Healthy Skepticism

Improving health by reducing harm from misleading drug promotion.
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The Secretary of the Committee
Senate Select Committee on the Free Trade Agreement between Australia and the United States of America

Submission from Healthy Skepticism Inc

Healthy Skepticism Inc (formerly the Medical Lobby for Appropriate Marketing) www.healthyskepticism.org is an international non-profit organisation for health professionals and everyone with an interest in improving health care. We aim to improve health by reducing harm from misleading drug promotion. We do this through advocacy, education and research.

Members of Healthy Skepticism, and in particular Director and Founder, Dr Peter Mansfield, are internationally recognised for their expertise on the impact of pharmaceutical marketing with publications in numerous medical journals including the British Medical Journal. Dr Mansfield has toured Canada and New Zealand to provide advice about Direct to Consumer Advertising (DCTA) to politicians and other key decision makers.

Healthy Skepticism is deeply concerned about the potential impact of the Free Trade Agreement (FTA) on the delivery of quality affordable health care in Australia.

We wish to express our concerns in person at the next meeting of the Committee in Adelaide in June 2004.

We will mainly focus on Annex 2-C which describes (albeit in limited detail) the changes which will be made to the pharmaceutical regulatory system in Australia.

Annex 2-C

The impact on the Pharmaceutical Benefits Advisory Committee (PBAC)
We are concerned that the effectiveness of the PBAC may be weakened by the FTA.

We do not agree with the repeated emphasis on the need for swift approval for all new drugs.

The right to control costs (para 1 c)
The Pharmaceutical Benefits Scheme (PBS) reduces the cost of drugs, thus improving access to appropriate pharmaceutical products. Paragraph 1 (c) does not refer to any party's right to control costs and section (d), although difficult to decipher, could be interpreted as suggesting that attempts to use the PBS to control drug prices could be challenged as being contrary to the 'operation of competitive markets'.

The clause 'appropriately valuing the objectively demonstrated therapeutic significance of a pharmaceutical' suggests that attempts to centrally negotiate drug prices could be challenged through the arbitration system.

Direct To consumer Advertising (DTCA) of prescription medications (part 5)
DTCA that names prescription drugs is has been avoided in Australia but so called "disease awareness" promotion has been allowed and this has been advocated for recently by a representative of the drug industry association Medicines Australia.[1] Drug companies have been pushing the boundaries of "disease awareness" promotion.[2]

According to a Pharma in Focus (a reliable industry news website): *"the ad experts don't use the politically correct language - to them these campaigns are direct to consumer (DTC)*

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advertising - unbranded perhaps but DTC none-the-less. And, as with DTC advertising anywhere else, no-one in the marketing game kids that the objective is to do anything other than drive patients towards specific products and have those products prescribed by GPs."[3]

The New Zealand government has used Trans-Tasman harmonisation as an opportunity to ban DTCA. New Zealand Minister of Health, Annette King, has said that *"the sooner we can do it* [ban direct to consumer advertising] *the better"* but predicted that the pharmaceutical industry will fight against the ban.[4] Consequently it is reasonable to fear that the pharmaceutical industry would take up any opportunity to move towards DTCA in Australia. The FTA has provided such an opportunity by apparently allowing a form of internet advertising. We are concerned that drug companies will use TV, radio and written media advertising to refer consumers to websites to find the name of the drug. This is already happening with drugs for erectile dysfunction.

The Galbally Review of Drugs, Poisons and Controlled Substances Legislation in 2001 examined DTCA and recommended against it.[5]

In early April 2004 a Canadian parliamentary health committee published a report on prescription drugs "Opening the Medicine Cabinet".[6] One of the main findings of that report has been summarised as follows:
"The committee also acknowledged a new threat to safe and appropriate drug use: increased direct-to-consumer advertising of prescription-only drugs. The fix for this problem -- laws prohibiting such marketing practices – is already in place, but enforcement is lax and largely ceded to industry self-regulation. The committee's solution? Close regulatory loopholes and strictly enforce the ban on consumer-targeted advertising of prescription-only drugs."[7]

The problems with DTCA in New Zealand have been examined by a group including all the professors of general practice in New Zealand who recommended that it be banned.[8] We agree with Professor Les Toop, who was the first author of that report, who would prefer a ban on both direct to consumer and disease awareness campaigns.
"If you leave even a small chink in your regulations then you have got to have a strong enforcement capacity with some decent penalties to stop people from keeping on pushing the envelope. It is easier to have a complete ban on promotion because then they have either broken the law or they haven't".[4]

<u>The review process (para 2 f)</u>
Under the proposal, if a drug is rejected, or has restrictions placed on its use, if the pharmaceutical company does not agree with the price at which it is being offered or is not satisfied with outcome of the PBAC determination/recommendation, the company may apply for a review by an 'independent process'.

