Assessing Risk and Benefit Communication in Direct-to-Consumer Medication Website Advertising

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Drug manufacturers have been increasingly marketing their prescription medications using Direct-to-Consumer (DTC) advertisements. This research examines the effects of integrating and separating risks and benefits within prescription drug DTC Website ads and presenting the risk and benefits at different levels of the Website. Two different drug Websites and two different task types (general browsing and item search) were used. Risk and benefit recall, recognition, time-on-task, click rate, and task success for risk and benefit search, as well as risk noticeability, were measured. The risks and benefits were found faster, with fewer clicks, and remembered more often when they were placed higher in the Website and in separate sections. Risks on a fourth level page without a link from the home page were difficult to find. Risks were rated most noticeable when they were presented separately on the home page. Guidelines are provided for the development of DTC Websites.

Key Words
Prescription medications; Website advertisement; Direct-to-Consumer

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INTRODUCTION

Since the mid 1980s, considerable research has been conducted on how warnings influence people's knowledge and cautionary behavior. However, experimental research into the effectiveness of pharmaceutical warnings is relatively limited. Effective pharmaceutical labeling is crucial, as the general public is often unaware of the associated risks and side effects (1). Besides the information provided by physicians and other healthcare providers, the primary sources of prescription medication information have traditionally been drug labels and inserts, and more recently Direct-to-Consumer (DTC) advertising.

Some DTC ads are used to market prescription drugs directly to the general public. Drug companies employ many different types of media in their prescription drug DTC ad campaigns, including print, broadcast and the World Wide Web.

The U.S. Food and Drug Administration (FDA) (2) promulgates regulations for communicating risks and benefits on prescription drug DTC ads. For example, print ads must include a section with all of the risks, whereas broadcast ads only require the most important risks with a pointer to all of the risk information given elsewhere. Although there has been some research conducted with respect to print and broadcast DTC ads, there has been little research on the factors that facilitate (or hinder) the communication of this information on the World Wide Web. Little research has been published to date concerning how best to present risks and benefits in DTC drug ad Websites. Should risks be integrated with a drug's benefits to increase the likelihood that they are both encountered and read (3), or should the risks be separated from the benefits allowing for the use of highlighting to attract attention (4)?

Related to this question is the effect of risk placement within a Website's hierarchy on the likelihood of seeing and reading the information. Should risks be placed on the drug's home page with the benefits to ensure that they are seen and read (5) or can the risks be placed on a different page, at a lower level of the Website's hierarchy, and still be as likely to be found and read? The most effective method of presenting the risks and benefits may also depend on the strategies (or task type) that individuals use while browsing a Website.

Research has shown that task type can influence the strategies people use while visiting a

TABLE 1

Experimental Conditions	
Condition	Description
Control:	No risks or benefits given on the Website
Integrated-home:	Risks and benefits presented in the same paragraph on the home page
Separated-home:	Risks presented separately from the benefits on the home page
Separated-mixed level:	Risks presented on a 2nd level page. Benefits presented on the home page. A link to "Risks" prominently placed in the left navigation bar
Separated-second level:	Risks and benefits presented on two separate 2nd level pages. Two salient links labeled "Benefits" and "Risks" prominently placed in the left navigation bar
Integrated-second level:	Risks presented with the benefits on a 2nd level page. A "Benefit and Risk Information" link prominently placed in the left navigation bar
Separated-fourth level:	Risks presented on a 4th level page. Benefits presented on the home page. A link to "Risks" located on a 3rd level page

Website (6). For example, when browsing, an integrated risks/benefits section might better convey the information. Conversely, if searching for specific information then a separate and distinct risk section might best capture people's attention.

In the present research, the placement of risk and benefit information within the Websites for two prescription drugs (Celebrex® and Singulair®) was manipulated to determine their effects on the likelihood of people noticing and reading the risks. The risks and benefits were either integrated together or separated, and placed on the same page or on different pages at different levels of the Website. Two different drugs and task types (general browse and item search) were employed. Finally, ratings of how well participants noticed risk were also conducted.

