

## Warning Disclosures in Televised Over-the-Counter Drug Advertisements

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### ABSTRACT

*This study investigated the effects of warning disclosure variations in two over-the-counter (OTC) drug televised mock advertisements, Paranol and Parachlor on warning recall and recognition. Experimental design was a nested-factorial. Number of warning statements (one, two and four) was nested within two levels of warning specificity (specific and general) whereas warning conspicuousness (high and low) and warning specificity were arranged in a factorial design. Total of 252 undergraduate students at Chiang Mai University, assumed as non-experts on drug knowledge, were assigned randomly to Paranol advertisement and other 196 students to Parachlor advertisement. Participants viewed a 20-minute television drama program embedded with mock advertisement and then were asked to complete a questionnaire. All data were analyzed by ANCOVA with involvement of self-medication as a co-variable. The effects on warning recall showed that there were significant main effects of warning conspicuousness ( $p < .01$ ) for Paranol. Warnings presented in high conspicuous conditions produced greater recall than those presented in low conspicuous conditions for all levels of number of warning statements. For Parachlor, a significant interaction effect between warning conspicuousness and number of statements was found ( $p < .01$ ). While high conspicuous warnings produced greater recall than low conspicuous warnings in two-and four-statement specific warnings, there were no differences between high and low conspicuous conditions in one-statement general warning. The results on warning recognition showed significant interaction effects between warning conspicuousness and warning specificity for both Paranol and Parachlor ( $p < .01$ ). Although high conspicuous warnings produced greater recognition than low conspicuous warnings in specific warnings, there were no differences between high and low conspicuous conditions in general warning. These results implied that successful communication by television depends on warning conspicuousness, number of statements and warning specificity. To enhance warning memory, especially in specific form, warnings should be presented in high conspicuousness.*

**Key words:** Warning, Over-the-counter (OTC) drug advertisement, Conspicuousness, Warning specificity, Number of statements, Recall, and Recognition

### INTRODUCTION

Over-the-counter (OTC) drugs are commonly used for self-medication and are viewed as safer than prescription drugs (Morris et al., 1985; Morris et al., 1998). Although OTC drugs are generally considered safe, they can occasionally cause significant and dangerous side effects, particularly when consumers overuse, misuse or combine them with other drugs,

foods or medical conditions (Cirone, 1997; Ellen et al., 1998; Johnson, 2001; Elliote, 2002). To avoid such problems, giving sufficient and proper OTC drug information is important for consumers' decision-making.

Advertising is one important source for giving OTC drug information to consumers. Several studies have indicated that consumers acquire information about OTC drugs through advertising (Strutton and Lumpkin, 1992; Eppright and Cunningham, 1994; Blenkinsopp and Bradley, 1996; Bennoson et al., 1997). Although advertising is an important channel through which drug information can be communicated, many studies have found that drug advertisements may not provide sufficient information on effectiveness and sometimes are judged to be misleading (Wilkes et al., 1992; Herxheimer et al., 1993; Lal, 1998; Chandra and Holt, 1999). Misleading advertisements could lead to inappropriate comprehension of product information and incorrect product selection, resulting in product misuse and possible adverse effects.

Risk information or warnings are supposed to give supplemental information to aid in consumers' decision-making as well as to protect the advertiser from accusations of misleading or deceptive advertising (Foxman et al., 1988; Hoy and Stankey, 1993). To prevent misleading advertising of OTC products, the Thai Food and Drug Administration (Thai FDA) requires all pharmaceutical companies to provide warning disclosures for OTC drugs. Warning messages in advertisements on television must be clear and conspicuously presented in both audio and visual forms. A number of studies in Thailand have found that some warning messages of OTC drug advertisements are not presented clearly and fail to abide by the regulations (Pingsuttiwong et al., 1992; Prasert, 2001; Chowwanapoonpohn et al., 2003). For example, warnings are often presented in small print, placed in a non-attractive position and briefly shown. Vocal warnings are frequently presented at high speed, hence consumers cannot understand and are unaware of the drug usage. From these problems, it is clear that OTC drug warning messages may not guarantee that the warning is fully effective.