This suggests that the PBAC will no longer be the final arbiter and that some other as yet undefined body will be involved. We are concerned that the end result will be a fundamental undermining of the current PBAC processes.

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Medicines Working Group (part 3)
The purpose of the Medicines Working Group is to 'promote discussion and mutual understanding of issues relating to this annex'.

Healthy Skepticism seeks clarification on the proposed powers, purpose and membership of this committee. We are concerned that public sector decision makers received a balanced perspective.

Regulatory cooperation (part 4)
'The Parties shall seek to advance the existing dialogue between the TGA and the FDA with a view to making innovative medical products more quickly available to their nationals.'

We are concerned that this may provide a mechanism whereby the United States government, on behalf of the American pharmaceutical industry, may pressure the PBAC and the TGA into fast-tracking the approval of their products.

Fast tracking of pharmaceutical products rarely results in better health. Many drugs are found to be undesirable only after they have been in general use for several years and it is not unusual for drugs to be banned or restricted due to recognition of adverse effects after their general release.[9]
Very few new drugs that are so vastly superior to older, well understood medications, that the public would have benefited by them being rushed through the system in the manner suggested in the FTA. Most new drugs offer only modest, if any advantage over older drugs, and most are considerably more expensive.[10]

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[1] Haynes S. Unhealthy cynicism. Pharma in Focus 2004; 29 March http://www.pharmainfocus.com.au/opinion.asp?opinionid=12
[2] Sweet's potent drug. Media Watch ACB TV http://www.abc.net.au/mediawatch/transcripts/s1071337.htm
[3] State of awareness. Pharma in Focus. 2004; 29 March http://www.pharmainfocus.com.au/feature.asp?featureid=39
[4] Burton B. Drug industry to fight New Zealand's move to ban direct to consumer advertising. BMJ 2004;328:1036 (1 May), doi:10.1136/bmj.328.7447.1036-d http://bmj.bmjjournals.com/cgi/content/full/328/7447/1036-d
[5] Rhonda Galbally Review of Drugs, Poisons and Controlled Substances Legislation Final Report Therapeutic Goods Administration (Australia) 16 October 2001 http://www.health.gov.au/tga/docs/html/rdpdfr.htm
[6] OPENING THE MEDICINE CABINET: FIRST REPORT ON HEALTH ASPECTS OF PRESCRIPTION DRUGS. REPORT OF THE STANDING COMMITTEE ON HEALTH. House of Commons. Canada. April 2004 http://www.parl.gc.ca/InfocomDoc/Documents/37/3/parlbus/commbus/house/reports/healrp01-e.htm
[7] Steve Morgan and Barbara Mintzes. Opening more than the medicine cabinet. Winnipeg Free Press April 11th, 2004
[8] Les Toop, Dee Richards, Tony Dowell, Murray Tilyard, Tony Fraser, Bruce Arroll. Direct to Consumer Advertising of Prescription Drugs in New Zealand: FOR HEALTH OR FOR PROFIT? Report to the Minister of Health supporting the case for a ban on DTCA. New Zealand Departments of General Practice, Christchurch, Dunedin, Wellington and Auckland Schools of Medicine. February 2003 http://www.chmeds.ac.nz/report.pdf
[9] Lasser KE, Allen PD, Woolhandler SJ, Himmelstein DU, Wolfe SM, Bor DH. Timing of new black box warnings and withdrawals for prescription medications. JAMA. 2002 May 1;287(17):2215-20.
[10] Lexchin J. Are new drugs as good as they claim to be? Aust Prescr 2004;27:2-3 www.australianprescriber.com/index.php?content=/magazines/vol27no1/2_3_editorial.htm