METHOD

MATERIALS

Websites for two existing prescription drugs (Celebrex®, Pharmacia Corporation, Peapack, NJ, and Singulair®, Merck & Co., Inc. Whitehouse Station, NJ) were used. For each drug, seven Website versions were created differing only by their placement of the risks and benefits. The risks and benefits were:

1. Either placed in the same paragraph (integrated) or in separate sections (separated),
2. Either placed on the same page or different pages of the Website, or
3. Either placed on the same level of the Website or on different levels of the Website's hierarchy.

See Table 1 for descriptions of the conditions.

To control for the amount and complexity of risk information the same set of 12 risks was used for both of the drug Websites. Six other product (nondrug) Websites (distractor sites), comparable in size and complexity to the experimental Websites, were used. These Websites were realistic in appearance and functionality, and represented a wide range of consumer products (soap, kitchen/bath cleaner, photocopying service, beverage distributor, a restaurant, and art supplies). All Websites were saved to a local hard drive to control download times and to keep users with delimited Web domains.

A dedicated computer system with a 17-inch IBM P-70 monitor was used to view the Websites (IBM® 300-GL personal computer: Intel® Pentium I 200 MHz processor, 8 GB hard drive, 64 MBRAM running Windows® 98). The monitor resolution was set to 1024 X 768 (pixels) and 16-bit color. A timer with an audible buzzer alarm was used during the browse task.

PROCEDURE

Upon entering the study, participants completed a consent form and the demographics questionnaire (see Tables 2 and 3 for demographic questions). To conceal the true nature of the study, the consent form did not mention the purpose of the study or the manipulation of the drugs' Websites. Only participants with some

TABLE 2

Participant Demographics (N = 164)					
Gender	**%**	**Ethnic Background**	**%**	**Prescribed Medications in Last 2 Years**	**%**
Male	65	African American	11	$M = 1.02$ ($SD = 1.65$)	53
Female	35	Asian	6		
		Caucasian	74	**Current**	
		Hispanic	3	**Medications Used**	
Current Medical		Middle Eastern	1	None	57
Conditions		Native American	1	1–2 medications	30
Arthritis	9	Other	4	3–4 medications	9
Asthma	1			5 or more	4

experience surfing the Web were allowed to participate.

Participants were then provided with a general overview of the tasks that they would be asked to perform. Participants were randomly assigned to one of the two tasks and drug conditions. Within each task, product Website order, drug Website, and experimental version were randomized. Tasks not concerning risk and benefit information about the drug and other non-drug products were included to further conceal the true nature of the study.

Item Search Task. The item search task required participants to find specific pieces of information using a predetermined version of one of the experimental Websites. This condition was rotated an equal number of times across participants. Participants were told that:

1. They were involved in a usability study of a drug Website,
2. They were going to search for particular pieces of information on the Website, and
3. When they found that information, they were to record the answer on a response sheet.

TABLE 3

Participant Familiarity and Experience Rating Percentages					
Familiarity Ratings:	**Not at All or Not Very**		**Moderately Familiar**	**Very or Extremely Familiar**	
Celebrex	85		10	5	
Singular	88		5	7	
DTC ads in magazines	45		42	13	
DTC ads on TV	29		42	29	
DTC ads on World Wide Web	87		11	2	
Experience Ratings:	**Not at All or Not Very**		**Moderately Experienced**	**Very or Extremely Experienced**	
Computers	1		35	64	
Web surfing	1		30	69	
Online shopping	33		38	29	
Amount of Time Spent Surfing	**Few Times a Day**	**Few Times a Week**	**Few Times a Month**	**Few Times a Year**	**Never**
Time spent surfing:	63	30	6	1	none

Participants were instructed on how to use the Web browser and completed three practice tasks before starting. ErgoBrowser® (ErgoSoft Laboratories®, Austin, TX) was used to track participants' progress through the Websites (clicks per task), their time on task, and whether they found the correct information (risk/benefit task success). ErgoBrowser is a software package that provides basic Web browser functionality (eg, forward/back buttons, and up/down left/right scrolling) and contains a task-tracking mode requiring participants to press a "start task" and "stop task" button upon starting and completing a task. All tasks started at the home page.

