested/proven” claims with respect to therapeutic attributes are limited to those included in the TMA – new clinical results that would expand the scope of claims cannot be used until authorized by Health Canada in an amended PL
Key rules for NHP advertising (cont’d):

• Two head-to-head clinical trials are required to support comparative therapeutic claims (NHP vs. NHP only)

• An advertisement must not make claims about health or promotion of health, unless such claims are included in the NHPs TMA

• An ingredient can only be described as “natural” if it is obtained from a natural source material, is in a form found in nature, and has undergone only minimal processing

• An advertisement may never say that a product acts “naturally”, since all NHPs modify the body’s physiological processes

• All advertisements must include a safety information disclosure (read label, risk/cautionary statement, source of additional information)

• An advertisement may never say that a product is “Safe” or “Side Effect Free” – all NHPs carry some degree of risk

• Superscripts and footnotes should not be used to correct an otherwise erroneous impression
Advertising of Foods

- Use Health Canada’s Guide to Food Labelling and Advertising as your general reference (Chapter 8 is devoted to Health Claims).
- Health claims are classed into 4 categories:
  - Disease risk reduction claims
  - Therapeutic claims
  - Function claims
  - General health claims

“Health” Related Food Claims

- Disease risk reduction claims link a food to a reduced risk of developing a diet related disease.
- Only 4 disease risk reduction claims are currently authorized by Health Canada:
  - Sodium to reduce risk of hypertension
  - Fruits, vegetables to reduce risk of cancer
  - Calcium to reduce risk of osteoporosis
  - Saturated and trans fats to reduce risk of coronary heart disease
- Rules and verbatim claim language are set out in Section B.01.603 of the Food and Drug Regulations, C.R.C., c.879
“Health” Related Food Claims cont.

• Therapeutic claims link a food to the treatment or mitigation of a disease or health related condition
• Only 5 therapeutic claims are currently authorized by Health Canada:
  • Barley products and lowering blood cholesterol
  • Unsaturated fat and lowering blood cholesterol
  • Psyllium products and lowering blood cholesterol
  • Oat products and lowering blood cholesterol
  • Plant sterols and lowering blood cholesterol
• Verbatim claim language is not set out in the *Food and Drug Regulations* yet, but published on Health Canada’s website

“Health” Related Food Claims cont.

• Function claims link a food to the benefits it has on normal growth, development and functions of the body
• Only 3 function claims are currently authorized by Health Canada:
  • Coarse wheat bran and laxation
  • Green tea and antioxidant effect on blood
  • Psyllium and laxation
• Verbatim claim language is set out in Table 8-2 of Health Canada’s *Guide to Food Labelling and Advertising*
“Health” Related Food Claims cont.

All other general "health" related claims:

• No single food can be described as “healthy”

• Foods can be described as “nutritious”, “wholesome” or “good for you” if they are a source (5%) of at least one nutrient

• Foods can be described as “part of healthy eating”, a “healthy choice” or “better for you” if accompanied by a linking statement relating the food to a pattern of eating recommended in Health Canada’s *Eating Well with Canada’s Food Guide*

• Foods can be described as “natural” if they do not contain an added vitamin, mineral, artificial flavouring or additive, and have not been submitted to a process that has significantly altered its original physical, chemical or biological state

Advertising Preclearance

• NHP advertising preclearance is “highly recommended” by Health Canada, but is not required by law (nor is food advertising)

• Advertising Standards Canada (ASC) is authorized to pre-clear NHP and food advertising

• Costs between $100 and $520 with 2 to 10 day turnaround

• Pros and Cons
Health Canada Enforcement

- Advertising disputes are adjudicated by ASC at first instance (may be escalated to Health Canada)
- In first instance, Health Canada generally adopts a “risk to health” approach (vs. punishment and deterrence)
- Non-compliant advertising (when brought to Health Canada’s attention) generally results in a regulatory cease and desist letter
- If the non-compliant activity is not ceased, Health Canada will consider other enforcement options

Natural Health Products Compliance and Enforcement Policy (POL-0044) (2010/08/27) – Health Canada

Health Canada Enforcement cont.

