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Self-Regulation in Canada

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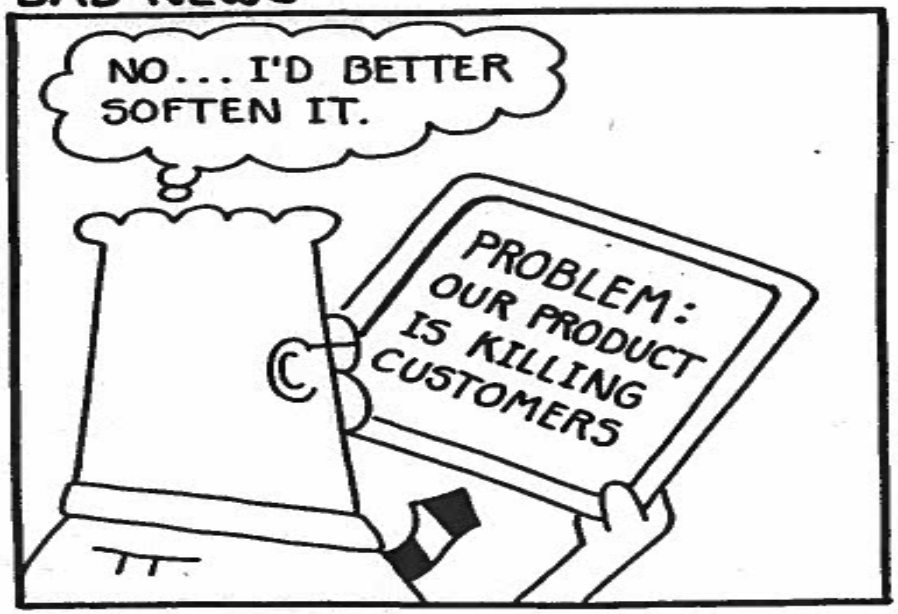
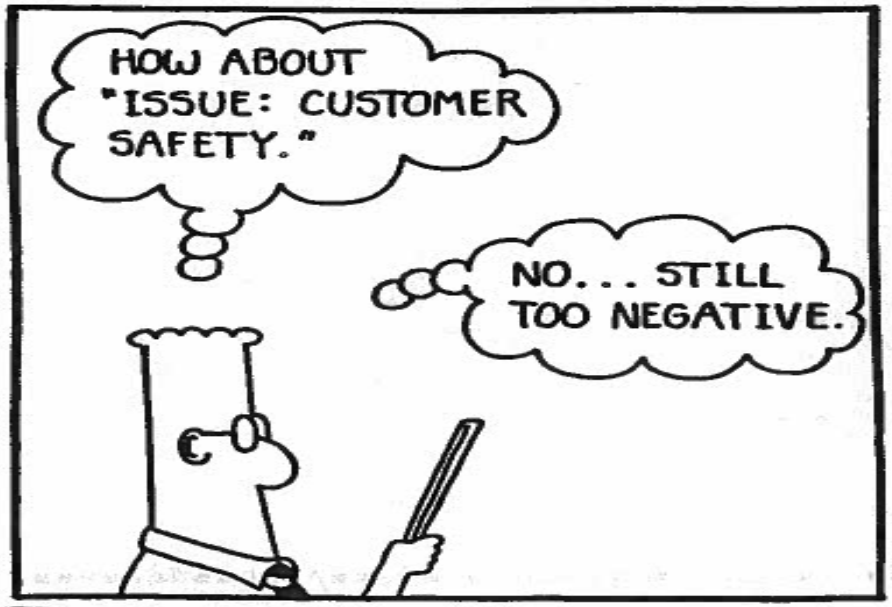
WEASEL WORDS, BLUFFING, AND LYING

PRESENTING BAD NEWS

NEVER PRESENT BAD NEWS. IT JUST MAKES THE AUDIENCE HATE YOU. EMPHASIZE THE POSITIVE, EVEN IF THERE ISN'T ANY.