Experimental investigation is needed to examine the influence that format and content of warnings have on all stages involved in consumer information processing. Lehto and Miller (1986) described eight sequential human information-processing steps that they deemed important for a warning to be effective: 1) exposure to the warning, 2) attending to the warning, 3) actively processing the warning, 4) comprehending and agreeing with the warning, 5) storing the warning in memory and doing search and retrieval as necessary, 6) selecting the appropriate response, 7) performing the response, and 8) responding adequately. Failures at any of these stages will decrease the effectiveness of the warning. For example, if a warning is small in size, it might not be noticed, consequently the user would not realize the information.

Since the effectiveness of any warning depends initially on whether all stages are processed, especially the initial noticeability of warnings, presentation of warnings is often manipulated to ensure that they will be seen. The purpose of the present study was to identify factors which affect warning processing of consumers. This study examined the effects of format (warning conspicuousness) and content (warning specificity and number of statements) of warning variations for OTC drug advertisements on warning recall and recognition.

It was expected that highly-conspicuous warnings would be noticed more often and the messages that they contain would be more likely remembered compared to less-conspicuous warnings. The increase in number of warning statement would increase the amount of information processing. Increase in information processing is presumed to lead to greater memory

of warnings. The specificity of the product warnings was also assumed to influence information processing. It was expected that specific warnings would produce greater memory than general warnings.

The results could be useful for policy makers to determine and consider the most appropriate form of warning in OTC drug advertisements. In addition, the results could be beneficial for drug manufacturers and marketers to design more effective advertisements, especially warnings, which would provide clearer and more accurate information for consumers.

## MATERIALS AND METHODS

### Design

The experimental design was a nested-factorial design. The number of warning statements was nested within two levels of warning specificity (general and specific), whereas two levels of warning conspicuity and two levels of warning conspicuity (high and low) were arranged in a factorial design. Seven conditions, in which no warnings served as a control, are shown in Figure 1.

In this study, involvement of self-medication was used as a co-variable because previous studies indicated that an individual's level of involvement had an effect on consumer information processing (Celsi and Olsson, 1988; Solomon, 1999).

**Figure 1.** Nested-factorial test design.

		<u>Test Group</u>			<u>Control Group</u>
		General Warning	Specific Warning		
		1 statement	2 statements	4 statements	
Warning Conspicuousness	Low	General (1) Fast speaking rate + plain, white, small print on ad background, placed at bottom	Specific (2) Fast speaking rate + plain, white, small print on ad background, placed at bottom	Specific (4) Fast speaking rate + plain, white, small print on ad background, placed at bottom	
	High	General (1) Normal speaking rate + bold, black, large print on white background, placed in the middle	Specific (2) Normal speaking rate + bold, black, large print on white background, placed in the middle	Specific (4) Normal speaking rate + bold, black, large print on white background, placed in the middle	

Warning message specificity was divided into two categories: general and specific warnings. From the real situation of warning presentation, the Thai regulations require warning disclosures for specific products where a general warning is usually presented in one statement. Therefore, general warnings of test advertisements were presented in one statement whereas specific warning messages were presented in two or four warning statements.

The numbers of warning statements were divided into 3 levels: one, two, and four statements, in which one statement was included in the general warning and two and four statements were presented with specific warnings.

Conspicuousness of warning was categorized into high and low. Conspicuousness of warning was manipulated by varying the type size, message contrast background, position on the screen and speaking rate. High conspicuous warnings used a bold, black, large print on a white background, placed in the middle of the screen and with the announcer speaking at a normal rate. Low conspicuous warnings used a plain, white, small print on the ad background, placed at the bottom of the screen and with the announcer speaking rapidly.