Upon completing the practice tasks and becoming familiar with the ErgoBrowser, participants were given six drug-specific tasks to complete as listed on separate response sheets. Two tasks required participants to find the drug's risks and benefits.

Browse Task. Participants freely browsed seven different product Websites and then rated them on: the usefulness of the information, its attractiveness, and willingness to use the product. Participants were encouraged to freely browse the Websites without drawing specific attention to the drug's risks or benefits. The order of the six distractor Websites and one of the experimental drug's Websites was randomized for each participant. Participants were given a three-minute time limit to browse each Website before making their ratings.

After rating all of the Websites, participants were given a "surprise" recall test in which they were to record as many of the risks and benefits that they could recall from the drug's Website. Participants were then given a risk recognition task asking them to identify 12 of the drug's risks embedded within a list of 24 distractor items. Next, participants were given a benefit recognition task which asked them to identify the drug's benefits embedded within a list of distractor items. Not all of the benefits presented on the Websites were given in the recognition tasks. Benefits that would cue the participant to other targets and obvious benefits were not used. The Singulair benefit recognition test contained 4 benefits and 12 distractor items; the Celebrex version had 6 benefits and 12 distractor items.

Risk Noticability Rating Task. After completing one of the experimental tasks, participants were shown all seven versions of the Website for one of the drugs (including the version they had viewed). Each version was randomly opened in a separate window. Participants were allowed to browse through each Website as many times as they liked and were allowed to toggle between the different windows to compare the different versions of the drug's Website. Participants were then asked to rate the seven versions of the Website on how likely they were to notice the risk information using a 7-point Likert-type scale anchored with 1= extremely unlikely to 7= extremely likely. There was no time limit imposed on this task.

PARTICIPANTS

One hundred and sixty four participants (24 for each of the 7-risk/benefit placement conditions; 12 participants in each risk/benefit placement X task type and drug condition) were recruited from introductory psychology courses at North Carolina State University, and were given course credit for their participation. Table 2 provides participant demographics. Table 3 provides participant familiarity and experience ratings.

RESULTS

SCORING

Because of the substantial variability in the time data, the item-search time-on-task scores (measured in seconds) were transformed into Log_{10} scores. Both Log_{10} and nontransformed scores are described below.

For the browse task, participants were given a point for each risk and benefit they correctly recalled and recognized. Points for each participant were then summed for a total risk and benefit recall and recognition score. Scores were transformed into percentages to allow relative comparisons across the recall and recognition tasks.

Two judges, blind to experimental conditions, scored the browse task risk and benefit recall responses. Interrater reliability was determined by correlating the sets of total scores for the risk and benefit recall tasks and drugs for both judges. The interrater reliability coefficients were: $r = .91$ and $r = .99$ for Celebrex and Singulair risks ($Ns = 42$, $ps < .0001$); and $r = .96$ and $r = .85$ for Celebrex and Singulair benefits ($Ns = 42$, $ps < .0001$). Only the scores produced by the first judge were used in the analysis.

ANALYSES

To control for the effects of type I error multivariate analyses of variance (MANOVAs) were first conducted to determine interactions among the independent variables. If the interaction model was not significant, separate MANOVAs were conducted with the main effect models.

Statistically significant MANOVA models were followed by analyses of variance (ANOVAs). Significant ANOVAs were followed by post hoc tests. Fisher's Least Significant Difference (LSD) test was used to determine if the means differed significantly from one another ($\alpha = .05$). Simple effects tests were conducted on significant interactions.

The results section is organized as follows:

1. Analysis of the search and find scores,
2. Browse task scores, and
3. Risk noticability ratings.

Within each section the risk and benefit results are discussed separately. Only statistically significant analyses are described ($ps < .05$).

SEARCH AND FIND SCORES

The one-way Website version MANOVA on the item search scores was significant: Wilks Lambda = 0.17, $F(36, 319) = 4.40$, $p < .0001$. The significant one-way Website version ANOVAs were: time to find risks: $F(6, 77) = 8.77$, $p < .0001$; number of clicks to find the risks: $F(6, 77) = 4.65$, $p < .001$; risk task success: $F(6, 77) = 8.49$, $p < .0001$; time to find the benefits: $F(6, 77) = 9.33$, $p < .0001$; number of clicks to find the benefits: $F(6, 77) = 11.70$, $p < .0001$; and benefit task success: $F(6, 77) = 10.20$, $p < .0001$.