Current Environment

- Concerns about soaring government expenditures
- Concerns about soaring health insurance costs
- Concerns about over utilization
- Concerns about the exercise of independent medical judgment by physicians
- Concerns about patient safety
- Concerns about patient privacy
- **low trust levels for pharma industry**

U.S. Experience

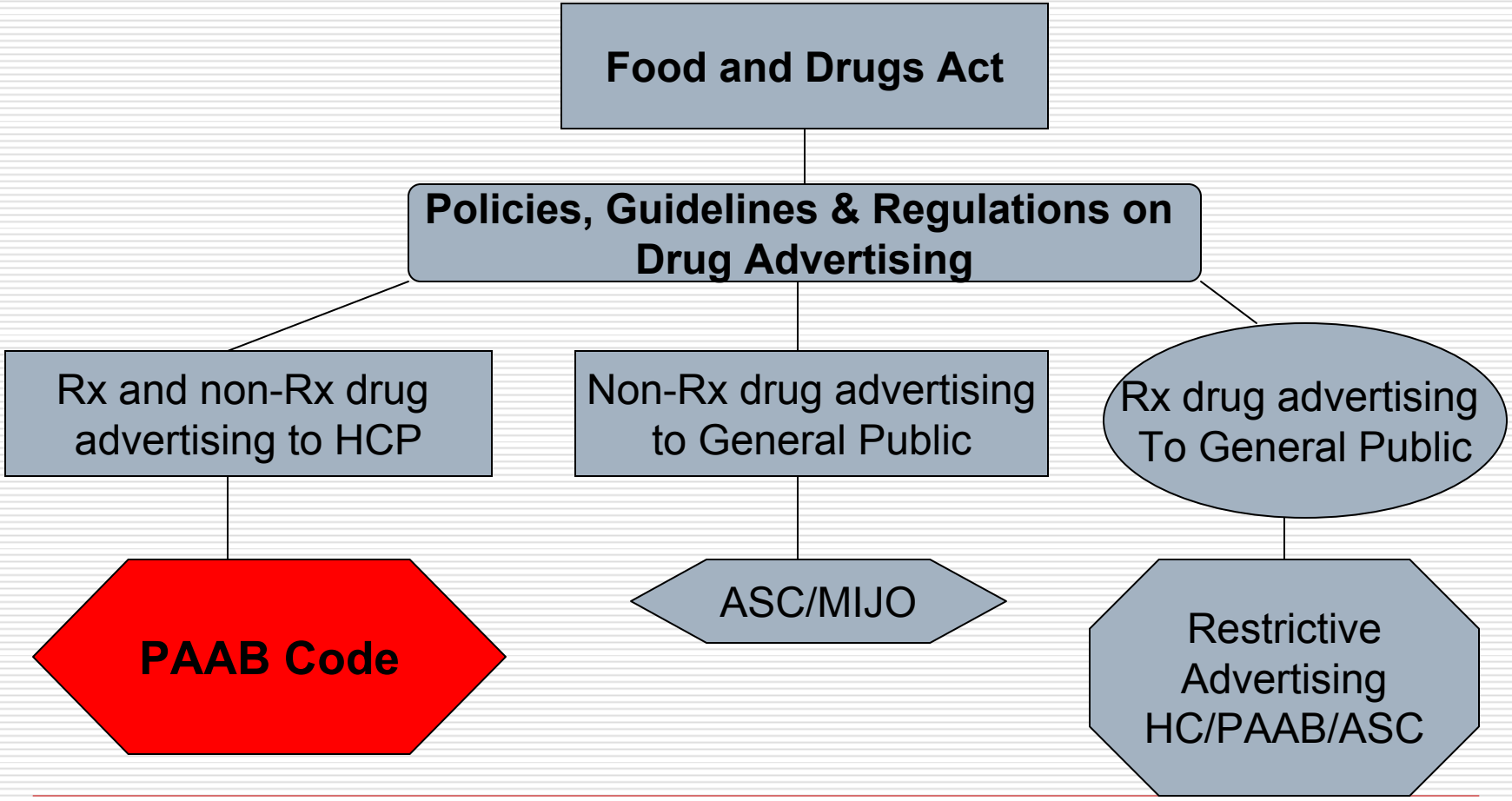
- $12+ billion in fines and criminal penalties since 1999
- OIG, DOJ, FDA, DDMAC, FBI, state AGs, FTC, SEC, DC
- PhRMA guidelines revision - DTCA, gifts, etc
- state & city laws imposing compliance - reporting
- DOJ investigating CME re off label
- More qui tam cases under seal
- Senate scrutiny e.g. Physician payments, clinical trials, price
- FDA DDMAC expanded 50% and elevated to “Office”

CANADA

Self-regulation

government regulation

Regulatory Overview of Healthcare Product Advertising in Canada



Self-Regulation

- goal is to benefit society
- law is the minimum standard
- direct participation by industry
- helps maintain "level playing field"
- flexible alternative to legislation
- no tax dollars, less expensive
- continuous monitoring

"20% of the regulated population will automatically comply with any regulation, 5% will attempt to evade it, and 75% will comply so long as they think the 5% will be caught and punished."

