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Influence of presentation modality on communication of pharmaceutical risk information in direct-to-consumer (DTC) television commercials

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Abstract

Direct-to-consumer (DTC) prescription drug advertising markets medications requiring a physician's script to the general public. In the U.S., DTC prescription drug advertising includes risk disclosures (i.e., side effects and contraindications) in auditory (voice) or both auditory and visual (text) parts of the commercials. Little research has examined the factors that affect the communication of risk disclosures. This research attempted to identify factors that influence recall and recognition of risk disclosures in DTC prescription drug television commercials. The results showed that risk disclosures presented either visually or visually and auditorily increased the likelihood of recall and recognition compared to no presentation. Risk disclosures presented concurrently in visual and auditory modalities produced the highest recall and recognition. The results suggest visual risk disclosures produce better recall and recognition than auditory risk disclosures. Finally, concurrent presentation of non-risk disclosures with risk disclosures produced lower recall and recognition compared to presenting only risk disclosures. Implications for the design of DTC prescription drug television commercials as well as directions for future research are discussed.

Keywords: Direct-to-consumer (DTC) television commercials, prescription drugs, risk communication

1. Introduction

Effective labeling of pharmaceutical products is important because the general public needs to know the risks, side effects, and contraindications associated with many types of drugs. Effective communication of drug benefit and risk information comprises a complex set of issues and has become more complicated and important given the increase of direct-to-consumer (DTC) prescription drug advertisements. The purpose of DTC prescription drug advertising is to market a prescription drug directly to the public even though they cannot purchase it directly. To purchase a prescription drug, individuals must get approval via a prescription written by a physician or other licensed medical professional. In the U.S., there must be a balanced presentation of benefit and risk information in DTC prescription drug advertisements (Prescription Drug Advertising, 2001). However, despite the importance of drug information for health and safety, there has been very little research examining the factors that facilitate or hinder the communication of this information.

The advantage of DTC prescription drug advertising is that it can be a useful way to provide prescription drug information to the public. These ads alert people to new treatment options and newly

marketed prescription drugs and encourage them to talk to their physician or pharmacist about drugs they have seen advertised (Pharmaceutical Research and Manufacturers of America, 2002; Redmond, 2002; Rosenthal et al., 2002). Proponents further posit that DTC prescription drug advertising can enhance the patient-physician relationship by encouraging people to take an active role in their own health.

However, some physicians and insurance companies criticize DTC advertisements for potentially harming the patient-physician relationship, in part, because physicians must spend more time dissuading patients that they do not need the drug they heard about (Lyles, 2002; Pinto, Pinto & Barber 1998). A related problem is that DTC prescription drug advertising may inadvertently increase the number of unnecessary physician visits (Redmond, 2002).

Another argument leveled against DTC prescription drug advertising is that these ads do not adequately communicate the risks of the drug being advertised (National Health Council, 2002). Using trained pharmacists to assess 39 print DTC prescription drug ads, Roth (1996), for example, determined that fully one-third of the ads did not present a fair balance of risk and benefit information. Unfortunately, advertisements that do not present a fair balance of a drug's risks and benefits may lead people who see them to believe that a drug is safer to use than it is in actuality.

One issue with current U.S. Food and Drug Administration (FDA) policy is that it does not require manufacturers to demonstrate the efficacy of their DTC prescription drug ads. As a result, it is not clear whether adherence to legal requirements governing the content and format of these ads translates into effectiveness. Given the serious consequences that may result from inappropriate use of prescription drugs, this fact suggests there is a need to systematically investigate the factors that facilitate or hinder the communication of risk information in DTC prescription drug advertisements, including individual components of the current legal requirements.

One component of the FDA prescription drug regulations requires that DTC prescription drug television ads include information relating to the major side effects and contraindications of the advertised drugs in either audio only or both audio and visual. In the U.S., most prescription drug television commercials present risk disclosures only in the auditory modality.

The purpose of this study was to investigate potential factors that may influence the communication of risk disclosures in DTC prescription drug television commercials. One issue addressed is whether risk disclosures are better conveyed by presentation in both visual and auditory modalities or one or the other alone as indicated by recall and recognition measures. An additional issue is whether concurrently presenting non-risk (benefit) disclosures in a competing modality will negatively affect risk communication by distracting people from focusing on the risk-related information when it is presented in a DTC television commercial.

