

WARNINGS IN OTC PRINT ADVERTISEMENTS TO HELP CONSUMERS SELF-SELECT NONPRESCRIPTION MEDICATIONS

Mark Mulvaney, BS, PharmD Candidate, R William Soller, PhD, Lorie Rice, MPH, Michael J Negerete, PharmD

Center for Consumer Self Care, Department of Clinical Pharmacy University of California, San Francisco. School of Pharmacy. *SelfCare*2012;3(6):138 - poster1

BACKGROUND

- U.S. consumers often self care using over-the-counter (OTC) medications^{1,2}. Estimated U.S. OTC sales in 2006 were \$15.4 billion (excluding Wal-Mart). 82% of U.S. women and 71% men report using an OTC medicine in the last six months to treat at least one common health ailment.
- Consumer understanding of the risks associated with OTC medicines is concerning². 30% of consumers felt there was no risk with OTC analgesics. 44% report taking more than the recommended dose on the label.
- Many OTC products have come under renewed scrutiny due to safety concerns (e.g., acetaminophen, children's cough & cold products, and phenylpropranolamine)
- FDA has renewed its emphasis on medical product risk communication³. Recent approaches include OTC Drug Facts Label, Patient Information Sheets, and risk management programs such as iPLEDGE. Implicit in this is the expectation of increased responsibility by the consumer.
- FDA regulates Rx direct-to-consumer advertising, and requires a written or voice over brief summary as part of print or audio DTC advertising of Rx drugs. But, it is the Federal Trade Commission (FTC) which regulates OTC advertising. Although the FTC requires fair balance of claims in these advertisements, it does not require OTC ads to bear product warnings.

RESEARCH OBJECTIVES

Research question: Do California licensed pharmacists and UCSF School of Pharmacy interns support the use of warnings in OTC print advertising to help consumers self-select nonprescription medications?

Aims: 1. Assess whether severity and/or frequency of an ADE affects pharmacist opinions as to the need for warnings in OTC drug advertising. 2. Assess preferences in warning language for a model OTC ingredient with a known serious risk. 3. Determine preference as to how warning in OTC print advertisements should be formatted.

METHODOLOGY

• Prospective design. • Self administered online survey using www.surveymonkey.com distributed via email. • Participants included California Pharmacist Association members and UCSF School of Pharmacy interns. • Data was collected between November 2007 – March 2008. • No incentives were given for completing the survey. • Survey question included evaluation on a 5 point Likert scale and one open ended response question. • Response rate of 24.8%, with pharmacists responding at 21% (n=253) and pharmacy interns at 34% (n=168). • Completion rate of 84.2%, with 500 survey starts, and 421 completions. • Results analyzed using Chi Square Goodness of Fit Test and Chi Square test for trends.



RESULTS

Should OTC print advertisements contain warnings?

Figure 1. Overwhelming support for warnings in OTC print ads 'Do you favor warnings in OTC drug print advertising?' (n=421, p<.0001)

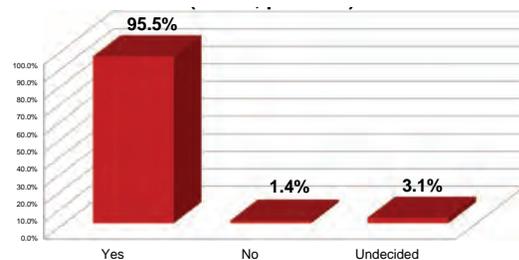


Figure 2. 'Would warnings in OTC advertisements help consumers self-select medications?' (n=431, p<.0001)

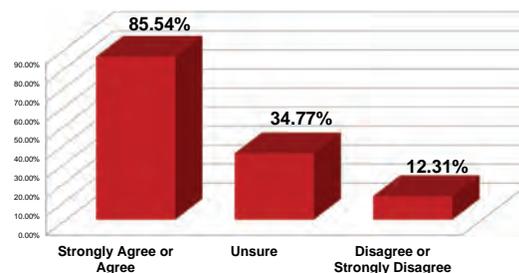


Table 1: Demographics - Pharmacists and Interns

The majority of participants were women with ≥ 7 years in community practice who regularly counseled patients on OTC medications

Age (n=482)		Gender (n=482)	
20-25 years old	21.8%	Male	41.5%
26-30 years old	19.9%	Female	58.5%
31-40 years old	10.4%		
41-50 years old	13.3%	Years in community practice (n=460)	
51-60 years old	20.3%	Never	8.0%
61-70 years old	10.4%	Less than 1 year	15.2%
71 or older	3.9%	1-3 years	24.3%
		4-6 years	7.8%
		7 or more years	44.6%
Area of Practice (n=482)		Patients counseled on OTC's per week (n=460)	
Pharmacy Administration	5.6%	0-5 patients	43.7%
Community Pharmacy	36.5%	6-10 patients	17.8%
Inpatient Pharmacy	5.0%	11-20 patients	13.0%
Pharmacy Intern	40.2%	More than 20 patients	25.4%
Other	12.7%		
Patients counseled each day (n=460)			
0-5 patients	41.7%		
6-10 patients	19.6%		
11-20 patients	12.2%		
More than 20 patients	26.5%		

