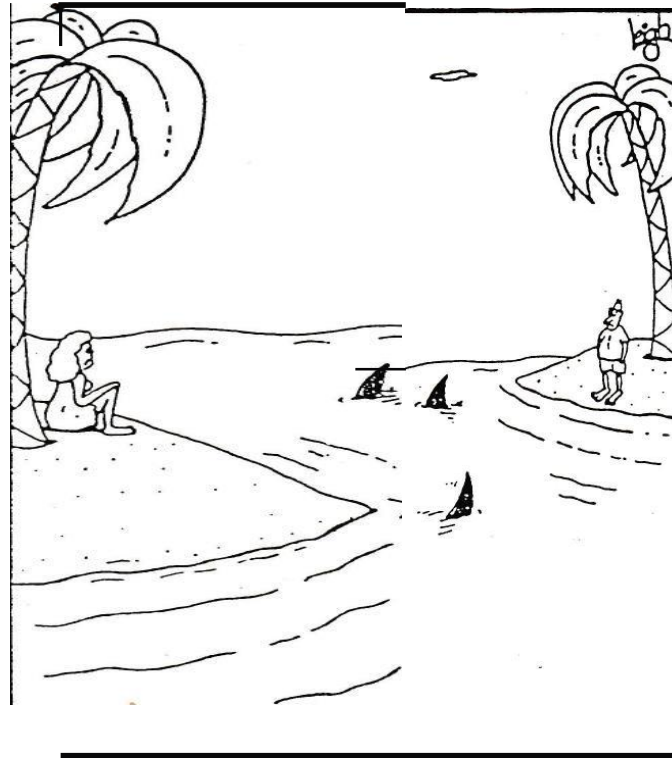


THERAPEUTIC ADVERTISING PREVETTING SYSTEM

February 16 2017

Nigel Andrews

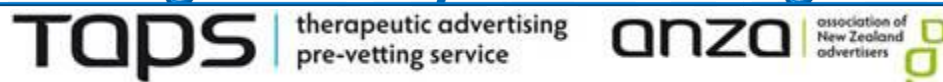




► **Effective birth-control methods
of the South Pacific.**

Therapeutic Advertising prevetting system.(TAPS)

Briefing February 16 2017. Nigel Andrews



- ▶ **ITEMS:**
- ▶ **1] Web Banner Digital Advertising Prescription Medicines and OTC Medicines**
- ▶ **2] Google Ad Words**
- ▶ **3] Testimonials**
- ▶ **4] Key Legal Decisions and Advertising Standards Complaints Board (ASCB) Decisions & ASA UK.**
- ▶ **5] Substantiation of Claims. OTC Medicines.**
- ▶ **6] New company approval systems. Veeva.**

BANNER DIGITAL ADVERTISING.LEGISLATION & CODES.

Prescription Medicines Consumers.

- ▶ Medicines NZ Code 3.14.6
- ▶ 1] First mention of brandname.©™
- ▶ 1]First Screen must include as minimum the mandatory information in 5.11.10 of this code
- ▶ 2] A statement on first screen that readers can access the further information required in section 5.11.11 of this code
- ▶ 3] First screen may also link through to promotional and/or therapeutic claims.

BANNER DIGITAL ADVERTISING.LEGISLATION & CODE

Prescription Medicines Consumers.



- ▶ 5.11.10 DTCA for prescription medicines, in language and format that is easily understood by members of the public, must include the following information:
- ▶ 1] The medicine's classification.
- ▶ 2] The brand and approved name (usually the INN) of the medicine.
- ▶ 3] The quantities of the active ingredients in the medicine.
- ▶ 4] The name of the sponsor and the locality of the registered office.
- ▶ 5] The approved indication of relevance to the advertisement.
- ▶ 6] A statement that "Brand Name X has risks and benefits".
- ▶ 7] A statement that additional product information and Consumer Medicine Information (CMI) can be obtained, and how it can be accessed.



Prescription Medicine. First mention of brandname.

