The PAAB Code and Canadian Laws Prohibiting Deceptive Advertising of Healthcare Products

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Truth in Advertising – An Advertiser's Perspective

- *Tell the Truth: Honesty is Your Most Powerful Marketing Tool*, by Sue Unerman and Jonathan Salem Baskin, BenBella Books, 2012
  - "Truth is a tricky issue to discuss, but Unerman and Baskin do a great job in explaining how to be truthful **and yet create effective advertising messages**."
    Al Ries, Coauthor, *War in the Boardroom*
  - "Truth is the only defensible competitive advantage. I'm not sure why **this is controversial**, but it's true."
    Seth Godin, Author, *We Are All Weird*
  - "Truth in advertising is **no longer an oxymoron**. It is an absolute necessity if a brand wishes to compete in today's increasingly transparent marketplace."
    Joseph Jaffe, Author, *Flip the Funnel*

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Legal Test for Determining Truth in Advertising - "General impression as well as literal meaning"

Overview

- The PAAB
  - Mandate, Vision, Mission
- The PAAB Code
  - Scope
- Specific deceptive advertising laws under the federal *Food and Drugs Act* and associated regulations (**F&DA**)
  - Roles of Health Canada (**HC**) and the PAAB, and importance of the PAAB Code
  - Possible enforcement actions and sanctions under the PAAB Code and the F&DA if these laws are contravened

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Overview

- Laws of general application on deceptive advertising under federal *Competition Act*
  - Roles played by Industry Canada and Competition Bureau
  - Pertinence of the PAAB Code to the Competition Bureau's mandate
  - Possible enforcement actions and sanctions under the *Competition Act* if these laws are contravened

- When, in the case of allegedly deceptive advertising of healthcare products, will
  - the PAAB and/or HC take the lead in enforcement action
  - the Competition Bureau take the lead in enforcement action
  - each take enforcement action concurrently

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Overview

- Won't cover lots of other stuff, including compliance with applicable
  - Canadian privacy laws (federal and provincial; personal information and personal health information), especially in the context of the use of Big Data in advertising – so-called online behavioural advertising (**OBA**), currently a major concern of the Office of the Privacy Commissioner of Canada and its counterparts globally
  - Canadian laws on substantiating ad claims, disclaimers, use of surveys, programmatic advertising, telemarketing, environmental claims, claims of "new and improved", sponsorship, copyright, trade-marks, passing off, endorsements/testimonials (especially celebrity endorsements on social media), pricing, contests, Quebec's *Charter of the French Language*, etc.
  - Canadian laws on so-called reactive marketing, experiential marketing and guerrilla marketing

The PAAB

- Promoting and protecting truth in advertising
- Mandate
  - To be an independent review agency whose primary role is to ensure that healthcare product communication is **accurate**, balanced and evidence based, and reflects current and best practice
- Vision
  - **Trusted** healthcare product communication that promotes optimal health
- Mission
  - To provide a pre-clearance review that fosters **trustworthy** healthcare communications within the regulatory framework

The PAAB Code of Advertising Acceptance

- Scope of the PAAB Code
  - Applies to all advertising messages directed to healthcare professionals, healthcare institutions, and to patient information that will be distributed by healthcare professionals
  - The PAAB also provides an advisory service on direct-to-consumer promotional activities regarding the treatment of disease by prescription drugs
  - The PAAB's advisory review is recognized by HC
  - The PAAB maintains a liaison with HC regarding the regulation of promotional activities for healthcare products

Deceptive Healthcare Product Advertising Laws under F&DA

- Section 9(1) F&DA
  - Prohibits healthcare product advertising that is false, misleading or **deceptive**, or is likely to create an erroneous impression regarding the healthcare product's character, value, quantity, composition, merit or safety
  - Possible contraventions include advertising that: (i) emphasizes only product benefits without including safety information – i.e., no fair balance; (ii) discusses off-label use of a product; or (iii) makes a comparative claim that is unsubstantiated or conflicts with the terms of market authorization (**TMA**) of the compared products

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Deceptive Healthcare Product Advertising Laws under F&DA