Main effect means and standard deviations can be found in Table 4. Risks were found significantly faster in the separated second and mixed level page conditions compared to the integrated-home page, separated-fourth level page, and control conditions. Also, risks were found significantly faster in the integrated home and second level page conditions, the separated-home page condition, and the fourth-level page condition compared to the control conditions.

The risks were found in significantly fewer clicks in the separated second and mixed level page conditions compared to the separated-fourth level page and control conditions. The risks were also found in significantly fewer clicks in the integrated home and second level page conditions and the separated-home page condition compared to the control conditions.

All of the experimental conditions produced significantly higher risk task success scores than the control conditions. The same was true for the benefit task success scores.

The benefits were found significantly faster in the separated home and separated second and mixed level page conditions compared to the separated-fourth level page condition. The same was true for the separated second and mixed level page conditions compared to the integrated-second level page conditions. The control condition produced the slowest benefit search time compared to all other conditions.

In addition, benefits were found in significantly fewer clicks in the separated second and mixed level page conditions and the home page conditions compared to the separated-fourth level page condition. The benefits were found in significantly fewer clicks in all of the experimental Website conditions compared to the control condition.

Other analyses indicated:

1. The risks were found significantly faster and in fewer clicks when they were placed on a second level page compared to the home page,
2. The risks were found significantly faster and in fewer clicks when they were placed on a second level page compared to a fourth level page, and
3. The benefits were found significantly faster and in

TABLE 4

Search and Find Task Scores for Each of the Experimental Website Versions

Website Version	Risk Time			Risk Clicks			Risk Correct		
	Mean	(STD)	Significance*	Mean	(STD)	Significance*	Mean	(STD)	Significance*
Separated-Mixed	18.43	(14.99)	A	2.33	(0.89)	A	1.00	(0.00)	A
Separated-Home	19.49	(26.04)	A	2.42	(1.24)	A	0.92	(0.29)	A
Integrated-Second	59.62	(105.62)	AB	5.25	(6.28)	AB	1.00	(0.00)	A
Separated-Second	69.67	(86.52)	AB	7.50	(9.46)	AB	0.83	(0.39)	A
Integrated-Home	120.37	(151.65)	B	7.33	(8.61)	AB	0.83	(0.39)	A
Separated-Fourth	126.59	(90.67)	B	11.42	(6.80)	BC	0.92	(0.29)	A
Control	260.80	(202.64)	C	17.67	(16.68)	C	0.25	(0.45)	B
Website Version	**Benefit Time**			**Benefit Clicks**			**Benefit Correct**		
	Mean	(STD)	Significance*	Mean	(STD)	Significance*	Mean	(STD)	Significance*
Separated-Mixed	13.95	(13.04)	A	2.25	(0.87)	A	1.00	(0.00)	A
Separated-Home	67.60	(175.23)	A	3.08	(4.17)	A	0.92	(0.29)	A
Integrated-Second	66.03	(93.43)	A	5.67	(6.26)	AB	0.83	(0.39)	A
Separated-Second	16.61	(14.15)	A	2.42	(1.17)	A	1.00	(0.00)	A
Integrated-Home	39.61	(48.98)	A	3.42	(4.78)	A	1.00	(0.00)	A
Separated-Fourth	84.61	(84.14)	A	5.58	(8.07)	B	0.83	(0.39)	A
Control	216.31	(120.68)	B	18.42	(9.78)	C	0.25	(0.45)	B

*Means with different letters are significantly different ($p < .05$).

fewer clicks when the risks were placed on the home and second level page compared to when the risks were placed on a fourth level page.