- ▶ **Example:**
- ▶ ***Efexor[®]-XR, Venlafaxine 37.5,75,150mg,***
- ▶ ***Prescription Medicine***
- ▶ ***For the treatment of major depression***
- ▶ ***Efexor[®]-XR has risks & benefits***
- ▶ ***For product information check Consumer Medicine Information on www.Medsafe.govt.nz & click for further info)****
- ▶ ***Pfizer NZ Ltd. Auckland. NA 5177***
- ▶ **** 5.11.11 of code***

BANNER DIGITAL ADVERTISING.LEGISLATION & CODES.

Prescription Medicines Consumers.



- ▶ Plagued by major depression. Check with your healthcare professional
- ▶ *Your possible solution. Ask your doctor if Efexor®-XR is right for you.*
- ▶ *Efexor®-XR, Venlafaxine 37.5,75,150mg,*
- ▶ *Prescription Medicine*
- ▶ *For the treatment of major depression*
- ▶ *Efexor®-XR has risks & benefits*
- ▶ *For product information check Consumer Medicine Information on*
*www.Medsafe.govt.nz & click for further info.**
- ▶ *Pfizer NZ Ltd. Auckland.*
- ▶ ** 5.11.11 of Code NA 5177*

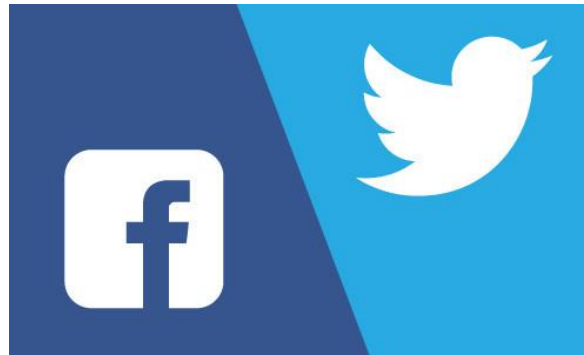
Banner 1.

Banner 2.

BANNER DIGITAL ADVERTISING.LEGISLATION & CODES.

Prescription Medicines Consumers.

- ▶ Prescription Medicines.
- ▶ Applies to web banners, digital, Facebook, Social Media.



BANNER DIGITAL ADVERTISING

LEGISLATION & CODES. Prescription Medicines HCPs



- ▶ 3.13.6 Branded web banner advertisements directed at HCPs must comply with the requirements for a short advertisement.
- ▶ **4.1.3.2 A short advertisement must contain:**
 - ▶ a) The medicine classification
 - ▶ b) The approved indication(s) of relevance to the advertisement.
 - ▶ c) Appropriate precautions for the use of the product.* (see next slide)
 - ▶ d) The TAPS or DA approval number.
 - ▶ e) The brandname of the product.
 - ▶ f) The New Zealand approved name(s), usually INN, of the active ingredient
 - ▶ g) The name of the sponsor and the locality of the registered office
 - ▶ h) A clear statement directing the prescriber to review the Data Sheet before prescribing the medicine
 - ▶ i) Reference to where the Data Sheet is immediately accessible.

BANNER DIGITAL ADVERTISING

LEGISLATION & CODES. Prescription Medicines HCPs



Section 4.1.3.2 Short Ads (Healthcare Professionals (HCPs) Only)

This section defines the 'mandatory' information for a reminder advertisement to HCPs

Clarification from Medsafe and TAPS for 4.1.3.2. (c) *appropriate precautions for the use of the product*

- ▶ *Before prescribing [Medicine] please refer to the data sheet for information on dosage, contraindications, precautions, interactions and adverse effects. The data sheet is on the Medsafe website at www.medsafe.govt.nz.*

BANNER DIGITAL ADVERTISING

LEGISLATION & CODES. Prescription Medicines H



- ▶ First mention of brandname.
- ▶ “Efexor[®]-XR. Venlafaxine 37.5,75,150mg
- ▶ Prescription Medicine.
- ▶ *For the treatment of major depression*
- ▶ Before prescribing Efexor[®]-XR please review the data sheet for information on dosage, contraindications, precautions, interactions and adverse effects. The data sheet is available at www.medsafe.govt.nz
- ▶ Pfizer NZ Ltd, Auckland. NA 6592.