- Other healthcare product advertising provisions enforced by HC (but not specifically relating to "deception")
  - Prohibition on consumer-directed ads for healthcare products (including medical devices) which claim to treat, prevent or cure any of the serious diseases, disorders or abnormal states listed in Schedule A of the F&DA, such as cancer, depression and hypertension (although Schedule A prevention claims are permitted by regulation for over-the-counter drugs and natural health products)
  - Prohibition on advertising to the general public any drugs on the Prescription Drug List other than with respect to the brand name, proper name, common name, price and quantity of the drug
  - Under the *Controlled Drugs and Substances Act* (**CDSA**) and its regulations, the (i) prohibition on any advertisement to the general public respecting a narcotic and (ii) a requirement that any permitted advertisement of a narcotic must display the symbol "N" clearly and conspicuously

Roles of HC and the PAAB

- HC
  - Is the national regulatory authority and has ultimate responsibility for administering, directing compliance with, and enforcing the healthcare product advertising rules under the F&DA
  - HC issues policies and guidelines for the interpretation of these rules (such as *The Distinction Between Advertising and Other Activities* and *Therapeutic Comparative Advertising Directive and Guidance Document*), and oversees regulated healthcare product advertising activities and enforcement
  - HC works in collaboration with the PAAB but always reserves the right to enforce the healthcare product advertising rules in the F&DA whether or not the advertisement has been pre-cleared by the PAAB
  - For this reason, HC says it does not, strictly speaking, "endorse" any advertising pre-clearance agency (APA), including the PAAB – see definition of APA in section 1.4 of HC's guidance document *Health Canada and Advertising Preclearance Agencies' Roles Related to Health Product Advertising*
  - HC acts as an advisor to the PAAB and is an *ex officio* observer on the PAAB's board of directors
  - HC has access to the complaints and appeals procedures under the PAAB Code

Roles of HC and the PAAB

- The PAAB
  - Is an independent, multi-disciplinary Canadian advertising pre-clearance agency (APA), with which HC collaborates to achieve the common goal of maintaining integrity in healthcare product advertising
  - Provides, via a self-regulatory and voluntary system, healthcare product advertising pre-clearance review and complaint adjudication services to advertisers and their agencies
  - Uses HC guidance documents as well as its own documents (which include the PAAB Code, guidance, advisories and research)
  - Reviews and pre-clears advertising to help advertisers ensure (i) compliance with the regulatory provisions of the F&DA as well as the CDSA and Regs and the Natural Health Product Regs) and (ii) consistency with various HC guidance documents as well as the PAAB Code
  - This includes ensuring consistency with the HC-authorized TMA and verifying that the advertising is accurate, balanced, evidence- based, and reflects current and best practice

Importance of the PAAB Code

- Provides a fair, consistent, effective and detailed articulation of the F&DA rules on healthcare product advertising expanding on several key areas including
  - Claims, Quotations and References
  - Data Presentations
  - Comparisons

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Importance of the PAAB Code

- Also provides a mechanism for resolving disputes between competitors and other interested complainants arising from allegedly non-compliant healthcare product advertising
  - Sanctions for violating the PAAB Code may include: (i) **penalties** – e.g., a direction to publish a corrective notice (on a website or in an annual report or newsletter) or to issue public letters of apology; the Commissioner may also inform appropriate trade associations to assess the complaint ruling for further penalties if warranted (e.g., Rx&D's Code of Ethical Practices obliges members to comply with the PAAB Code and violations of the Rx&D Code are subject to fines of $25K/$50K/$75K for 1st/2nd/3rd violations within a one year period ... and $100K for each subsequent violation); (ii) **remedial measures** (as required by the Commissioner where the deception is substantial or where the advertising may cause inappropriate healthcare product use or constitutes an imminent and/or significant health hazard); (iii) **public reporting** (i.e., "public shaming" by a identifying a repeat offender or advertiser who refuses to comply with a Commissioner's ruling or a Review Panel decision); (iv) **reporting to the PAAB board of directors**; and, most significantly, (v) **reporting to HC**