Violation of the FDA/FDR:
- For NHPs:
  - Suspension of PL
  - Fine not exceeding $5000
  - Imprisonment for a term not exceeding 3 years
- For Food:
  - Fine not exceeding $250,000
  - Imprisonment for a term not exceeding 3 years
  - Penalties to increase when Safe Foods for Canadians Act comes into force ($5,000,000 and 2 years prison)

Food and Drugs Act, R.S.C. 1985, c. F-27, Section 31)
Other Enforcement

- Hefty fines under *Competition Act* ($10,000,000), also fines under *Consumer Packaging and Labelling Act* and *Consumer Protection Acts* ($50,000 - $250,000)

- Until recently, enforcement of NHP/food law was left largely to Regulatory bodies/agencies…

- Enter plaintiff’s class action counsel

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Statutory Framework

Five requirements for certification under section 5 of the Class Proceedings Act:

a) pleadings disclose a cause of action;

b) identifiable class of two or more people;

c) claims of the class members raise common issues;

d) class proceeding would be preferable procedure for resolution of the common issues; and

e) proper representative plaintiffs
• Claims based on:
  • **Competition Act**
    • 52(1) No person shall, for the purpose of promoting, directly or indirectly, the supply or use of a product or for the purpose of promoting, directly or indirectly, any business interest, by any means whatever, knowingly or recklessly make a representation to the public that is false or misleading in a material respect.
  • **Consumer Protection Act (Ontario) 2002**
    • 14(1) It is an unfair practice for a person to make a false, misleading or deceptive representation.
    • 17(1) No person shall engage in an unfair practice.
  • **Consumer Protection Act (Quebec), c. P-40.1**
    • 219 No merchant, manufacturer or advertiser may, by any means whatever, make false or misleading representations to a consumer.

• **Business Practices Consumer Protection Act (B.C.)**
  • 172(1)(a) The director or a person other than a supplier, whether or not the person bringing the action has a special interest or any interest under this Act or is affected by a consumer transaction that gives rise to the action, may bring an action in Supreme Court
  • 4(1) “deceptive act or practice” means, in relation to a consumer transaction,
    • (a) an oral, written, visual, descriptive or other representation by a supplier, or
    • (b) any conduct by a supplier that has the capability, tendency or effect of deceiving or misleading a consumer or guarantor

• **Fair Trading Act (Alberta)**
  • 6(1.1) It is an offence for a supplier to engage in an unfair practice.
  • 6(2)-6(4) defines “unfair practice”
  • e.g. 6(4)(a) a supplier doing or saying anything that might reasonably deceive or mislead a consumer
“False Claims” Litigation in the U.S.

- Judges have not been sympathetic to plaintiffs where the claims would not have misled reasonable consumers

  - **Manchouck v Nabisco (Cal. 2013)**
    - Claim that ‘real fruit’ labelling on Newton® cookies was misleading because fruit purée in cookies was processed
    - Allegation that a reasonable consumer would think that Newtons “made with real fruit” excluded fruit purée “strains credibility”
    - Defendants’ motion to dismiss granted

“False Claims” Litigation in the U.S. (cont’d)

  - **Simpson v Kroeger (Cal. C.A. 2013)**
    - Claim that product contained only butter, when it also contained canola oil and olive oil
    - C.A. confirmed trial decision dismissing claim on the basis that “no reasonable person could purchase these products believing they had purchased a product containing only butter”
**“False Claims” Litigation in the U.S. (cont’d)**

- Common issues may pose certification problems

- **Ackerman et al v. Coca-Cola Co et al (NY 2013)**
  - Class action alleging that defendants engaged in the deceptive labelling and marketing of “Vitaminwater®” by promoting it as a “nutrient-enhanced water beverage”
  - Judge Levy recommended certification of an injunctive class action, but refused to recommend certification for the purpose of seeking monetary relief because “proof that each class member paid a premium for “Vitaminwater” over another beverage would not be susceptible to generalized proof.”

- **Astiana v. Kashi Co (Cal. 2013)**
  - Claims that various Kashi® products misled consumers with “All Natural” or “Nothing Artificial” claims
  - Court certified class in relation to “Nothing Artificial” claims only
  - Most challenged ingredients in the “All Natural” claims were allowed in organic foods, and the court found that consumers hold ‘organic’ to a higher standard; named plaintiffs had different expectations as to what was “all natural”; and Kashi had also provided a definition of natural on its website;
  - However, unlike “All Natural,” “Nothing Artificial” had a clearly ascertainable meaning - no artificial or synthetic ingredients; for class certification purposes it was shown that the ingredients might be considered artificial or synthetic, and that reliance occurred

- "All natural” claims litigation is increasingly common, but plaintiffs face challenges
“False Claims” Litigation in the U.S. (cont’d)

- **Pelayo v Nestle USA Inc et al (Cal. 2013)**
  - Allegations that various pasta products were misleadingly labelled or advertised as “All Natural”
  - Court granted defendants’ motion to dismiss
  - "plaintiff cannot state a claim […] because she fails to offer an objective or plausible definition of the phrase “All Natural,” and the use of the term “All Natural” is not deceptive in context"

“False Claims” Litigation in the U.S. (cont’d)