BANNER DIGITAL ADVERTISING

LEGISLATION & CODES. Prescription Medicines HCPs

- ▶ Want a fresh option from tricyclics and SSRIs?
- ▶ Trying to manage relapse & recurrence of major depression?
- ▶ Efexor®-XR could be your solution. Still fully funded.
- ▶ Efexor®-XR. Venlafaxine 37.5,75,150mg
- ▶ Prescription Medicine.
- ▶ *For the treatment of major depression*
- ▶ Before prescribing Efexor®-XR please review the data sheet for information on dosage, contraindications, precautions, interactions and adverse effects. The data sheet is available at www.medsafe.govt.nz
- ▶ Pfizer NZ Ltd, Auckland. NA 6592.

Banner 1.

Banner 2.

BANNER DIGITAL ADVERTISING LEGISLATION & CODES. OTC Medicines.



- ▶ Applies to both Consumer & HCP Digital Ads.
- ▶ *“Always read the label. Use only as directed. If symptoms persist see your healthcare professional.”*
- ▶ *GlaxoSmithKline Consumer Healthcare, Auckland.”*

BANNER DIGITAL ADVERTISING LEGISLATION & CODES. OTC Medicines.

- ▶ *Plus Class Statements where applicable*
- ▶ *“Incorrect use may be harmful,” salicylic acid and salts (aspirin), NSAIDs, codeine, paracetamol*
- ▶ *may cause drowsiness (avoid alcohol & driving) sedating antihistamines,*
- ▶ *do not use if you have stomach ulcers” NSAIDs*

BANNER DIGITAL ADVERTISING LEGISLATION & CODES. OTC Medicines.

- ▶ *“Voltaren© Rapid 25. A medicine to treat pain and inflammation.*
- ▶ *Always read the label. Use only as directed. If symptoms persist see your pharmacist. Incorrect use may be harmful. Do not use if you have stomach ulcers. GlaxoSmithKline Consumer Healthcare, Auckland.”*

BANNER DIGITAL ADVERTISING LEGISLATION & CODES. OTC Medicines.

- ▶ A solution for treating serious pain and inflammation. Do you want rapid relief?
- ▶ *“Voltaren® Rapid 25. A medicine to treat pain and inflammation, for rapid relief.*
- ▶ *Always read the label. Use only as directed. If symptoms persist see your pharmacist. Incorrect use may be harmful. Do not use if you have stomach ulcers.*
- ▶ *GlaxoSmithKline Consumer Healthcare, Auckland.”*

Google Ad Words.

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- ▶ Unbranded Ad Words OK e.g. asthma, COPD, Wheezing & want relief, asthma controlled?
- ▶ Company pays for these and no mandatories required as unbranded.
- ▶ Google will direct consumer to green URL site like <https://COPD Breo Ellipta>
- ▶ Not regarded as advertising as direction is by Google and mandatories in full would appear on Home Page of site.

The Google logo is displayed in its characteristic multi-colored font, with the letters 'G', 'o', 'o', 'g', 'l', and 'e' in blue, red, yellow, blue, green, and red respectively.

Patient Testimonials - Testimonials Advertisements to Consumers

For Prescription Medicines, OTC Medicines, Medical Devices

NZ Medicines Act

58 Further restrictions on advertisements

(1) Subject to section 60, no person shall publish, or cause or permit to be published, any medical advertisement that—

c) directly or by implication claims, indicates, or suggests that a medicine of the description, or a medical device of the kind, or the method of treatment, advertised—

(iii) has beneficially affected the health of a particular person or class of persons, whether named or unnamed, and whether real or fictitious, referred to in the advertisement;

Patient Testimonials –Advertisements to Consumers

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General Guidance

- ▶ *Use future tense e.g. “Product X will help keep you moving” not “Product X has helped keep her moving”*
- ▶ *Avoid use of ‘first person’ e.g. “I have used Product X”*
- ▶ *Use ‘You may respond’ or ‘He/She may respond’*
- ▶ *Avoid showing people taking the medicine and gaining benefit from it*
- ▶ *Extreme caution because of broad wording of section 58 of Medicines Act. Err on conservative side.*
- ▶ *Patient experience of disease state and symptoms is OK.*

Patient Testimonials – Advertisements to Consumers

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Key Legal Decisions. Australian Competition & Consumer Commission (ACCC). Nurofen® Case.