### Participants

Participants were undergraduate students who enrolled in academic year of 2004 at Chiang Mai University. All were presumed to lack drug knowledge. They were ineligible if they were studying health sciences. For *Paranol*, 252 students were assigned randomly to the seven conditions. Fifty-nine percent of the participants were female. For *Parachlor*, other 196 students were assigned randomly to the seven conditions. Of these participants, 58% were female.

### Materials

Mock advertisements were created for two different category drugs, a pain relief (*Paranol*) and a cold medication (*Parachlor*). Each advertisement was included in a 20-minute television program along with commercials for other products and services. A drama program previously aired on Thai Channel 3 was selected because this program frequently shows OTC drug advertisements during commercial breaks. Each of three breaks contained five commercials, viz., one drug advertisement randomly placed and the remaining four commercials concerning non-OTC-related products. The remaining four commercials in each break included either those on alcoholic or stimulant beverages in which two commercials were mandated to present warning disclosures.

The warnings used in this study were constructed from the current warning on OTC drug labels. A general warning statement for *Paranol* and *Parachlor* was presented in the same word by using one statement which was "read the warnings every time before using the medicine". The specific warning statements for both advertisements were presented in two and four statements, but were presented in different words. Two warning statements of *Paranol* were 1) overusing this medicine may lead to liver damage and 2) read the warning every time before using the medicine. The four warning statements for *Paranol* were 1) do not use this medicine for relief of muscle pain which is caused by strenuous working, 2) while using the medicine, alcoholic beverages should not be drunk, 3) patients who have liver or kidney diseases should consult a physician or pharmacist before using this medicine, and 4) take the medicine by the indicated dosage and do not continue using the drug for more than 5 days. The two warning statements for *Parachlor* were 1) this medicine may cause drowsiness; consequently, do not drive or operate machinery after consumption and 2) overusing the medicine may lead to liver damage. The four warning statements for *Parachlor* were 1) this medicine may cause drowsiness; consequently, do not drive or operate machinery after

consumption, 2) overusing the medicine may lead to liver damage, 3) avoid taking the medicine with alcoholic beverages, and 4) do not give to children <1 year old, to asthmatic or glaucoma patients, patients with prostatic hypertrophy, or with urinary problems.

### Procedure

The participants were not informed about the fact that the purpose concerned warnings. They were asked to sign a consent form, view the entire drama program and complete the questionnaire on self-medication. After the participants had watched the program, the questionnaire was distributed.

The questionnaire composed of four parts. The first part measured involvement of self-medication. Involvement was measured by a four-item, five-point Likert-type rating scale. The second part of the questionnaire measured free recall of the warnings where the participants were asked to write, as specifically as possible, any product-related warnings that they saw or heard during the program. The third part measured cued recall of warnings content with open-ended question. The participants were asked to write down all of the warning messages in the drug advertisement that they could remember. The last part was a 7-checklist questionnaire assessing warning recognition. After the participants had completed the questionnaire, all of them were debriefed and paid.

Although the participants wrote down all warning message recalls for open-ended question, the scores corresponding only to warning recall on the test product were used for the analysis. Each answer was scored one point. The scoring for each statement was considered as follow: zero point for no answer or a completely-incorrect answer, 0.25 point for an incorrect answer which contained recognizable parts of the warning, 0.50 point for mostly-correct, but insufficiently-precise response, 0.75 point for a nearly-correct answer with grammatical variation, and 1 point for exact recall. The total warning recall score is the summation of a free recall score together with the cued recall score. The scoring of warning recognition was straightforward: one point for a correct choice and zero for an incorrect one.

Since the warning recall and recognition scoring was one point for each statement, therefore, the scores for the three levels of statements (1, 2, and 4 statements) were one, two, and four points, respectively. To compare these three levels on the same scale as warning recall and recognition, the scoring of one and two statements were transformed into four points.

The classrooms at Faculty of Pharmacy, Chiang Mai University and the study rooms of Chiang Mai University's dormitories were used for the test setting.