- Recent Settlements
  - **Pappas v Naked Juice (Cal.; settled 2013)**
    - Class action alleging certain claims by Naked Juice®, on labels and through advertising, were misleading; “100% Juice”, “100% Fruit”, “All Natural”, “Non-GMO” etc.
    - Settlement: Naked Juice set up a $9 million settlement fund, and agreed to change future labelling and advertising with “all natural” claims; it also agreed to set up a new quality assurance and verification system to confirm the “Non-GMO” statement on its labels
“False Claims” Litigation in the U.S. (cont’d)

Dennis v Kellogg (Cal.; settled 2013)
- Claim filed in 2009 that Kellogg falsely advertising that Mini-Wheats® improved kids’ attentiveness, memory and other cognitive functions to a degree not supported by competent clinical evidence
- Settlement fund of $4 million

Green v Dr. Pepper Snapple Group Inc (Cal.; settled 2013)
- Claim that the marketing of certain 7-UP® sodas misled consumers into believing they contained antioxidants from fruits rather than from added vitamin E
- Settlement: Dr. Pepper agreed to remove vitamin E from its products and the antioxidant labels, and paid $237,500 in legal fees

Recently Filed Claims

“All Natural” Claims
- Leo v Pepperidge Farm – Pepperidge Farm Goldfish® that contain GMOs
- Cox v General Mills – Green Valley® vegetables that contain GMOs
- Hansen v Dole Fresh Vegetables – salad kits that contain xanthan gum, sodium benzoate, phosphoric acid or ascorbic acid

Listing “Evaporated Cane Juice” Instead of “Sugar”
- Avila v Green Valley Organics – yogurt
- Avoy v Turtle Mountain – dairy-free desserts
- Leonhart v Nature’s Path Foods – cereals

Other Recent ‘False Claims’
- Buren v. Doctor’s Assocs.; Pendrak v. Subway Sandwich Shops – Subway® sandwiches marketed as foot-long actually shorter
- Careathers v Red Bull GmbH – “gives you wings” claim misleading because it gives energy comparable to coffee
Key Differences Between US and Canada

- no requirement of predominance (common issues predominate over individual issues)
- no requirement of typicality (representative plaintiffs “typical” of class in respect of all issues)
- express judicial consideration of goals of access to justice, judicial economy and behaviour modification
- greater chance of certification in Canada

Why Plaintiffs’ Counsel Like These Claims

- small number of common issues which, if resolved, will advance the litigation
- substantial damages due to large class of purchasers
- influx of foreign products
- documentary discovery rights in parallel Canadian/US proceedings
- opportunities for US plaintiffs firms to expand their reach into Canada
Canadian “Copycat” Cases from the U.S.

- *Emmanuelle Sonego v. Danone Inc.* (Quebec)
  - claim for misrepresentation of performance characteristics and benefits of Activia® and DanActive®
  - 2009 U.S. case settled
  - Settlement agreement was approved by the Quebec Superior Court on May 27, 2013
  - Class members to receive between $30 and $100 each; Danone to donate products up to $500,000 value to charity

Canadian “Copycat” Cases from the U.S. (cont’d)

- *G. Del Zoppo v. All Market Inc.* (Quebec)
  - Vita Coco® coconut water
  - Claim for deceptive, misleading, false and unfair advertising of product as containing more electrolytes than regular sports drinks
  - U.S. case (settled in 2012 for $10 m)
  - On January 30, 2013, the Quebec Superior Court approved settlement agreement
  - Class members to receive between $6 and $25 each
  - All Market agreed to modify the labels, advertising and communications relating to Vita Coco® coconut water sold in Canada
Canadian “Copycat” Cases from the U.S. (cont’d)

• A. Charles v. Boiron Canada Inc. (Quebec)
  • motion for authorization brought April 2012 against Boiron Canada and Shoppers Drug Mart regarding Oscillo®
  • allegations of deceptive, misleading, false and unfair advertising
  • marketed as having ability to cure flu with active ingredient
  • allegation that testing found product to have no health benefits
  • U.S. case settled in 2011
  • case continues

  • Vitaminwater® - allegations of deceptive/unfair trade practices by marketing as healthy beverage
  • actions in Alberta, British Columbia and Québec
  • motion for authorization filed in Québec in 2011
  • Alberta: no recent activity
  • BC: certification motion heard May 2013 under reserve
  • Quebec: two motions on evidentiary matters have been brought
• Arshi and Rosos v. Iovate Health Sciences Inc. & HMD Formulations Ltd. (Ontario)
  • claim of misleading representations for promoting the sale of Hydroxycut®
  • 2003 U.S. claim settled
  • Ontario claims inactive since 2010

• Energy Drinks (Ontario)
  • 2009 certification sought in series of class actions against manufacturers and distributors of various energy drinks
  • Coke, Pepsi, Wet Planet Beverages, Monster Beverages, Red Bull, Rockstar
  • allegations of false, misleading and deceptive representations on product labels
  • no recent activity
  • U.S. cases also ongoing (e.g. Monster Rehab, Phusion Four Loco, Redline Energy Drink)
Canadian “Copycat” Cases from the U.S. (cont’d)