2. Method

2.1 Participants

Participants were 180 (M = 20.6 yrs, SD =4.6) undergraduate students attending North Carolina State University. Fifty-seven percent (n = 103) of the participants were male. The average education level was 13.2 years (SD = 1.4) or a sophomore in college.

2.2 Materials and Design

Television commercials for six prescription drugs, 12 consumer products (distractors), and six primetime news programs were recorded from cable television using a digital video camera and then uploaded and stored on a Macintosh G4 computer. The names of the drugs, identities of the consumer products, and titles of the news program excerpts are presented in Table 1.

Digital video-editing software was used to alter the means by which risk and non-risk disclosures were presented in the prescription drug commercials. Initially, the six prescription drug commercials were stripped of all auditory and visual content besides the name of the drug. The stripped commercials served as the control condition for each drug commercial and were used as the foundation for developing the other five experimental conditions. A description of the type of information included in each of the manipulated conditions is presented in Table 2. Visual content presented on the top and/or bottom of the screen in the original drug commercial was removed by adding black bars, while content in the middle was removed by deleting scenes. Auditory content was removed by turning off the auditory track.

The five conditions that included risk disclosures (all except the Control) had content consisting of four side effects and two contraindication statements. The two conditions that included non-risk disclosures, Visual Risk & Auditory Non-Risk (VR & ANR) and Auditory Risk & Visual Non-Risk (AR & VNR), had content consisting of five indications and one adequate provision statement. The adequate provision statement consisted of (a) an Internet web page (URL) address, (b) a toll-free number to contact the manufacturer, or (c) an instruction to contact their physician for further information.

Table 1
Program content, names, and topic for the commercials (prescription drug and distractor) and program excerpts.

Program Content	Name	Topic
Prescription Drug Commercials	Advair	Asthma
	Ambien	Sleep aid
	Elidel	Eczema
	Paxil	Anxiety
	Prevacid	Acid reflux
	Zyrtec	Allergies
Distractor Commercials	Charmin	Toilet paper
	Clorox	Bleach
	Colgate	Toothpaste
	Equal	Sweetener
	Gain	Laundry Detergent
	Glad	Trash bags
	Merita	Bread
	Pledge	Furniture Polish
	Quaker	Breakfast cereal
	Stouffers	Read to eat meals
	Suave	Lotion
	Visine	Eye drops
Primetime News Excerpts	Colin Powell	
	Down the Drain	
	Dr. Sharistani	
	Lionel Tate	
	Moving Violations	
	Top Cop	

Table 2
Six variants of each prescription drug commercial were developed. Manipulated variables were type of information (risk vs. non-risk) and presentation format (visual vs. auditory).

Condition	Description
Control	No visual (text) or auditory (voice) disclosures
AR	Auditory risk disclosures only
VR	Visual risk disclosures only
VR & AR	Visual + auditory risk disclosures
VR & ANR	Visual risk + auditory non-risk disclosures
AR & VNR	Auditory risk + visual non-risk disclosures

Visual disclosures (both risk and non-risk) were presented such that only one statement was on the screen at a time. Auditory risk and non-risk disclosures conveyed the same information as their visual counterparts and were presented by a male voice at an average rate of 92 words-per-minute.

To prevent participants' familiarity with certain prescription drug commercials from affecting their memory of the information, the risk disclosures consisted of fictitious content. This was done to ensure that participants were recalling and recognizing risk disclosures from this study and not from past exposures to the actual commercials.

The re-configured commercials and news excerpts were combined to create six different programs. Each program contained six segments (i.e., pairings of a primetime news excerpt with a commercial cluster). Each commercial cluster was comprised of three 30-second commercials, one of which was a prescription drug commercial. Prescription drug commercial placement within the cluster was randomized to control for order effects. The pairings were arranged to ensure that all six drugs and all six experimental conditions were represented in each segment. No participant saw more than one disclosure version for each drug. Moreover, no participant saw a specific disclosure version more than once. A five second blank section was inserted after each segment to provide the experimenter with time to stop the program so the participants could rate the preceding segment. The completed programs were exported to DVD to allow presentation on a 48.26-cm (19-in.) color television.