## RESULTS

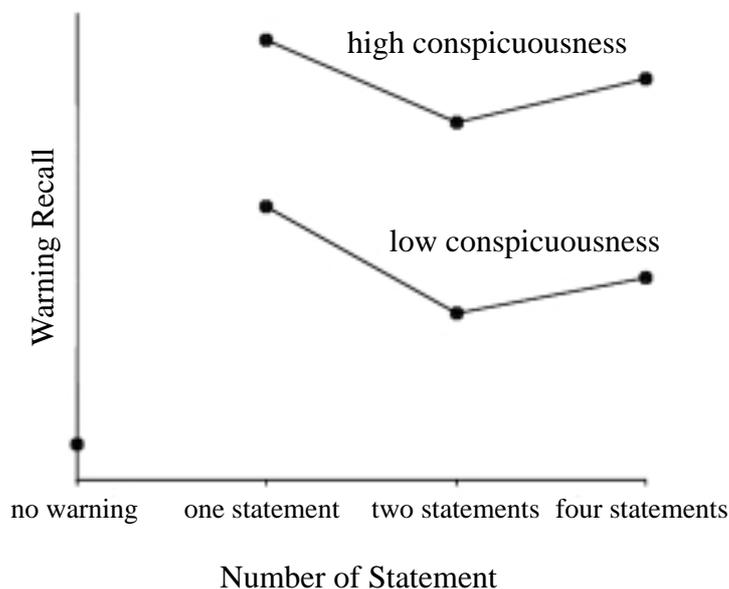
Data were analyzed by an analysis of covariance (ANCOVA) with involvement of self-medication as a co-variable. The alpha level of 0.05 was set for a priori. Results are shown in two parts by dependent variables: warning recall and warning recognition. In each part of dependent variables, the results are presented separately for each drug, *Paranol* and *Parachlor*. The means of these two dependent variables are shown in Table 1.

**Table 1.** Mean of warning recall and warning recognition.

	No Warning	Low Conspicuousness			High Conspicuousness		
		General		Specific	General		Specific
		One	Two	Four	One	Two	Four
<b>Warning recall</b>							
<i>Paranol</i>	0.24	2.33	1.49	1.77	3.81	3.04	3.43
<i>Parachlor</i>	0.02	3.07	0.91	1.06	4.86	4.64	2.68
<b>Warning recognition</b>							
<i>Paranol</i>	1.00	3.78	2.06	2.53	3.78	3.11	3.42
<i>Parachlor</i>	0.25	3.57	1.50	1.75	4.00	3.36	3.29

**Warning recall*****Paranol* drug advertisement**

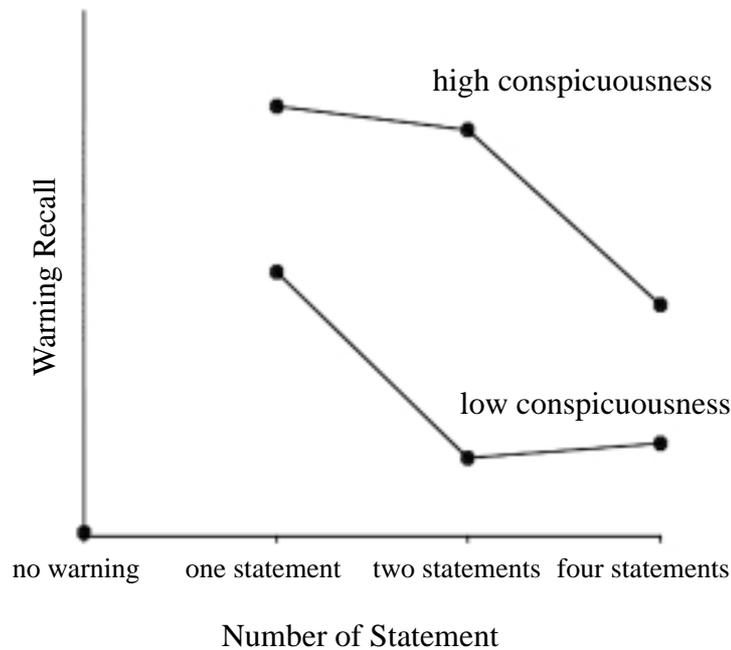
Figure 2 shows the significant main effects of warning conspicuousness [ $F(1, 244) = 30.02$ ,  $p < .01$ ] and warning specificity [ $F(1, 244) = 4.57$ ,  $p = .03$ ] on warning recall for *Paranol* drug advertisement. Warnings presented in high conspicuous conditions had greater recall than warnings presented in low conspicuous conditions for all conditions; 1) one statement within a general warning ( $M$  3.81 vs. 2.33), 2) two statements within a specific warning ( $M$  3.04 vs. 1.49), and 3) four statements within a specific warning ( $M$  3.43 vs. 1.77). Moreover, general warning messages were recalled more than specific warning messages for both high warning conspicuousness ( $M$  3.81 vs. 3.24) and low warning conspicuousness ( $M$  2.33 vs. 1.63).