- *Long v. Beiersdorf Canada Inc./ Dray v. Beiersdorf Canada Inc. (Québec)*
  - Nivea My Silhouette™ Slimming & Reshaping Gel-Cream
  - deceptive, misleading, false, and unfair advertising
  - claims that regular use would result in a significant reduction in body size
  - U.S. settlement 2011: $900,000
  - Settlement December 2012
    - Nivea to remove product from stores in Canada, refunds to maximum of $100 per purchaser, administrative penalty of $380,000 to Competition Bureau

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Canadian “Copycat” Cases from the U.S. (cont’d)

- *Petit v New Balance (Québec)*
  - allegations of false advertising in relation to “toning” footwear
  - motion to authorize filed in 2012
  - settlement in 2013
  - class members entitled to between $100 - $200 each to a maximum settlement of $155,000
Canadian “Copycat” Cases from the U.S. (cont’d)

- **Chagnon v Crayola** (Quebec)
  - allegations of false claims regarding Crayola® washable markers
  - motion to authorize March 2012
  - settlement approved September 2013
  - class members to receive up to $12 without proof of purchase, or to be reimbursed with proof of purchase; costs of cleaning and property damage;
  - crayola also agreed to stop production of certain products and change labelling, advertising and stain-removing guides in regards to others

Track Record on Certification in Canada

- No established track record on contested certification in Canada in the food, beverage or natural health products sectors.
Track Record on Certification in Canada (cont’d)

- **Singer v. Schering-Plough Canada Inc. (ONSC 2010)** (certification dismissed)
  - Coppertone® sunscreen
  - plaintiffs alleged misrepresentation of effectiveness of product
  - US case settled September 2012 for $3-$10 million
  - motion for certification dismissed

Lessons learned: **Singer v. Schering-Plough Canada Inc.**

- plaintiffs did not properly plead causes of action, which was fatal to certification
  - **Negligence:**
    - not really a negligence claim, but a claim of negligent misrepresentation; however, not properly pleaded because no pleading that plaintiffs relied on misrepresentations and suffered damages; Court found that plaintiffs did not plead “negligent misrepresentation” for “obvious reason” that proof of reliance and causation could only be done on individual basis and be fatal to certification
  - **Breach of warranty:**
    - fundamental problem that there was no contract between the consumer and the manufacturer
Lessons learned: Singer v. Schering-Plough Canada Inc.

- **Breach of Consumer Protection Act, ON:**
  - Manufacturer not a ‘supplier’ under the CPA; no pleading of any agreement between consumer and manufacturer; no pleading of any ‘dealings’ other than purchasing the products; no facts pleaded to support assertion of a “consumer transaction”; remedies under CPA were limited - as between the manufacturer and the consumer, there was no agreement to rescind and no money to refund;

Lessons learned: Singer v. Schering-Plough Canada Inc.

- **Breach of Competition Act**
  - Under s. 52(1) not necessary to establish that any person was actually deceived or misled;
  - However, it is s. 36 of the Act that establishes the cause of action, and under s. 36, plaintiffs must show the materially false or misleading representation to the public caused the plaintiffs damages;

- **Unjust Enrichment:**
  - claim in unjust enrichment failed because the plaintiffs purchased the product from a retailer, not from the defendant; defendant did not experience a corresponding enrichment
Recent Cases re Consumer Protection Legislation in Class Certification Context

- **Miller v Merck Frosst Canada Ltd (BCSC 2013)**
  - Motion for class certification re Proscar® and Propecia® drugs;
  - Claims included deceptive practices under the *BPCPA* for “failing to disclose the material fact that the side-effect of sexual dysfunction may continue after disuse of the drug”
  - Court certified class including for claims under the *BCPA*
    - Manufacturer was a “supplier” and the transaction was a “consumer transaction” (contrary to *Singer*)
    - There is no “immediacy” requirement in the consumer transaction; consumer protection legislation is to be liberally construed
    - A “consumer transaction” includes one in which a learned intermediary is involved
  - There was commonality of issues; *BCPA* claims concern misrepresentations to public at large, and do not depend on individual inquiries

Recent Cases re Consumer Protection Legislation in Class Certification Context

- **Wakelam v Johnson & Johnson (BCSC 2009)***  
  - Motion for particulars in context of certification of class action
  - Claim that representations and omissions regarding cough syrup safety for children were in breach of *BCPA*
  - Defendants’ motion for particulars dismissed
    - “This is not a claim on common law misrepresentation based on individual reliance. The plaintiffs is relying on specialized consumer protection statutes which focus the inquiry on the impact of the representation on the public at large.”