- ▶ In December 2015, following admissions by Reckitt Benckiser, the Court found that Reckitt Benckiser engaged in misleading or deceptive conduct between 2011 and 2015 by making representations on its website and product packaging that Nurofen® Specific Pain products were each formulated to specifically treat a particular type of pain, when this was not the case.
- ▶ ***In fact, each Nurofen® Specific Pain product contains the same active ingredient, ibuprofen lysine 342mg, which treats a wide variety of pain conditions and is no more effective at treating the type of pain described on its packaging than any of the other Nurofen Specific Pain products.***

Key Legal Decisions. Australian Competition & Consumer Commission (ACCC). Nurofen Case.

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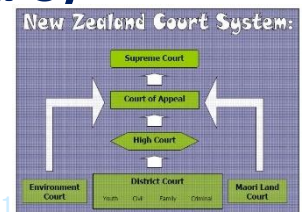
- ▶ **1] Reckitts got “Trumped!!”**
- ▶ **2] The Full (Federal) Court ordered Reckitt Benckiser to pay a revised penalty of \$6 million (up from \$1.7 million) for making misleading representations about its Nurofen Specific Pain products.**
- ▶ **3] “This is the highest corporate penalty awarded for misleading conduct under the Australian Consumer Law,” ACCC Chairman Rod Sims said.**
- ▶ **4] The Full Court found that the initial penalty of \$1.7 million was manifestly inadequate given the need for deterrence and the substantial consumer loss suffered.**
- ▶ **5] “The ACCC welcomes this decision, having originally submitted that a penalty of \$6 million or higher was appropriate given the longstanding and widespread nature of the conduct, and the substantial sales and profit that was made,” Mr Sims said.**

Key Legal Decisions. Australian Competition & Consumer Commission (ACCC). NZ. Nurofen.

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- ▶ NZ Consequences
- ▶ 1] Commerce Commission. Auckland District Court imposed fine of **\$1.08mio** under Fair Trading Act.
- ▶ 2] TAPS had approved such advertising based on Medsafe Ministerial Consent (& TGA Consent in Australia) i.e. legal OK by a government department. Approvals based on label claims.
- ▶ 3] This decision forms a legal precedent & principle in Australia & NZ & most countries.
- ▶ 4] No complaint to Advertising Standards Complaints Board (ASCB). Difficult to guess decision. However, complaint probably not be upheld re Electoral Commission vs Cameron & Ors (ASCB) Appeal Court decision. (similar to approach taken by TAPS)



Key Legal Decisions. Australian Competition & Consumer Commission (ACCC). NZ. Nurofen Ca

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- ▶ NZ Consequences.
- ▶ 5] Any similar case would probably attract large fine under Fair Trading Act.
- ▶ 6] Specific Nurofen products such as **Tension Headache, Period Pain, Migraine Pain, Back Pain**, removed by company prior to court decision.
- ▶ 7] TAPS would caution advertisers on such a practice. This has happened with one complementary advertiser where there were about four labels with same ingredients for difference purposes/claims.



Key Legal Decisions. Australian Competition & Consumer Commission (ACCC). NZ. Nurofen.

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- ▶ NZ Consequences.
- ▶ Should not apply for different formulations re absorption e.g. Nurofen© Zavance & Panadol© Optizorb where claims confined to faster absorption and not different pain types.
- ▶ Caution re “targeted pain” claims to different body parts.
- ▶ Check formulations e.g. Voltaren© Emulgel and Voltaren© Osteo Gel.
- ▶ Likely changes in Medsafe evaluation process based on these court decisions.