**Figure 2.** Mean warning recall for high and low warning conspicuousness by the number of warning statements for *Paranol* drug advertisement.

**Parachlor drug advertisement**

The results showed that there was a significant interaction between warning conspicuousness and the number of statements [ $F(1, 188) = 9.22, p < .01$ ]. This indicated that the effects of the different warning conspicuousness were not the same for all numbers of statements (Figure 3). In order to interpret the interaction effects, the simple effects of three levels of the number of warning statements were examined separately. For one-statement general warning, there were no significant differences between high and low conspicuous conditions. For two-statement specific warnings, warnings presented in high conspicuous conditions had significantly greater warning recall than warnings presented in low conspicuous conditions ( $M 4.64$  vs.  $0.91, p < .01$ ). For four-statement specific warnings, there were also significant differences between high and low conspicuous conditions ( $M 2.68$  vs.  $1.06, p < .01$ ).

**Figure 3.** Mean warning recall for high and low conspicuousness by the number of warning statements for *Parachlor* drug advertisement.

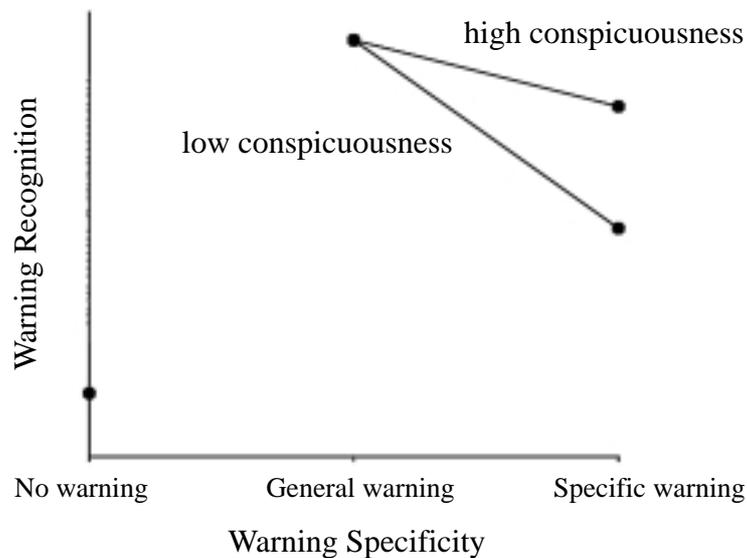


**Warning Recognition**

**Paranol drug advertisement**

There was a significant interaction between warning conspicuousness and warning specificity [ $F(1, 244) = 10.67, p < .01$ ] on warning recognition (Figure 4). The results also indicated that the effects of various warning conspicuousness were different for all levels of warning specificity. In order to interpret interaction effect, the simple effects for specific and general warnings were analyzed separately. In two- and four-specific warning statements, warnings presented in high conspicuous conditions had significantly greater recognition than warnings presented in low conspicuous conditions ( $M 3.42$  vs.  $2.53, p < .01$  and  $M 3.11$  vs.  $2.06, p = .04$ , respectively). In general warning message, there were no significant differences between high and low conspicuousness.