BROWSE SCORES

The one-way Website version MANOVA on the browse task scores were significant: Wilks' Lambda = 0.57, $F(24, 259) = 1.92$, $p < .01$. The significant one-way Website version ANOVAs were: percentage of risks recalled: $F(6, 77) = 3.94$, $p < .01$; percentage of risks recognized: $F(6, 77) = 3.99$, $p < .01$; and percentage of benefits recognized: $F(6, 77) = 2.81$, $p < .05$.

Main effect means and standard deviations can be found in Table 5. Significantly more risks were recalled in the separated second and mixed level page conditions compared to the integrated-home, separated-fourth level, and control conditions. Also, significantly more risks were

TABLE 5

Browse Task Scores for Each of the Experimental Website Versions

Website Version	Risks Recalled			Risks Correct Recognized			Benefits Recalled			Benefits Correct Recognized		
	Mean	(STD)	Significance*	Mean	(STD)	Significance*	Mean	(STD)	Significance*	Mean	(STD)	Significance*
Separated-Mixed	2.42	(2.23)	A	4.75	(3.25)	A	1.50	(1.09)	A	3.17	(1.53)	AB
Separated-Second	2.00	(1.81)	A	4.50	(2.15)	AB	1.42	(0.67)	A	4.17	(1.47)	A
Integrated-Second	1.50	(1.68)	AB	3.67	(3.17)	AB	1.00	(1.04)	A	2.42	(1.44)	B
Separated-Home	1.33	(1.37)	ABC	3.00	(2.26)	ABC	1.50	(1.24)	A	3.75	(1.22)	A
Integrated-Home	0.58	(1.17)	BC	2.75	(2.53)	BC	1.17	(0.94)	A	4.08	(1.16)	A
Control	0.33	(0.65)	BC	1.25	(1.06)	C	1.00	(0.60)	A	3.08	(1.68)	AB
Separated-Fourth	0.25	(0.62)	C	1.42	(1.44)	BC	1.00	(1.13)	A	3.17	(1.59)	AB

*Means with different letters are significantly different ($p < .05$).

recalled in the integrated-second level page condition compared to the separated-fourth level page condition.

Significantly more risks were recognized in the separated-mixed level page condition compared to the integrated-home, separated-fourth level, and control conditions. Likewise, significantly more risks were recognized in the integrated and separated second level page conditions compared to the control conditions.

Significantly more benefits were recognized in the integrated and separated home page conditions and the separated second-level page condition compared to the integrated-second level page condition. Other analyses indicated:

1. Significantly more risks were recalled and recognized when they were placed on a second level page compared to the home page,
2. Significantly more benefits were recognized when the benefits were placed on the home page than integrated with the risks on a second level page, and
3. Significantly more benefits were recognized in the separated-second level page condition compared to the integrated-second level page condition.

RISK NOTICABILITY RATINGS

The one-way Website version MANOVA and subsequent ANOVA on the risk noticability ratings were significant: Wilkes Lambda = .19, $F(6, 1169) = 845.61$, $p < .0001$. Main effect means and standard deviations can be found in Table 6. The results indicated that both home page conditions (separated and integrated) and the

TABLE 6

Risk Noticability Ratings for Each of the Experimental Website Versions

	Noticability Rating		
Website Version	Mean*	(STD)	Significance**
Separated-Home	5.97	(1.04)	A
Separated-Second	5.78	(0.91)	A
Integrated-Home	5.80	(1.05)	A
Integrated-Second	5.52	(0.97)	B
Separated-Mixed	5.51	(0.94)	B
Separated-Fourth	2.33	(0.87)	C
Control	1.04	(0.22)	D

*Larger means are equivalent to higher risk noticability ratings.
**Means with different letters are significantly different ($p < .05$).

separated-second level page conditions were rated as significantly more noticeable than all other conditions. Also, the separated-mixed level page and integrated-second level page conditions were rated as more noticeable than the separated-fourth level page condition. Risk noticability was lowest for the control conditions compared to all of the experimental conditions.

Other analyses indicated:

1. Risks located on the home page were rated significantly more noticeable than risks on the second level page, which were rated significantly more noticeable than risks on a fourth level page,
2. Risks in the separated-second level page condition were rated significantly more noticeable than risks in the integrated-second level page condition, and
3. Risks were rated significantly more noticeable when presented on the home page compared to a second level page in the Celebrex drug condition.