Advertising Standards Authority UK Ruling on Nurofen

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- ▶ TV Ad. A TV ad for Nurofen®, seen in April 2016, showed a woman with back pain who subsequently took Nurofen Joint and Back. As she took the product an anatomical image showed it moving down her body and to her back while on-screen text stated "... *Also indicated for other aches and pains*". The ad then showed shots of the woman going about her usual activities without any pain, interspersed *with anatomical images of her back with a Nurofen symbol indicating where the pain relief was acting*. The voice-over included the claim, "... *Just a single dose of Nurofen Joint and Back provides you with constant targeted pain relief for up to 8 hours*".

Advertising Standards Authority UK Ruling on Nurofen.

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ASA ✓

- ▶ . Decision: We acknowledged that the concluding voice-over stated, "... provides you with constant targeted pain relief", but considered that, in the context of an ad focused on the *alleviation of back pain, and given the product name, viewers were likely to understand that Nurofen Joint and Back was specifically designed to relieve back and joint pain, rather than pain generally.* We also considered that viewers were likely to infer that the product had a special mechanism or contained an active ingredient which made it especially effective for back and joint pain in comparison to other painkillers. While we noted that, as the product was ingested, on-screen text stated, "*Also indicated for other aches and pains*", we considered that it was not sufficiently prominent to counter the overall impression that the product was specifically tailored for back and joint pain.

Advertising Standards Authority UK Ruling on Nurofen

Summary

- ▶ Take Home Messages:
- ▶ 1] Be careful re claiming “targeted pain” e.g. back pain. Pain relief over all the body & not targeted.
- ▶ 2] Avoid graphics that show targeting of specific body part and continued focus on “back” “head” etc
- ▶ 3] The “On screen small print” will not necessarily salvage the overall consumer perception/take-up. Consistent with Commerce Commission guidelines re small print.
- ▶ 4] Different brandname with same active ingredient is likely to be misleading for the consumer re targeting pain to specific part of body.



Key Precedent Decisions of Advertising Standards Complaints Board (ASCB) NZ



- ▶ 1] Depot-Provera©. 99/116. mandatories elsewhere in New Idea Mag. & not identified. Medical language e.g. diplopia, pruritis, amenorrhoea.
- ▶ (interpret in common sense manner..need to inform & protect consumer. Unlike US where vast amount of information was to protect the advertiser rather than the consumer.)
- ▶ 2] TV Viagra© decision 6 p.m. news (01/301). *(Timing of TV Ad during 6 p.m. news)*
- ▶ 3] Billboard Advanced Medical Institute “Want longer lasting sex?” (08/112) *(Exposure of ad on billboard. Medium used. in contrast to Solid Gold FM radio. Targeted to males 40-59 07/515. nasal delivery for premature ejaculation.*
- ▶ 4] Durex Poster positioned near McDonald’s outlet. 06/181
- ▶ *(placement of poster next to McDonalds outlet which attracted many children below age of 16. Did not meet due standard of social responsibility)*

Key Precedent Decisions of Advertising Standards Complaints Board (ASCB) NZ.



- ▶ 5] Xenical©. Back of the bus ad. (00/96). (ASCB: 1. Readability of mandatories. 2. Use of inappropriate slim naked body covered only by hair 3. indication was for seriously obese people 4. Picture on back of bus out of context re original TV ad. Many people will not have seen TV ad.)



Key Precedent Decisions of Advertising Standards Complaints Board (ASCB) NZ



- ▶ 6] Caci Clinic Decision 99/61. Similar theme. “Don’t let red veins spoil your face. (ASCB:*Claim was for veins of face. Naked female body naked down to waist shown, albeit covering her breasts*)
- ▶ 7] Meningococcal B Ministry of Health Back of Bus Ad. 04/373 (ASCB:*Readability of mandatories, Govt. Department subject to its own rules and ASCB decisions*)(Pharmac Letter to Doctors regarded as advertising)
- ▶ MeNZB™ is a prescription medicine. Please read the brochure or talk to your
- ▶ doctor about the benefits and any possible side effects.

Key Precedent Decisions of Advertising Standards Complaints Board (ASCB) NZ.