2.3 Procedure

After reading and signing a consent form, participants completed a questionnaire containing basic demographic items and questions about their television viewing habits. The experimenter next read a set of scripted instructions that told participants they would be asked about their perceptions of several primetime news programs.

Participants then viewed one of the programs described previously, one segment at a time. After

each segment, the program was stopped and participants were asked to rate the segment's importance and appeal. After all six segments were viewed and rated, participants completed three questionnaires that measured recognition and recall about the information presented, including the names of the drugs and risks associated with them. Upon completing the experiment, participants were debriefed and thanked.

2.4 Measures

The dependent variables included responses to three questionnaires that were designed to assess participants' ability to recall and recognize information about the commercials' risk disclosures. The first questionnaire was comprised of open-ended items, whereas a second questionnaire included items that assessed cued-recall of the risk disclosures.

A third questionnaire consisted of multiple-choice items intended to measure participants' ability to recognize information about the commercials' risk disclosures. Of the two risk recognition items, one asked participants to identify the side effects they saw or heard in a given prescription drug commercial by choosing from a list of six side effects and the other item asked them to identify the warning statements they saw or heard by choosing from a list of three candidate warning statements. Two distracter responses were included in the side effects list and one in the warning statements list to help correct for guessing.

3. Results

3.1 Scoring Procedures

Correct responses ("hits") received a "1" and incorrect responses received a "0." Responses to the open-ended recall items were considered correct if the participant identified either the drug's name or the condition the drug treated.

The cued-recall questionnaire responses were considered correct if the participant identified either the drug's name or what the drug treated and one or more risk disclosures for that drug. For each drug, a total of six correct risk disclosures could be reported. A proportion was calculated for each drug using the reported number of correct risk disclosures divided by the six possible correct risk disclosures. Scoring was lenient in the sense that the exact wording for each risk was not necessary to earn a point, although the participant's response needed to be synonymous with the correct answer to receive credit.

For the risk recognition questionnaire, participants were presented with two questions dealing with risk disclosures for each of the six prescription drugs. One item required participants to recognize the side effects they saw or heard in a given prescription drug commercial by choosing from a list of six side effects. The other item required participants to recognize the warning statements they saw or heard by choosing from a list of three warning statements. For both items, participants were asked to check all response options they believed were applicable. Of the six side effects, four of the response options were actually present in the commercials, whereas the other two were not presented in the commercials (they were distractors). Of the three warning statements, two of the response options were present in the commercials, whereas the third was a distractor. For purposes of scoring, the side effects and warnings responses for the two items were combined. Thus, there was a possibility of six correct responses and three incorrect responses per drug. The hit scores were calculated by summing the number of correct risk disclosures divided by the six possible correct risk disclosures.

Analyses of corrected hits were performed to correct for guessing. Corrected hit scores were calculated by subtracting the false alarm scores from the hits score. Since the results of analyses of the corrected hits closely paralleled those for the hits data, only the latter are reported here.

3.2 Risk Recall

A one-way ANOVA with six levels produced a significant effect of risk disclosure conditions, $F(5, 895) = 15.79$, $p<.0001$. Mean recall for the six risk disclosure conditions is provided in Table 3. Comparisons among means using Tukey's HSD test showed that any risk disclosure produced significantly higher recall than no risk disclosure. The combined VR & AR (M=.31) condition produced the highest mean recall, and this condition produced significantly higher recall than AR & VNR (M=.19).

Table 3
Mean risk recall for the six risk disclosure conditions

Condition	Mean Risk Recall (Proportion)
Control	.00
AR	.26
VR	.27
VR & AR	.31
VR & ANR	.29
AR & VNR	.19

3.3 Cued Risk Recall

A one-way ANOVA with six levels produced a significant effect of risk disclosure conditions, $F(5, 895) = 5.55$, $p < .0001$. Mean cued recall for the six risk disclosure conditions are provided in Table 4. Overall, risk recall was low across all risk disclosure conditions. Comparisons using Tukey's HSD test, however, showed that cued risk recall was significantly higher in the experimental conditions than in the Control condition in which no risk disclosure information was provided. VR & AR (M=.03) produced the highest mean cued recall and this condition produced significantly higher risk cued recall than AR (M=.01) or AR & VNR (M=.01).

