

Women and Health Protection



A national working group of the
Centres of Excellence
for Women's Health Program
<http://www.whp-apsf.ca>

Action pour la protection de la santé des femmes



Groupe de travail du Programme
des centres d'excellence
pour la santé des femmes
<http://www.whp-apsf.ca>

May 4, 2004

Division of Dockets Management (HFA 305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket #2004D-0042
Draft Guidelines for Industry and FDA
Brief Summary: Disclosing Risk Information in Consumer-Directed Print
Advertisements

We are responding to the request for opinions on the above draft guidelines. As a coalition of Canadian health consumer groups, activists and academics concerned about prescription drug policies, FDA guidelines on prescription drug ads affect us in two ways: (1) ads from American media "bleed" over the border and influence drug use of Canadian consumers and (2) Canadian policy makers are under pressure from industry to harmonize our policies with FDA policies.

Consumers in all countries need independent, unbiased information about drug use. Advertising to consumers contributes to over-use and misuse of drugs, drives up health care costs and requires costly monitoring that the FDA has not been able to provide. For these reasons, we believe the FDA should ban DTCA. Although the above-mentioned draft guideline states that "truthful, non-misleading and scientifically substantiated" advertising "can convey useful information to patients" (p 7), this description depicts an elegant glass shoe while advertising by its very nature is an unwieldy foot. By contrast, an independent system of information could fit the above requirements with ease. This is why we recommend, below, that research to assess what information is most useful to consumers *always include a control group in which the information is prepared by an independent, unbiased source.*

In the past we have joined with like-minded organizations in the United States to promote an American ban on DTCA and we will continue to lobby the FDA until this goal is achieved. Our organization supports the Canadian ban on advertising of prescription drugs to consumers and has expressed concern to our government that the law is not being enforced. We are pleased that in its April 2004 report, *Opening the Medicine Cabinet: First Report on Health Aspects of Prescription Drugs*, an all-party committee of Canada's House of Commons concurred with this position and has recommended that the Canadian ban on DTCA be enforced, that funds for vigorous monitoring be provided, and that the federal government dedicate resources to providing unbiased, publicly funded information on prescription drugs to Canadians.

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We recognize that the current political environment in the US militates against an American ban on DTCA. We are therefore responding to the draft "Guidance for Industry" on print DTCA in the spirit of encouraging an interim guideline that will improve the present guideline until a ban can be imposed. We recommend the following:

- That the brief summary be in lay language and in easily legible font size;
- That the brief summary include efficacy information;
- That the brief summary highlight the most common and the most serious adverse reactions, contraindications, warnings and precautions;
- That the adverse reaction and efficacy information be given in absolute risk figures and that penalties be imposed for mixing absolute and relative risk figures;
- That a statement be included indicating how long the drug has been monitored in clinical trials and noting that some side-effects show up only after long-term use;
- That a statement be included indicating the number of people who have taken the drug in clinical trials;
- That a statement be included to remind consumers that FDA approval does not guarantee the drug is safe and efficacious for all users;
- That a statement be included to remind consumers that the information is not comprehensive and directing readers to a source of FDA-approved labeling information;
- That all ads be subject to pre-clearance by the FDA and that the FDA be given adequate funds for pre-clearance, post-publication monitoring and investigation of complaints;
- That the FDA commission research in which actual ads developed under the new guidelines are compared in controlled experiments with samples of unbiased information prepared by an independent source.

Respectfully submitted,



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for Women and Health Protection (Canada)