Chester Bowles - regulator and member in the 1941 U.S. Wartime Office of Price Administration

PAAB

Compliance – Drug Promotion

- Health Canada - federal law
- PAAB Code - ethics plus legal
- Rx&D Code - ethics plus legal
- Healthcare Professionals' codes
- Provinces – formulary issues

Ethics vs Law Conflicts

Ethics vs Law Conflicts

- Doing the right thing vs doing things right
- Individual responsibility vs Corporate responsibility
- Industry Codes vs Regulations
- Competitive marketplace

What is Advertising?

No one factor alone determines whether or not a message is advertising. Each message must be assessed individually. The purpose, content and context of the message is examined to determine if the intent is to promote the sale of a health product or to provide information. Other factors which must be considered include how and when the message is being delivered, to whom and by whom and how often the message is being conveyed.

- **Source: Health Canada "Overview of Health Product Advertising"**

Health Canada Policy

See

"***Distinction Between Advertising and Other Activities***"

on the Health Canada web-site

Health Canada Guideline

- What is the context in which the message is disseminated?
- Who are the primary and secondary audiences?
- Who delivers the message? (the provider)
- Who sponsors the message and how?
- What influence does the drug manufacturer have on the message content?
- What is the content of the message?
- With what frequency is the message delivered?

"No one factor in itself will determine whether or not a particular message is advertising."

Health Canada Santé Canada

- Health Canada is an ex-officio observer and advisor "without relinquishing authority under the Food and Drugs Act"
- PAAB Commissioner liaison with Manager, Advertising and Risk Communications Section, Marketed Health Products Directorate
- Consultation meetings
- "*PAAB and TPD Roles and Consultation Related to Advertising Review*"

Direct transfer to Health Canada

- Complaints including safety allegations
- Complaints about Direct-to-Consumer prescription drug advertising
- Complaints about advertising of unapproved products
- Noncompliance with PAAB rulings
  - applies to all companies

PAAB

VISION

- Trusted healthcare product communication that promotes optimal health

MISSION

- To provide a preclearance review that fosters trustworthy healthcare communications within the regulatory framework.

VALUES

- Integrity, Competency, Credibility, Independence, Excellence, Transparency

MANDATE

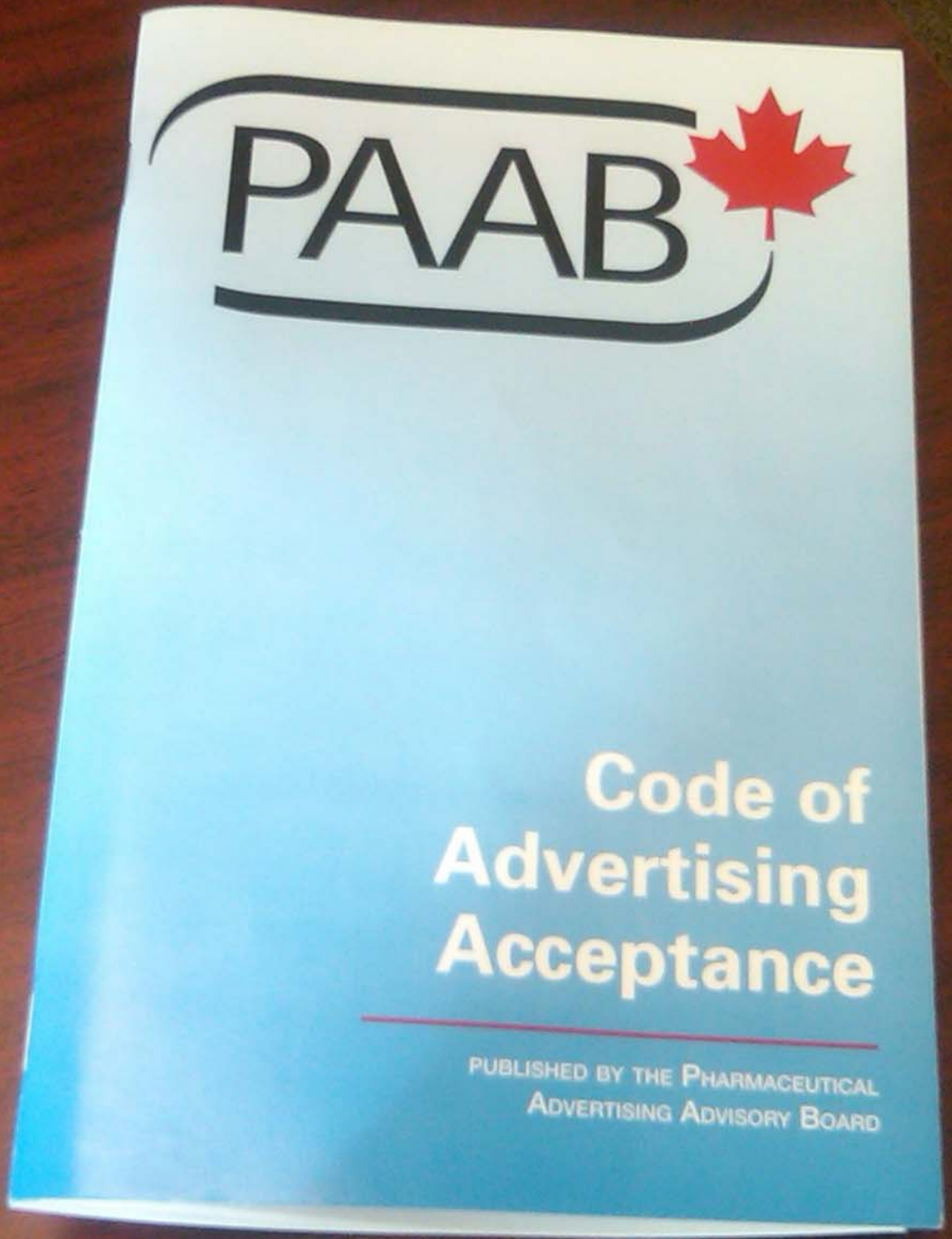
The PAAB is an independent review agency whose primary role is to ensure that healthcare product communication for prescription, non-prescription, biological and natural health products is accurate, balanced and evidence-based, and reflects current and best practice.