* under appeal
Certification Takeaways from Recent Case Law

- Common law causes of action pose difficulties for the certification framework since they involve individual determinations of reliance and causation

- Consumer protection legislation claims may be easier to certify (Ontario courts stricter than BC courts)

The Next Big Wave in Canada?

- large number of US class actions alleging false claims regarding food, beverage, natural health products and supplements, based on labelling and advertising

- wave of false claims
  - "all natural"
  - weight loss
  - nutrients
  - dangerous products
  - these will cross the border
Defensive Strategies

• careful review of labelling and advertising
• focus on pleadings, certification criteria
• no misrepresentation
• common issues
• reliance
• damages
REFERENCE MATERIALS
New Measures to Regulate Sports Nutrition Products in Canada

by Steven F. Rosenhek

In recent years, there has been an explosive growth in the worldwide demand for sports nutrition supplements, foods and beverages. Gone are the days when these products were marketed only to athletes and bodybuilders; they are now "lifestyle" products widely used by the general public.

In 2009, Canadian retail sales of energy and nutrition bars exceeded CAD$85 million, a figure that is expected to reach $93 million by next year. In the same year, the market for sports nutrition supplements reached a value of $114 million.

With increased popularity comes increased concern about regulation. Despite the fact that natural health products (NHPs) sold in Canada have been subject to the Natural Health Products Regulations (NHPRs) since 2004, the supplement industry is not heavily regulated. In an attempt to address this issue, Health Canada has begun to implement changes to the regulation of sports nutrition products.

Sports Nutrition Products as National Health Products

Historically, food and beverage products with added vitamins, minerals, caffeine or certain health claims were able to gain market access as NHPs. A number of these products were offered for sale without product licenses. In 2004, the introduction of the NHPRs meant unlicensed NHPs could no longer be sold in Canada. Since a large number of NHPs on the market did not meet the NHPRs, Health Canada became backlogged with licensing applications. Consequently, in 2010 the Natural Health Products Unprocessed Product License Applications Regulations (UPLARs) came into force to provide temporary authorization to NHPs awaiting market licenses. Exemption numbers were provided to allow for the legal sale of products awaiting review by Health Canada. The temporary system ended on...
Feb. 4, 2013, coinciding with the repeal of the UPLARs. By Sept. 1, 2014, all NHPs sold in Canada must have a Natural Product Number or Homeopathic Medicine Number. However, these changes will have little impact on sports nutrition products, which are being removed from the NHP regime.

Transitioning Sports Nutrition Products from NHPR to the Food and Drugs Act

As of December 2012, many sports nutrition products, including vitamin waters, sports drinks, energy bars and powders, and protein products, lost their eligibility to receive NHP classification. In an effort to address safety concerns, in April 2012, Health Canada began to transition NHP food and beverage products to the food and drug regulatory framework. In order to facilitate the transition process, eligible products are receiving Temporary Market Authorization Letters (TMALs). A TMAL allows a product (excluding energy drinks, which have already transitioned) to be marketed for an initial time period of two years, subject to conditions, while additional data about the product is collected. Regulatory amendments will not be finalized until the necessary data is submitted, at which time market authorization can be extended. Products that do not initially qualify for TMALs due to health and safety risks have the option to be reformulated or re-labeled in order to become eligible. The issuance of a TMAL removes the product from the NHP licensing queue.

Transitional products will also be subject to new labeling requirements. Since the products will be regulated as foods, they will now be subject to the Food and Drugs Act, Part B of the Food and Drug Regulations and the Consumer Packaging and Labeling Act and Regulations. Products that do not require any reformulation must meet these labeling requirements by March 2014.

Adulteration and Quality Assurance

In recent years, Health Canada released several warnings to the public concerning adulterated sports nutrition products, particularly those that promote weight loss and muscle definition. In particular, traces of sibutramine and phenolphthalein, which are not authorized for sale in Canada, have been found in various supplements.
In March 2012, the Canadian Centre for Ethics in Sport released an advisory notice warning that various sports supplements, including protein powders, energy drinks and vitamins, contain substances that have not been approved by Health Canada. It specifically warned about methylhexanamine, a banned substance that is often not listed on labels, either deliberately or due to contamination.

Currently, it is the responsibility of the product license holder to ensure the product is free from adulteration. Supplement manufacturers are required to provide documents supporting their compliance with GMPs (good manufacturing practices). Health Canada is now in the process of consulting on a new proposal that would create a two-prong quality assurance (QA) model. The proposed model would require an on-site inspection for companies demonstrating critical non-compliance with the regulations. The second prong would include an optional on-site inspection by a recognized third party to obtain a "seal of approval" for exportation and marketing purposes. Health Canada has said it will continue to focus on adulteration issues under the new approach.