Table 4
Mean cued risk recall for the six risk disclosure conditions

Condition	Mean Risk Recall (Proportion)
Control	.00
AR	.01
VR	.02
VR & AR	.03
AR & VNR	.01
AR & VNR	.01

3.4 Risk Recognition

A one-way ANOVA with six levels produced a significant effect of risk disclosure conditions, $F(5, 895) = 204.71$, $p < .0001$. Mean risk recognition for the six risk disclosure conditions are provided in Table 5.

Comparisons using Tukey's HSD test, however, showed that risk recognition was significantly higher in the experimental conditions than in the Control condition in which no risk disclosure information was provided. VR & AR (M=.52) produced the highest mean recognition and this condition produced significantly higher risk recognition than both conditions with non-risk disclosures presented simultaneously with the risk disclosures, AR & VNR (M=.44) and VR & ANR (M=.44), respectively. VR (M=.50) produced significantly higher risk recognition than VR & ANR and AR & VNR.

Table 5
Mean risk recognition (proportion) for the six risk disclosure conditions

Condition	Risk Recognition (Proportion)
Control	.00
AR	.47
VR	.50
VR & AR	.52
VR & ANR	.44
AR & VNR	.44

4. Discussion and Conclusion

The purpose of this study was to determine how recall and recognition of risk disclosures in prescription drug television commercials is affected by how that information is presented. Given the results, several important implications for informing current guidelines governing the content and format of DTC prescription drug ads emerged.

First, the pattern of data seem to indicate that dual modality risk disclosure in DTC television commercials may be superior to either visual or auditory modalities alone. Dual modality presentation has other benefits, as well. For example, presentation in the visual modality would allow persons who are hearing impaired to read the risk disclosures, whereas presentation in the auditory modality would allow the vision impaired to hear the risk disclosures.

These results also show that when risk disclosures are presented in prescription drug commercials, they should not be presented concurrently with non-risk disclosures. The best way to prevent this from occurring is to concurrently present the risk disclosures in both visual and auditory modalities and to present non-risk information separately.

Finally, these data provide indirect support that presentation of risk disclosures is somewhat better in visual than auditory modality. Three findings support this conclusion. First, VR produced significantly

greater risk recall for hits compared to the Control condition, while no significant difference was found between AR and Control. Second, VR produced significantly greater risk recognition compared to VR & ANR and AR & VNR, while AR was not significantly different from these two. Third, across all three dependent variables, AR was only found to produce significantly greater recall and recognition than the Control condition.

Taken together, the findings suggest that FDA guidelines should be modified to increase the likelihood that consumers receive the information they need to use prescription drugs safely. More specifically, the results of this study indicate that concurrent presentation of both visual and auditory modalities may be best. The option of auditory only in television commercials should be removed because it is deficient compared to dual modality and is somewhat worse than visual only.

It is noteworthy that across all risk disclosure conditions, risk recall was very low, ranging from .00 in the Control condition to .03 in the combined Visual and Auditory Risk condition. There are several possible explanations for this finding. First, recall generally produces lower information retrieval than recognition because the latter includes cues that facilitate retrieval. In this study, no cues (e.g., actual risk disclosure statements) were provided in the risk recall questionnaire that would have assisted the participants' recall. Instead, they had to rely on their memory to retrieve the specific risk disclosures for a given drug. Second, participants were exposed to 30 risk disclosure statements. Assuming that all the risk disclosure statements were encoded into long-term memory, participants would be required to retrieve and match each risk disclosure statement with the correct drug. Thus, the complexity of this task may have impacted their performance in retrieving the needed information for each drug. Finally, an incidental exposure paradigm was used, meaning that participants did not know they would be exposed to DTC prescription drug commercials, nor were they informed that they would be asked to recall information about each drug's risks. The relatively low scores may simply be the reality given single, incidental exposure to medication information. This notwithstanding, it probably mirrors the conditions of everyday life in that people do not give their fullest attention to DTC prescription drug commercials while watching television at home.

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