- ▶ 8] Beclazone Decision 02/410 AWAP 02/15. (ASCB.Lack of substantiation. Advertiser unable to provide substantiation owing to confidentiality agreement.)
- ▶ 9] Nurofen© for Children TV 06/222. (leaning over baby's cot, who is only 6 months old and is feeling like this (volcano eruption cartoon) (ASCB: Baby portrayed not younger than 6 months, Age restrictions given."Do not give to babies under 6 months, Seek medical advice before giving to baby under 1 year. (additional statements included over & above that required by ASA code.)
- ▶ 10] Codral© Soldier On. 12/430"The world doesn't stop for sick. Soldier on."



ASCB Chairman said the intent of the advertisement was a light hearted promotion of the use of Codral in easing symptoms of colds and flu rather than implying that people should attend work if they are sick. Did not reach threshold to breach high standard of social responsibility.

Key Precedent Decisions of Advertising Standards Complaints Board (ASCB) NZ



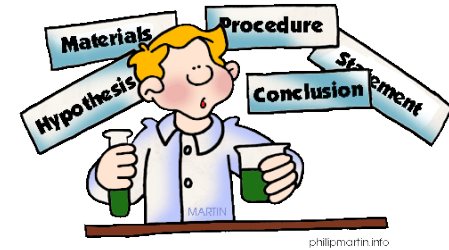
- ▶ **11] Nurofen© Cold & Flu 14/362. Teacher featured in class.**
Complaint: irresponsible to go to work. focused on relieving the symptoms of cold and flu and provided an illustration of the types of scenarios where the use of the product could help people “get on with their day” when it was necessary to do so. It also noted the disclaimer in the advertisement which encouraged people with persisting symptoms to seek advice from a healthcare professional.



Substantiation of Claims. OTC Medicines.

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- ▶ **Substantiation of Claims – References**
- ▶ **Recommended you have 2-3 peer-reviewed papers to support key claims (c.f. SMI Complaints Panel)**
- ▶ **Check carefully the primary objective of study as per methodology and summary**
- ▶ **Be wary of using secondary objective or analyses (Data dredging)**
- ▶ **Check the author's own limitations to the study in the "Discussion at the end"**
- ▶ **Main benchmark "Prospective, randomised, double-blind study against placebo or active comparator in wide use". Other observational, meta-analyses or retrospective studies useful as backup (where results are similar and therefore trend is established).**
- ▶ **Use caution on quoting specific figures unless confirmed in other studies. Check the trend in studies.**
- ▶ **NZ Formulation different from trial formulation.**

Substantiation of Claims. OTC Medicines.

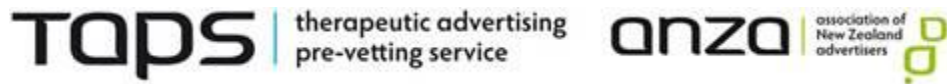
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- ▶ References for key claims should be quoted. Other references should be available on request. Balance of references and clutter. Difference between healthcare professionals and consumer advertising)
- ▶ Recommendation is to use peer-reviewed journals for scientific robustness
- ▶ If possible, references should be reasonably current. However old references of 10 years back can still be valid (Particularly for OTC medicines)
- ▶ Statistical results should be valid re –p value of <0.05 or lower as a rule of thumb. i.e. 1 chance in 20 that result was by chance. Lowest level of significance.
- ▶ Preferable to have Intention To Treat (ITT) analysis to allow for withdrawals and dropouts. Regarded as more robust statistically. Last Observed Case (LOC) can also be reasonable
- ▶

Substantiation of Claims. OTC Medicines.