It will be interesting to see what impact Health Canada's new initiatives will have on the growing market for sports nutrition products. While Canada has a long way to go before resolving the problem of adulterated products, these initial changes are a step in the right direction.

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Ingrid VanderElst is a partner in the firm’s Life Sciences group. Ingrid handles pharmaceutical, natural health product, biotechnology, medical device, pharmacy and food matters, intellectual property issues, including licensing and transfer of patents and trademarks, patent and trademark prosecution, patent listing under the patented medicine (Notice of Compliance) regulations and data protection. She also advises on regulatory issues relating to product manufacturing, advertising, marketing and distribution product recalls, GMP compliance and establishment licensing, product licensing, packaging and labeling, drug pricing (including PMPRB compliance) and formulary listing. Ingrid also provides guidance on health privacy issues in connection with clinical trials, sponsored research, patient support programs and pharmacy operations. In addition, Ingrid works with clients who invest in life sciences companies, providing guidance in the evaluation of technology and intellectual property portfolios. Her scientific endeavors included the development of anti-metastatic chemotherapeutics and the study of gene regulation during oncogenesis.

Ingrid is a registered trade-mark agent.

Presentations

- Labelling and Marketing Natural Health Products in Canada: Regulatory Issues and Class Actions, Life Sciences Group (Fasken Martineau Institute), November 28, 2013
- Food Fights – The Intersection Between Food Regulation and Food Litigation, Strategy Institute Food Regulatory & Quality Assurance Summit, October 21, 2013
- Crowd Sourcing – the Ultimate Collaboration, VentureLabs MedEdge Summit 2013, June 20, 2013
- IP Update: Ensuring Ample Proprietary Rights are Imposed on Your Organization’s Valuable Creative Works, Advertising and Marketing Law Conference, The Canadian Institute, January 22, 2010
- The Merck v. Integra Decision and its Impact on Research and Licensing Agreements, Licensing Executives Society, October 2005

Publications

- "Isolated Human Genes are No Longer Patentable in the United States”, Life Sciences Bulletin, June 17, 2013
- "Canada to Change the Regulation of “Food-Like” Natural Health Products”, Health Law in Canada, June 2012
Italian


"Proposed Amendments to the Patented Medicines", Pharmaceutical Law Insight, June 2008


"New Rules for Labeling and Importation of Cosmetics in Canada", Update Magazine, November 30, 2005

"New Canadian Consumer Advertising Guidelines for Marketed Health Products", Update Magazine, August 1, 2005

"Recalls of Medical Devices Requested by Health Canada: The Legal Landscape", MEDEC Pulse, June 1, 2004

Memberships and Affiliations

- Member, Canadian Bar Association

Rankings and Awards


Community Involvement

- Committee member, Animal Care Committee, Toronto Centre for Phenogenomics, (2010-2012)
Steven F. Rosenhek

Partner

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A leading Ontario litigator, Steven Rosenhek has experience as a senior trial and appellate counsel before all levels of Court in Canada, and a wide range of provincial and federal administrative tribunals and regulatory bodies. His practice encompasses all aspects of civil and administrative litigation, including complex commercial litigation, class actions, commercial arbitrations, product liability, life sciences, antitrust, and insurance. He has handled both prosecution and defence briefs before a wide array of regulatory, professional discipline and administrative bodies. Steven is also admitted as as solicitor in England and Wales.

Steven is a recognized expert in trial advocacy, having taught extensively in that area in a variety of capacities, including as Special Lecturer at both law schools in Toronto, the University of Toronto Faculty of Law (1987-2000) and Osgoode Hall Law School (1988-1990). He has also served as Instructor and Team Leader for the Intensive Trial Advocacy Programme for lawyers (1988-present) and the Part-Time LL.M Programme (1988 to present), both at Osgoode Hall Law School.

Steven has written and lectured widely in Canada, the United States and Europe on a wide variety of subjects, including class actions, trial advocacy, mediation and dispute resolution, commercial litigation, antitrust matters, drug and medical device litigation, regulatory proceedings, product liability, insurance and natural health products.

Apart from his own litigation caseload, Steven has client responsibilities for managing litigation and other legal teams for a number of major firm clients. Steven is a well known speaker in the areas of effective litigation management and alternative fee arrangements. He has had a longstanding involvement as an executive member of the Canadian Corporate Counsel Association (Toronto branch).

Steven is a Past President of the Ontario Bar Association (1998-99), the largest provincial bar association in Canada with over 17,000 members. He is Chair of the OBA Foundation, the charitable arm of the Ontario Bar Association. In 2010, Steven received the OBA Award for Distinguished Service. That award recognizes exceptional career contributions and achievements by an OBA member to the legal profession, jurisprudence or the residents of Ontario. Steven was also invited to be a Fellow of the American Bar Foundation, an honorary organization of lawyers, judges and legal scholars, whose public and private careers have demonstrated dedication to the welfare of their communities and the highest principles of the legal profession.