Importance of the PAAB Code

- When, in pre-clearance review, will the PAAB escalate to HC?
  - For clarifications from HC, such as (i) clarifying the advertiser's interpretation of the TMA (in the face of the PAAB's concern that the claim conflicts with or expands upon the TMA) and (ii) any claims being made which require a change to the TMA
- When will PAAB decline to adjudicate a complaint and report it directly to HC?
  - When the complaint relates to advertising which, in the PAAB's judgement, contravenes the F&DA, the CDSA and their respective regulations and
    - > is suspected to present an imminent and/or significant health risk or
    - > the PAAB has been unable to achieve compliance (due to wilful non-participation or non-compliance of the advertiser)
  - When the complaint relates to the advertising of healthcare products that are not authorized for sale in Canada
  - When the complaint relates to advertising directed to the general public of prescription drugs or biologics (including vaccines)

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HC's Enforcement of F&DA Ad Rules

- Failure to comply with the F&DA requirements for healthcare product advertising is a criminal offence, punishable by up to two years' imprisonment, a fine of up to $5 million, or both
- Additionally, a person who knowingly makes a false or misleading statement to the federal Minister of Health or who recklessly causes a serious risk of injury in contravention of the F&DA could face a higher fine and up to five years in jail
- When HC receives a complaint about a healthcare product advertisement, it will take compliance and enforcement action as required using a "risk-based approach"

HC's Enforcement of F&DA Ad Rules

- Once non-compliance and the health risk level (low/medium/high) of an advertisement have been determined, the immediate risk management actions HC may take include: (i) issuing a warning letter to the advertiser, (ii) requesting immediate cessation of the advertisement and (iii) issuing a risk communication

- See *Compliance and Enforcement Policy (POL-0001)* of HC's Health Products and Food Branch Inspectorate (the "**Inspectorate**")

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HC's Enforcement of F&DA Ad Rules

- The Inspectorate promotes F&DA compliance through educational activities and the sharing of information on regulatory matters
- Depending on the risks associated with any specific instance of non-compliance, the Inspectorate may have recourse to a range of "compliance measures" (either alone or in combination) including:
  - Consent to forfeit (i.e., an agreement between HC and the advertiser to surrender control of a healthcare product to the Crown)
  - Recall (i.e., a method of removing or correcting a distributed healthcare product where its labelling or advertising violates the F&DA and presents a risk to the health of the consumer)
  - Voluntary detention (i.e., an agreement between HC and the advertiser to maintain control of a particular healthcare product)
  - Voluntary disposal (i.e., an action by the advertiser to prevent further distribution of a non-compliant healthcare product)
  - Voluntary stop sale (i.e., a consent by the advertiser/distributor to stop the sale and distribution of a healthcare product at any level in the distribution chain)

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HC's Enforcement of F&DA Ad Rules

- Where the risks to health and safety are serious, HC has recourse to a range of tougher "regulatory measures" including:
  - Forfeiture following seizure or prosecution (i.e., control of a healthcare product is surrendered to the Crown)
  - Injunction (i.e., a court order that prohibits or orders a specific activity – usually considered where the F&DA violation constitutes a significant and immediate threat to health and safety)
  - Prosecution (i.e., a legal proceeding in which a criminal court determines whether there has been an F&DA violation. HC considers recommending charges be laid when the non-compliance can be linked to any of the following:
    - > it creates a health risk
    - > it is continuing in nature
    - > it was premeditated or done with recklessness or a marked departure from a reasonable standard of care
    - > other enforcement measures have proven unsuccessful

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HC's Enforcement of F&DA Ad Rules

- The tougher "regulatory measures" also include:
  - Refusal, suspension or amendment of establishment licence (i.e., where HC has reasonable grounds to believe that the F&DA ad rules have been contravened, the licensee has made a deceptive statement in their application for an establishment license, and it is necessary to protect health and safety)
  - Regulatory stop sale (i.e., HC may require the advertiser to provide evidence to address health and safety concerns and to refrain from selling the healthcare product until those concerns have been addressed)
  - **Suspension or cancellation of marketing authorization (i.e., HC may suspend/cancel the marketing authorization where a significant health risk exists, and there is no indication that the advertiser will comply)**