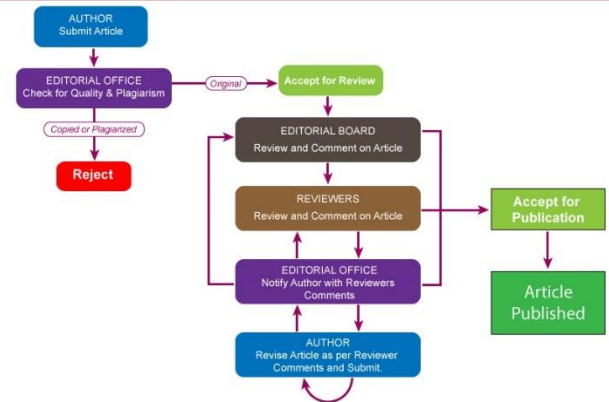


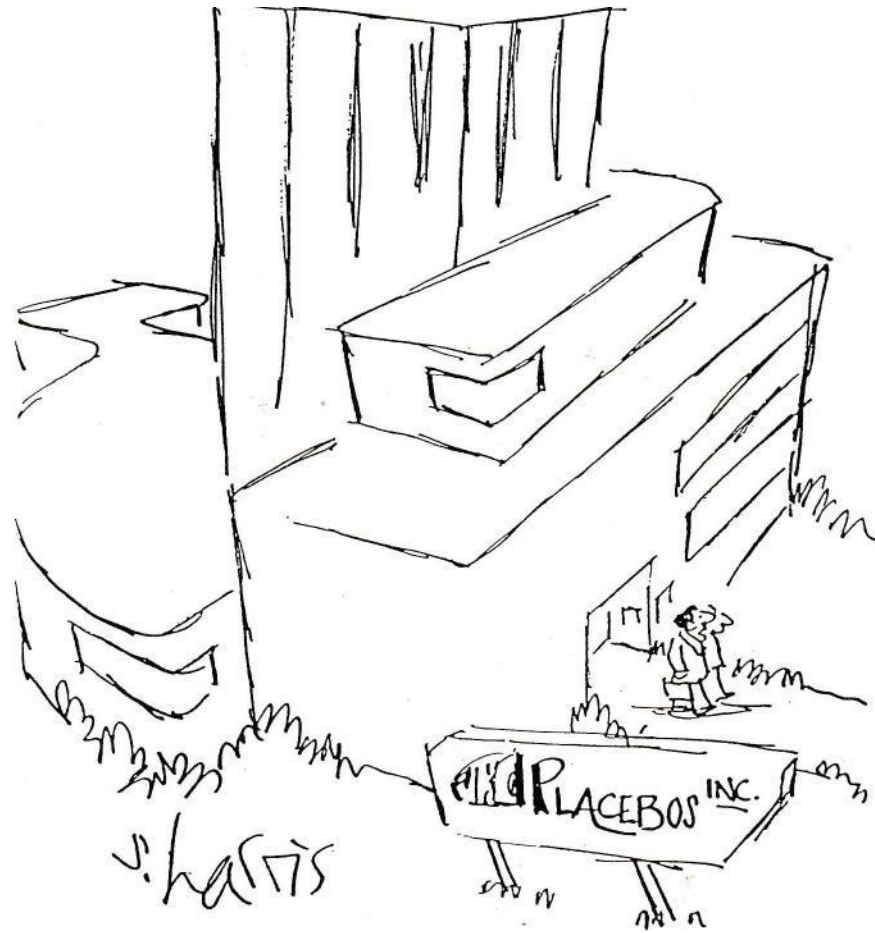
- ▶ **Benchmarks:**
- ▶ **Therapeutic Products Advertising Code, Comparative Code (ASA)**
- ▶ **SMI Code**
- ▶ **Advertising Standards Complaints Board (ASCB) Decisions**
- ▶ **Commerce Commission “Unsubstantiated Representations (Claims)” Fact Sheet re Fair Trading Act changes effective June 17 2014**
- ▶ **Datasheet and/or Approved Label (regulatory scrutiny & approval) Avoid extending claims beyond approval.**
- ▶ **Published studies in peer-reviewed journals e.g. BMJ, NEJM, JAMA,**
- ▶

New Company Systems. Veeva

- ▶ Zinc & Veeva.
- ▶ Useful to incorporate TAPS into the s
- ▶ TAPS willing to be trained on integration.
- ▶ TAPS experience with Veeva is that it should work well with some refinements.
- ▶ The TAPS system and the Veeva system can be work together for ease of advertiser's approvals.
- ▶ We embrace new technology.

Peer Review Process by Sci Forshen





"Yes, we're now the largest drug company in the country."