DISCUSSION

The first major finding of the current research is the greater likelihood of participants to find, read, and remember the risk information when it was placed higher in the Website hierarchy as compared to when it was placed on a fourth level page without a link from the home page. This suggests that risk information should be placed on the home page or prominently linked from the home page to facilitate the likelihood that it will be noticed and read. Placing risks deep within a Website (eg, three or more clicks) without a prominent link on the home page may result in consumers who are looking for the risks never finding them.

A related finding suggests that people are more likely to find, read, and remember the risk information when it is placed on a second level page as compared to the home page. This suggests that people tended to look for links to important information in the left navigation bar rather than search for the information on the drug's home page. However, this finding might have been influenced by the particular placement of the risks on the home page. When placed on the home page, the risks were placed lower than the benefits and other marketing information, which generally occurs in real Web advertisements (7). Nevertheless, had the risks been presented higher on the home page, before other information, they probably would have been easier to notice and find.

The finding that risks are difficult to locate when placed deep within a Website without a link in a prominent location on the home page is supported by other recent research. Hicks et al. (7) found that risk information tends to be less accessible in a survey of actual DTC prescription drug Websites than benefits. In general, more clicks are required to find the risks than benefits (7). Scrolling was also required more often to find the risks than benefits.

The second major finding from the current research suggests that presenting risks and benefits in separate sections can facilitate consumers' likelihood of finding both sets of information. Previous research involving DTC print advertisements has found greater risk acquisition when a distinct risk section is presented compared to when the risks and benefits were integrated (4).

Usually benefit information is given priority on the home page with respect to position and prominence (7). By providing a separate risk section, highlighting can be used to draw consumers' attention to the risk information on the home page. However, it should be noted that when risks are presented on a second level page, a link to the risk information should be highlighted and prominently placed on the home page (ie, the top of the left hand navigation bar or the top center of the page) (8).

The last major finding of the current research indicated that participants believed that the risk information was more noticeable when it was separated from the benefits and presented either on the home page or the second level page. However, participant ratings slightly deviated from their performance. Performance scores indicated an advantage to placing the risks on a second level page versus the home page. Nevertheless, both sets of results fit previous Web usability research, which suggests important information should be placed on the most common entrance pages for a Website

(usually the home page) or within one click from the home page (8).

Finding that performance and subjective data do not exactly conform is not rare in warnings and Web usability research. The discrepancy between the performance and rating results might be related to the amount of attention the risks were given during the tasks. During the browse and search and find tasks, participants' attention was not specifically directed toward the risks. However, during the ratings task, risk placement was specifically pointed out to the participants on each of the Website versions. Thus, participants may have based their ratings partially on expectations such as previous experiences with surfing the web and they way important information is placed on Websites, which in most cases would be the home page (8).

FDA regulations require an unbiased, balanced presentation of prescription drug information in DTC ads (2). Accordingly, manufacturers are required to provide the consumer with a comparable amount of risks and benefits within the ad, including all the major risks associated with a drug. This balanced presentation of risk and benefit information is intended to enable better consumer decision making (2).

However, the FDA regulations do not specifically address information placement and accessibility on the balanced presentation of risks and benefits. Presenting the same number of risks as benefits on DTC drug Websites (or any DTC drug ad) does not guarantee that the consumers will notice, retain, or base their decision upon a balanced amount of risk and benefit information. The current results suggest that DTC prescription drug Website guidelines should be directed toward facilitating access to important risks and benefits rather than simply requiring similar amounts of risk and benefit information without regard to how it is presented.

Shortly after the creation of DTC ads, the FDA's Division of Drug Marketing, Advertising, and Communications issued numerous warning letters and notices of violations to drug manufacturers and their sales and marketing representatives about ad content (9). Many of these letters cite 'lacking in fair balance' of risks and benefits (9). To potentially reduce this problem a set of guidelines for the placement of risk and benefit information can be created. These guidelines should include: present risks and benefits in separate sections, and prominently present risks and benefits (eg, large size or bright color) on the home page or prominently linked to from the home page.

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