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Laws of General Application on Deceptive Advertising under the federal *Competition Act*

- Deceptive Advertising
  - Civil (Generally): Prohibits making a representation to the public that is deceptive in a material respect for the purposes of promoting a good or service or a business interest
  - Civil (Deceptive Electronic Messages): Prohibits making a deceptive representation in either the "sender information" or "subject matter information" of an electronic message, or the "locator" – i.e., the name or other information used to identify the source of data in a computer system (like the URL)
  - Criminal (Generally): Prohibits ***knowingly or recklessly*** committing the civil violation
  - Criminal (Deceptive Electronic Messages): Prohibits ***knowingly or recklessly*** committing the civil violation
  - In all cases, the general impression conveyed by an ad, as well as its literal meaning, will be taking into account when determining whether or not the representation is deceptive
  - **Note:** There is no "materiality" requirement for the "deceptive electronic messages" provisions (a consequence of Canada's Anti-Spam Law or CASL) – so likely easier for Competition Bureau to enforce

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Roles of Industry Canada and the Competition Bureau

- Industry Canada
  - Has an educational, policy and advocacy role
- Competition Bureau
  - Is an independent law enforcement agency and has primary authority for enforcing the *Competition Act*
  - Has the power to refer "civil" matters to the Competition Tribunal, Federal Court or provincial Superior Courts
  - "Criminal" matters under the *Competition Act* are prosecuted in the criminal courts by the Director of Public Prosecutions which has decision-making power independent of the Competition Bureau

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Pertinence of the PAAB Code to the Competition Bureau's Mandate

- Under the *Competition Act*, before an advertiser can make a claim in an advertisement relating to product performance, comparisons or preferences, the advertiser must have "adequate and proper" testing supporting the claim
- "Adequate and proper" is not defined in the *Competition Act* in order to preserve flexibility (especially in complex and technical areas)
- While not legally binding on the Competition Bureau, the PAAB Code (and its associated guidance, advisories and research) is pertinent in that it provides an accessible statement of current and best practice in the healthcare product industry on which the Competition Bureau may be persuaded to rely when evaluating the substantiation of the claims in healthcare product advertising under the deceptive advertising provisions of the *Competition Act*

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Laws of General Application on Deceptive Advertising under the federal *Competition Act*

- Sanctions for Deceptive Advertising under the *Competition Act*
  - Violating the "Civil" Provisions : For the first violation, the maximum administrative monetary penalty (**AMP**) is $750,000 (for an individual) and $10 million (for a company); for each subsequent violation, the maximum AMP is $1 million (for individuals) and $15 million (for companies)
  - Committing a "Criminal" Offence: On summary conviction, a fine of up to $200,000, imprisonment for up to two years, or both; on indictment (most serious charges), fines without upper limits at the discretion of the court, or imprisonment for up to 14 years, or both
  - Private Right of Action (**PRA**): The *Competition Act* grants a PRA allowing private parties to sue in court for recovery of damages suffered (and seek injunctive relief) arising from a violation of the statute's criminal deceptive advertising provisions

    [**Note: Unlike the *Competition Act*, the FDA does not create a PRA: see *Harrison v. Alexa Life Sciences Inc.*, Supreme Court of British Columbia, April 23, 2015]**

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Allocating Responsibilities for Enforcement of Deceptive Healthcare Product Advertising Laws

- F&DA – HC and the PAAB
  - When the deceptive advertising threatens harm to patient health
- *Competition Act* – Competition Bureau
  - When the deceptive advertising threatens harm to competition in markets generally, or to the economic interests of customers and competitors
- Both
  - When the deceptive advertising threatens harm to both patient health and competition
- Whither the Memorandum of Understanding between HC and the Competition Bureau?