Amongst his many professional affiliations is his admission to the International Association of Defense Counsel (IADC), an invitation-only, preeminent organization of lawyers providing litigation services and counsel to corporations and insurers throughout the world.
Representative Experience

- Kia Canada enters into consent agreement with Competition Bureau
  Counsel to Kia Canada

Presentations

- Labelling and Marketing Natural Health Products in Canada: Regulatory Issues and Class Actions, Life Sciences Group (Fasken Martineau Institute), November 28, 2013
- The Impact of International Regulatory Actions and Marketing on United States Litigation, Drug, Device and Biotechnology Committee Annual Meeting, International Association of Defense Counsel, July 8, 2013
- Crisis Management: The Essentials, Webinar, International Association of Defense Counsel, June 2013
- Jurisdictionally Complex Class Actions, Regional Meeting, International Association of Defense Counsel, June 4, 2013
- False Labelling and Advertising Claims in the Food, Beverage and Natural Health Products Industries: A Cross-Border View, Life Science Group Seminar (Fasken Martineau Institute), November 20, 2012
- Classes Across Borders: Lessons from American and Canadian Counsel in Defending Class Action Claims, Litigation Group Seminar (Fasken Martineau Institute), September 13, 2012
- Toronto Fasken Martineau Symposium (2nd Edition), Fasken Martineau Institute, May 24, 2012
- Regulation of Medical Devices in Canada and the EU, MDMA Webinar, April 19, 2012
- Distribution Agreements: Avoiding the Pitfalls, Fasken Martineau Institute, November 22, 2011
- Follow the Money: Recent Developments on the Issue of Damages, Insurance and Product Liability Groups Seminar (Fasken Martineau Institute), November 10, 2011
- Litigation on a Budget - Managing the Case, the Cost and Outside Counsel, Canadian Corporate Counsel Association Annual Conference, August 2011
- Natural Health Products (NHP) in Canada: Key Legal Issues, Life Sciences Group Seminar (Fasken Martineau Institute), January 26, 2011
- Medical Devices in Canada: Hot Legal and Regulatory Issues, Life Sciences Group Seminar, April 6, 2010
- Legal Issues in the New Economic Order, Presented in conjunction with the Italian Chamber of Commerce of Toronto, October 22, 2009
- Turn Adversity Into Advantage, Fasken Martineau/Deloitte Joint Seminar, May 21, 2009
- Addressing Patient and Staff Safety Issues in Your Hospital, Hospitals and Foundations Seminar Series, May 14, 2008
BIOGRAPHY
Steven F. Rosenhek

- Divine Discoveries: Building a Great Case; and Preparing Yourself for Discovery: The Basics, Ontario Bar Association, December 2006
- Flexible Fee Arrangements with External Counsel - What's Out There?, Canadian Corporate Counsel Association programme, November 2006
- Mastering Mediation: What You Need to Know for a Successful Mediation, Ontario Bar Association (Young Lawyers Division/Alternative Dispute Resolution Section Joint Programme), May 2006
- Divine Discoveries: Building a Great Case; and Preparing Yourself for Discovery: The Basics, Ontario Bar Association, December 2005
- Winning Advocacy Skills, Demonstrator (cross-examination), Canadian Bar Association Annual Conference, August 2005
- Presentation of Evidence in Chief, Young Lawyers Nutshell Programme on Trial Skills, Toronto Lawyers Association, October 2004
- Essential Tips and Techniques for Today's Corporate Counsel, Joint Programme of the Canadian Corporate Counsel Association and Ontario Bar Association, June 2004
- Insurance Claims: Learn from the Pros, Ontario Bar Association, April 2004
- The E-Counsel Primer - Going Boldly Where Your Practice Did Not Go Before, Corporate Counsel Programme, OBA Annual Institute, January 2004
- Keeping One Step Ahead: The Latest in Shareholder Disputes and Remedies, Ontario Bar Association, May 2003
- The In-House Essentials, OBA Institute of Continuing Legal Education, Counsel Association Programme, 2003
- An Overview of Employer Liability and Legal Responsibilities, Ontario Public Health Association, November 2002
- Mass ADR: Class Actions and Settlement, Essential ADR Seminar, ADR Institute Conference, October 2002
- Multi-Jurisdictional Class Actions, Canadian Corporate Counsel Association Annual Meeting, August 2002
- Litigating Class Actions, The Canadian Institute, May 2002
- The Determination of Class Counsel Fees in Different Jurisdictions, The Canadian Institute, May 2002
- Troublesome Business Torts, Ontario Bar Association, April 2002
• The Duty of Good Faith, Canadian Bar Association Annual Meeting, 2002
• Business Host Liability: Practical Tips, Insight Information Seminar, 2002
• Bringing Evidence from American Litigation into Canada: The Vitapharm Litigation, Insight Information Class Action Litigators Conference, January 2002
• Troublesome Business Torts, Ontario Bar Association, November 2001
• Evidence Pitfalls in Complex Litigation, Metropolitan Toronto Lawyers Association, May 2001
• Class Actions: Exploding onto the Scene, Ontario Bar Association, April 2001