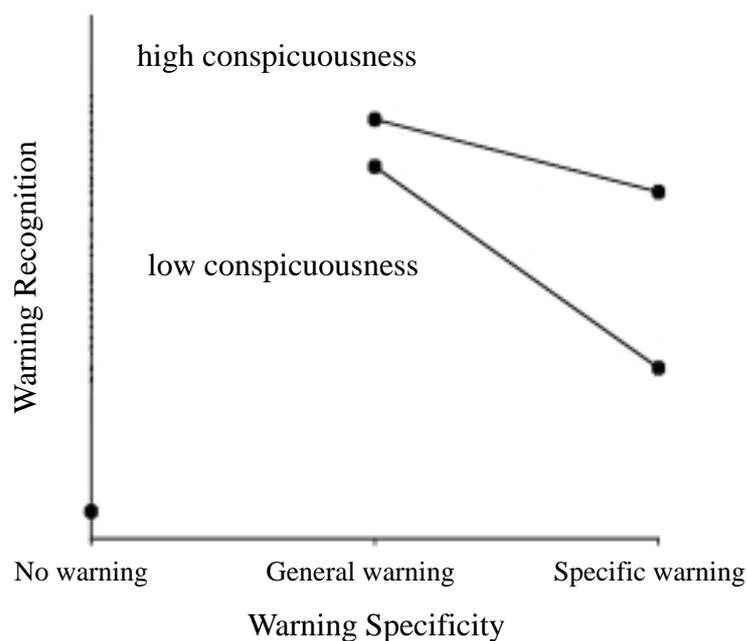
**Figure 4.** Mean warning recognition for high and low conspicuousness by warning specificity for *Paranol* drug advertisement.



#### ***Parachlor* drug advertisement**

The results of *Parachlor* drug advertisement were consistent with those of *Paranol*. Figure 5 shows the significant interaction effects between warning conspicuousness and warning specificity [ $F(1, 188) = 15.92, p < .01$ ]. In order to interpret interaction effect, the simple effects for specific and general warnings were analyzed separately. Consistency results were found in two- and four-specific statements, warnings presented in high conspicuous conditions had significantly greater recognition than warnings presented in low conspicuous conditions ( $M 3.29$  vs.  $1.75, p < .01$  and  $M 3.36$  vs.  $1.50, p < .01$ , respectively). In one statement within general warning message, there were no significant differences between high and low conspicuousness.

**Figure 5.** Mean warning recognition for high and low conspicuousness by warning specificity for *Parachlor* drug advertisement.



## DISCUSSION

Variations in warnings influenced the participants' recall and recognition in five aspects. First, all experiment conditions with warnings raised warning recall and recognition more than control condition containing no warning message. This result was consistent with Barlow and Wogalter (1993), who found that in some warning conditions, knowledge and memory about the hazards of alcohol consumption were greater than in control condition. Therefore, it could be indicated that warnings in television advertisements for OTC drugs can effectively communicate product-related warnings.

Second, high conspicuous warnings produced greater recall and recognition than low conspicuous warnings in specific warnings (both two and four statements). In order to enhance recall and recognition in specific warnings, warnings should be presented in a high conspicuousness. The results are consistent with several studies which showed that participants retain more information from highly-conspicuous warnings than from less-conspicuous warnings (Young and Wogalter, 1990; Barlow and Wogalter, 1993; Truitt et al., 2002).

Third, no differences between high and low conspicuousness on warning recall and recognition were found in one statement within general warning for several tests. This may cause prior exposure or familiarity with drug warnings. General warning stated as "read the warning every time before using the medicine" is not a novel statement. Based on Thai drug regulations, several OTC drugs must present the same general warning message in their commercials. In this study, 50.0% of the participants had seen OTC drug advertisements more than 3 times within one week. This finding may imply that about half of the participants knew about warning messages. They generally saw and/or heard this general warning message from other drug commercials, thus many were familiar with this statement. Godfrey et al., (1983) found that consumers who had greater familiarity with products rated them to be less hazardous, and they were less likely to look at the warnings. In addition, general warning was presented in short and simple phrase, thus general warning in both high and low conspicuous conditions can be easily remembered.