The PAAB also monitors trends in health product advertising and promotion and adjusts its code and practices as required to fulfill its mandate.

PAAB's Board of Directors

- three pharmaceutical trade associations
  - Rx&D, CGPA, CHPC, BioteCanada
- health professionals - CMA, CPhA, FMSQ, AFMC
- patients - Best Medicines Coalition (BMC)
- Canada's Assoc for the Fifty-Plus (CARP)
- Can Assoc of Medical Publishers (CAMP)
- advertising industry (AMAA)
- Chair, Vice-Chair, Treasurer

- maintain Code, approved by Board
- preclearance review
  - Rx and nonprescription advertising to health professionals
- advisory comments on DTCA Rx
- training
- complaints, penalties, reporting
- conscience


PAAB
Code of Advertising Acceptance
PUBLISHED BY THE PHARMACEUTICAL ADVERTISING ADVISORY BOARD

PAAB Code of Advertising Acceptance

- Standards including:
  - regulatory
  - scientific
  - clinical
  - ethical principles
- Dynamic, reflects current marketplace
- Works in best interest of patients

What Is The PAAB Looking For?

- Consistent with product monograph
- Unsubstantiated comparative or superiority claims
- Misleading by omission:
  - Failure to reveal or minimizing risk or safety info
  - Failure to reveal limitations on use
- Implied claims of broader indications or conditions of use, or a larger patient population than approved
- Fair Balance Safety information

What Is The PAAB Looking For?

- Claims based on preliminary or investigational data
- Drug-of-choice claims
- Company marketing plans that indicate off-label promotion
- Pseudo-CME
- Pseudo-patient info
- DTC ads that may be illegal or cause inappropriate prescribing and potential increased risk.

PAAB:
Serving the Two Headed monster

Canada's Research-Based Pharmaceutical Companies

R&D

Les compagnies de recherche pharmaceutique du Canada

Code of Ethical PRACTICES

Integrity

Trust

JANUARY 2010

www.canadapharma.org

Rx&D Code of Ethical Practices

- A violation of the PAAB Code may be a violation of the Rx&D Code s2
- Rx&D Code s8.2.4 & 8.2.5 re. rep activity

Complaints process - Code s9

- Approved by Senior Official for trade disputes
- Stage 1: intercompany
- Stage 2: reassessment by Commissioner
- Stage 3: appeal to external panel