Publications
• "The Supreme Court of Canada Clarifies the Rules for Canadian Price-Fixing Class Actions", Antitrust/Competition Perspectives, November 14, 2013
• "New Measures to Regulate Sports Nutrition Products in Canada", Natural Products Insider, June 2013
• "Certification of International Classes in Canadian Class Actions: Is Canada "Open for Business"?", The International Association of Defense Counsel Committee Newsletter, April 2013
• "Lessons Learned from a Landmark Denial of Certification in Canada: Martin v. Astrazeneca ", Drug, Device and Biotechnology Committee Newsletter, International Association of Defense Counsel, February 2013
• "Joint Defence Agreements in Canada", International Association of Defense Counsel Annual Meeting, July 2012
• "What You Need to Know Before Terminating a Distribution Agreement", Litigation and Dispute Resolution Bulletin, April 18, 2012
• "Canadian Contract Law: Termination of Distribution Agreements", Co-Author, DRI Commercial Litigation, Vol. 54 Iss. 3, March 2012
• "Canadian Contract Law: Termination of Distribution Agreements", For The Defense, March 2012
• "The Death of Indirect Purchaser Claims in Canada?", Antitrust/Competition & Marketing and Class Actions Bulletin, October 18, 2011
• "Ontario Court of Appeal Overturns Canada's Largest Environmental Class Action Judgment", Environmental Bulletin, October 18, 2011
• "Disgorgement of Profits Where No Injury? Canadian Court Considers "Waiver of Tort" Doctrine in Medical Devices Class Action", RX for the Defense, DRI Drug and Medical Device Committee, Vol. 19 Iss.2, October 14, 2011
• "Class Action Compendium - Canadian Chapter", Defence Research Institute, October 2011
• "The Death of Indirect Purchaser Claims in Canada?", The Business Suit, DRI Commercial Litigation, Vol. 14 Iss.2, July 14, 2011
“Canadian Medical Device Class Actions: A Work in Progress”, Featured Article, RX for the Defense, October 1, 2010

“Canada’s Largest Environmental Class Action Judgment Based on Pollution: Nickel Refinery to Pay $36M to Homeowners”, Litigation Bulletin, September 15, 2010

“Canada Enacts New Natural Health Product (NHP) Regulations”, Life Sciences Bulletin, August 31, 2010

“Medical Device Litigation North of the 49th Parallel: A Primer”, DRI, Rx for the Defence, May 5, 2010

“Canada Targets State Sponsors of Terrorism”, IBA Litigation Committee Newsletter, September 2009


“Mastering Mediation: What You Need to Know for a Successful Mediation”, Ontario Bar Association (Young Lawyers Division/Alternative Dispute Resolution Section Joint Programme), 2006

“Class Counsel Fees and Costs Awards in Canadian Class Actions”, Author, Class Action Reports, Vol. 27, September 2006


“Multi-Jurisdictional Class Actions: Emerging Issues and Future Dilemmas”, Canadian Corporate Counsel Association Annual Meeting, August 2002

“The Determination of Class Counsel Fees in Different Jurisdictions”, The Canadian Institute's Litigating Class Actions: The Roadmap for Bridging and Defending Class Actions in Western Canada Conference, May 2002

“Bringing Evidence from American Litigation into Canada: The Vitapharm Litigation”, Insight Information's Class Actions - The Litigators' Conference, January 2002

“Class Actions: Exploding onto the Scene”, Ontario Bar Association Conference, April 2001

“Class Actions Across the Border - A New Kind of Litigation Comes to Ontario”, Business Law Today, January/February 2001

Memberships and Affiliations

- Member, Canadian Bar Association
- Executive Member, Ontario Bar Association - Class Actions Section (2011-2012)
- President, Ontario Bar Association (1998-1999) and Chair, Paralegals Task Force (1999-present)
- Member, International Association of Defence Counsel
- Member, Defence Research Institute
- Member, Medical Devices Manufacturers Association
- Member, Canadian Health Food Association
Rankings and Awards

- Fellow of the American Bar Foundation
- Ontario Bar Association Award for Distinguished Service, 2010
- Dean's Key, University of Toronto Law School, 1982