Fourth, the main results showed that a general warning (one statement) produced significantly greater recall and recognition than specific warnings (two and four statements) in low conspicuous messages. There were no significant differences of warning specificity in high conspicuous warnings. However, warning presented in a general form tended to have greater recall and recognition than specific warnings. These findings were inconsistent with previous studies which have shown that specific information is better recalled than general information (Houston and Rothschild, 1980; Morris et al., 1989; Smith, 1990). With the same length of risk information, a warning that has an unambiguous or specific warning (e.g., "a side effect of the drug is gout") is easily elaborated. On the other hand, an ambiguous or general warning (e.g., "the drug causes serious side effects") is more difficult to elaborate because a general warning does not have an easily-available context, making it difficult for the consumer to form a distinctive memory trace (Schwanenflugel and Shoben, 1983). The explanations for the inconsistent results with previous studies may involve the amount, novelty and complexity of information. General warning in this study was presented in one statement in a shorter message whereas specific warnings were presented in two and four statements with longer message. Several studies have shown that both recognition and recall decline with increasing content (Roberts, 1972; Atkinson and Juola, 1973). Therefore, longer messages with two and four specific warnings would lead to the lower warning recall and recognition. In addition, general warning is not complicated and is not new to participants. As mentioned above, participants generally expose to general warning from other OTC drugs. They might have prior knowledge and memory of general warning. These details may

explain why participants who are exposed to general warning have greater recall and recognition than those exposed to specific warnings.

And fifth, although the results showed no differences in warning recall and recognition between two and four statements in specific warnings, the latter tended to have higher recall and recognition than the former. This finding concurs with Morris et al., (1989) who found that the disclosure of more-risk messages produced greater risk awareness (test recall) than shorter-risk messages. When more-risk information is presented up to some limit, an increase in elaborative processing of these risks is expected. Increased elaboration is presumed to lead to greater awareness of risks.

### **Limitations**

There were a few limitations in this study. First, the participants viewed new television commercials which might lead to greater attention level. Second, this study was performed in setting conditions while attempts were made to simulate natural viewing conditions. Thus, participants' attention levels to advertising might be greater than viewing at home. However, to minimize the impact of these two effects, the data were analyzed by comparing with the control group. And third, the participants were all undergraduate students, which could limit the results' generalizability to other subject populations. However, undergraduate students are one of several groups who purchase and take OTC drugs for self-medication

### **CONCLUSION**

The results from this study help clarify that in order to increase warning effectiveness, both format and content of warnings had to be taken in consideration. Variations in format and content of warnings had an impact on consumers' information processing.

Although no differences between high and low conspicuous conditions were found in a general warning message, high conspicuous warnings produced greater recall and recognition than low conspicuous warnings in specific warning messages. These results lead to the conclusion that the higher conspicuous warnings, the more recall and recognition increasing of specific warnings.

This study also found that warning presented in general form produced greater recall and recognition than warning presented in specific form. However, this finding could not be interpreted that general warning produced better recall and recognition than specific warnings. The reasons may be that general warning message was presented in one statement while specific warning messages were presented in two and four statements which were longer and more complex than general warning. Therefore, additional study should be performed to find the proper form of warning when compared with the same length of warning information.

While one statement within general warning produced greater recall and recognition than two-and four-specific warning statements, four statements tended to have higher recall and recognition than two statements. Therefore, within specific warnings, more-warning messages may produce greater recall and recognition than shorter-warning messages. However, further study is needed to find the proper number of warnings.

These results show that successful warnings in the televised advertisements depend on both format and content of warnings. The mere presence of a warning in advertising does not guarantee that it will be noticed, attended to or remembered. In order to increase warning effectiveness, public policy should force drug manufacturers and marketers to follow the regulations, especially warnings should be presented in highly-conspicuous condition.

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