- Complaints Reported to Public

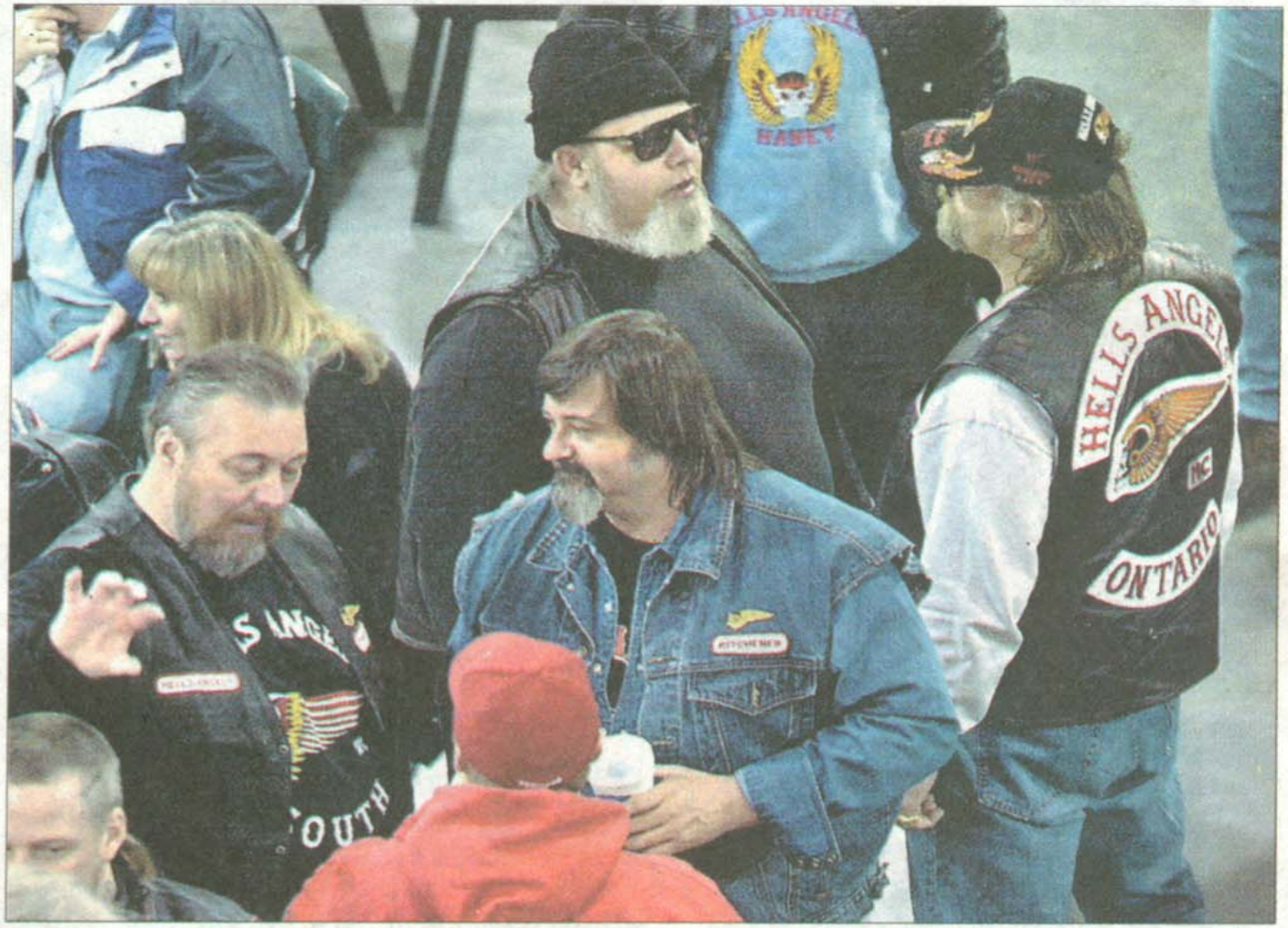
Sanctions

- Rapid Cessation of Advertising
- Recovery of Material
- Corrective Statements
- Published Complaint Outcomes
- Public Reprimand through Members
- Referral to Health Canada
- Referral to trade association - fines

Challenges

- Social Media
- Pseudo CME
- Industry awareness of rules
- Off label
- Fair comparisons

COMMISSIONER CHEPESIUK PROVIDES INSTRUCTIONS TO NEW PAAB CODE ENFORCEMENT OFFICERS



KEN FAUGHT/TORONTO STAR

Thank You