Figure 3. Should OTC medications with the following side effect profiles contain warnings in their print advertisements? (n=434, p<.0001)

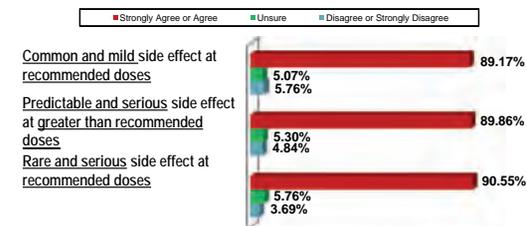


Figure 4. Should these drug-adverse effect associations be the subject of warnings? (n=423, p<.0001)

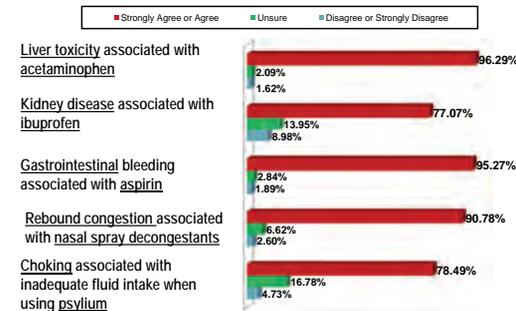


Figure 5. Preferences for content of warning in OTC advertising for acetaminophen containing products (n=431, p<.0001)

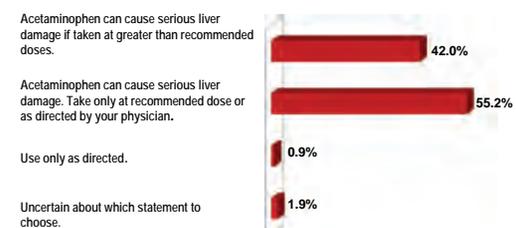
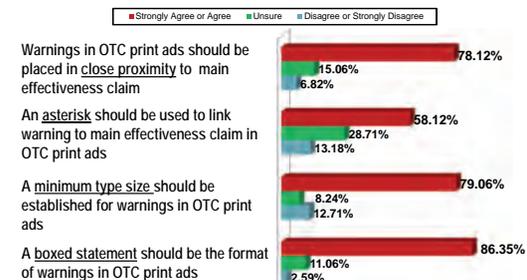
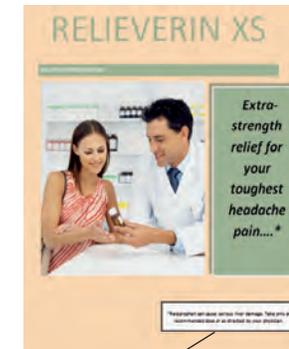


Figure 6. Format preferences for print warnings (n=425, p<.0001)



RESULTS

Preferred Warning Format for Mock OTC Print Ad (see figure 6)



- Boxed statement
- Font size ≥ 10 points
- Asterisk link to claim
- Close proximity to claim

*Releprophen can cause serious liver damage. Take only at recommended doses or as directed by your physician.

Note, Releprophen is a fictitious drug brand name

DISCUSSION

Limitations: The Pharmacy Foundation of California may represent a subset of pharmacists who are more engaged in health policy issues. However, pharmacy students had similar responses on this issue, suggesting many pharmacists in California share similar views. The survey was limited to California pharmacists. However there is no reason to believe other pharmacists would not share this viewpoint. The survey does not address what consumers would prefer to see, how they would use the information, and whether it would be of benefit to them in selecting OTC products This is area for further study. OTC advertising is comprised of media other than print including television and online which may provide more exposure to patients. Again, this is an area for further study.

CONCLUSION

Overwhelming majority of pharmacists and interns favored warnings in OTC print advertising. However, 34% expressed uncertainty about the impact of warnings on consumer self selection.

A majority of pharmacists and interns felt OTC print ad warnings would aid consumers in self-selecting OTC drug products.

There were strong formatting preferences regarding how to link the warning to the effectiveness claim.

REFERENCES

1. OTC Fact and Figures. Consumer Healthcare Products Association. Available at: <http://www.chpa-info.org/ChpaPortal/PressRoom/Statistics/OTCFactsandFigures.htm>. Accessed February 3, 2008
2. Attitudes and Beliefs About the Use of Over-the-Counter Medicines: A Dose of Reality. Available at: www.bemedwise.org/survey/summary_survey.pdf. Accessed March 3, 2008
3. FDA website. Available at: <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01648.html>. Accessed February 8, 2008