

WARNINGS NEEDED IN OTC DRUG ADVERTISING

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Summary of report by Greene et al. (2012)

Based on an analysis of benefit and risk information in all print and broadcast advertisements from 4 commonly used prescription drugs that were the subject of extensive Direct to Consumer Advertising (DTCA) promotion before and after OTC shift (i.e., loratidine Rx-to-OTC switch in 2002, omeprazole in 2004, orlistat in 2007, and cetirizine in 2008), Greene *et al* observed 'less presentation of potential harms, DTCA for OTC medications frequently omitted identification of drugs by their generic names, both of which are key tools for consumers seeking independent information on risks, benefits, and costs.'

The investigators concluded: 'The FDA's "fair balance" requirements covering prescription DTCA do not necessarily result in balanced presentations of risks and benefits, and these guidelines are known to be inconsistently enforced. However, our analysis suggests that DTCA after OTC switch presents even less information for making an informed decision, at a time when consumers must have more knowledge of whether medications' potential benefits are worth their risks and costs.' <http://jama.jamanetwork.com/article.aspx?articleid=1357255>

Greene *et al.* bring further visibility to unbalanced OTC drug advertising. We add the perspective of the licensed pharmacists regarding the need for warnings in OTC advertising of higher risk medicines such as acetaminophen (liver disease), ibuprofen (drug-induced allergy) among others. In recent work by Soller, Mulvaney *et al.* (2012)², a high majority (> 90%) of surveyed California pharmacists and pharmacy students (n=421) favor: warnings in OTC drug advertising for rare, serious side effects at recommended doses and for predictable serious side effects at greater than recommended doses; and specific warnings in OTC advertising for choking (psyllium with inadequate fluid intake); GI bleeding (aspirin); ibuprofen (kidney toxicity); and acetaminophen (liver toxicity). Most (78-86%) favor use of boxed warnings accompanying print advertising (e.g., "acetaminophen can cause serious liver damage. Take only at recommended doses or as directed by a physician"), use of minimum type size, and placement in proximity to the advertising claim.

In a bygone era, opposition to warnings in OTC advertising was framed on the supposition that, unlike patients, consumers get a comprehensively labeled carton or bottle at the time of purchase of an OTC medicine, and thereby receive all the drug information they need for

safe and effective drug use according to label recommendations. Today, however, patients (i.e., those under physician supervision) receive drug warnings from physicians, pharmacists, retail drug monographs distributed with dispensed medicines, medication guides, direct-to-consumer advertising and the Internet. Hence the opposition's proposition of the OTC label as the sole keeper of essential drug information for medication users at the point of purchase and customary use has a questionable basis.

There is no logical argument for why the rules of engagement governing fair balance in drug advertising should be so substantially different between Rx and OTC medicines. A change is needed through new regulations and/or a legislation encompassing a shift in authority for OTC advertising from the Federal Trade Commission to the Food and Drug Administration. Higher risk OTC medicines with potentially serious and life-threatening consequences due to use, misuse or abuse should be identified, and suitable warnings should be developed to accompany advertising of these medicines in all media.

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2. Soller RW, Mulvaney M, et al. Warnings in nonprescription drug print advertisements. *SelfCare* 2012;3(3):56-66