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Some Takeaways

- Regarding deceptive healthcare product advertising, there are healthcare product specific laws under the F&DA and laws of general application under the *Competition Act*
- Each can result in significant sanctions against the offending advertiser
- Prosecutions under the F&DA are rare (as they require the criminal standard of "proof beyond a reasonable doubt" and, more importantly, there are other enforcement tools that may achieve compliance more effectively and efficiently) – still criminal fines may be as high as $5 million

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Some Takeaways

- Enforcement actions and multi-million dollar penalties are being sought and imposed under the *Competition Act's* civil provisions with greater frequency

- So too, are private rights of action being launched by private party litigants seeking damages and sometimes injunctive relief

- The guidance in the PAAB Code is not only important for compliance with the F&DA rules on advertising but it is also pertinent for compliance with the advertising rules under the *Competition Act.*

- While the PAAB Code is not legally binding on the Competition Bureau (or on the courts in either civil or criminal proceedings), it may have persuasive force

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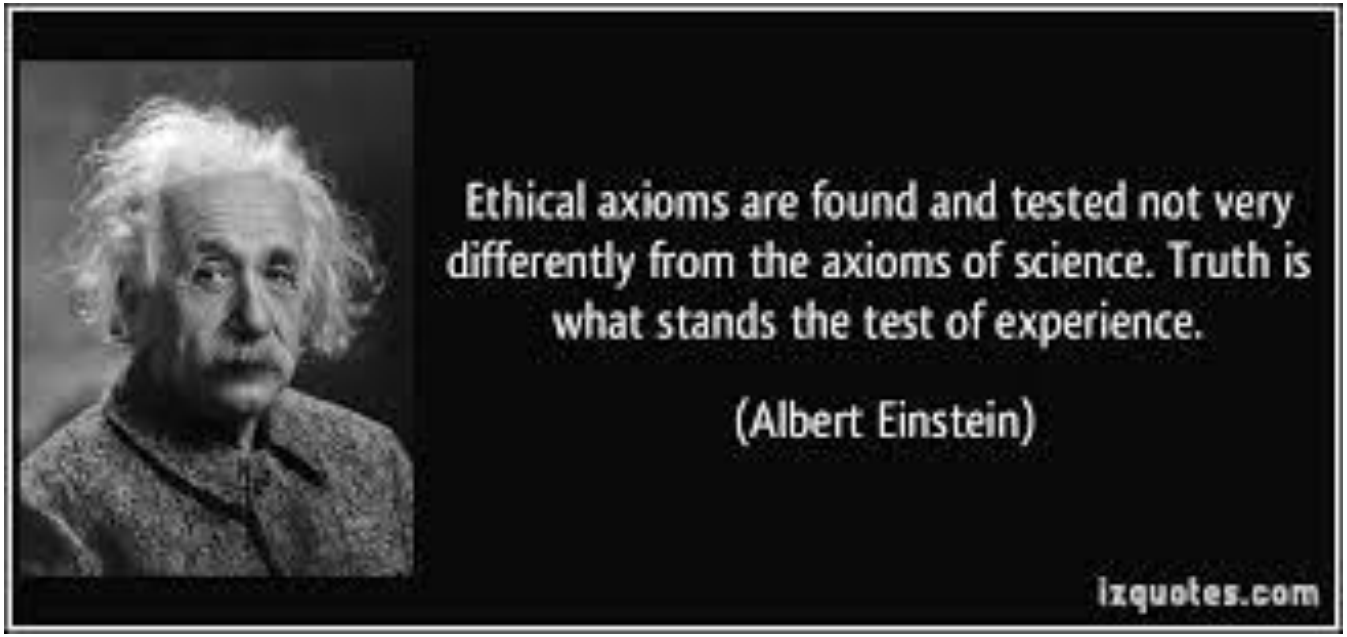
Questions



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Poking Fun at Some Trends in Advertising

Spoof on Reactive Marketing
(Reactvertising)

https://www.youtube.com/watch?v=FHp5_Gcpb9Q

Spoof on Experiential Marketing
(Exfeariential)

https://www.youtube.com/watch?v=4sxAOkAguqc

Thank You

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If you'd like a copy of two recent articles of mine on Canadian advertising laws pertinent to pharmaceuticals, please email me at bhearn@foglers.com