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The Effect of Qualifying Language on Perceptions of Drug Appeal, Drug Experience, and Estimates of Side-Effect Incidence in DTC Advertising

JOEL DAVIS

School of Journalism & Media Studies, San Diego State University, San Diego, California, USA

This study examined how the use of qualifying language in direct-to-consumer (DTC) pharmaceutical advertising affects consumers' perceptions of drug appeal, anticipated pleasantness of drug usage, and the expected incidence of side-effect occurrence. A sample of 669 individuals participated in a 2 × 8 complete factorial design. The design manipulated the number of side effects associated with drug use and the type of qualifying language used to describe the side effects. The eight experimental qualifying language cells represented one control condition (no qualifying language), three cells where each of three types of qualifying language were presented individually, and four cells where qualifying language was combined. The results indicate that qualifying language has a profound effect on drug perceptions, especially when used in combination. Drug appeal and the anticipated drug-using experience almost always were more positive in the presence of qualifying language. Qualifying language appears to exert its influence by causing individuals to reduce their estimate of the likelihood of experiencing individual side effects. Policy implications of the research, particularly for evaluation of "fair balance" and the reporting of side effects, are presented.

The form and content of direct to consumer (DTC) pharmaceutical advertising is governed by Food and Drug Administration (FDA) regulations (2005), whose goal is to make certain that DTC advertising provides a "fair balance" of risk and benefit information. The FDA believes that "fair balance" allows consumers to make an informed and accurate evaluation of the drug's benefits and risks. Nevertheless, it is clear that consumers have a better understanding of drug benefits versus drug risks after exposure to DTC advertising. Physicians report, for example, that the majority of patients who initiate a request for a new drug understand the drug's benefits much better than they understand the drug's risks (Aiken, 2003).

There are two underlying causes for this situation. First, consumers have difficulty finding risk information in DTC advertising. Risk information typically is presented in often-ignored smaller print; as part of a large, undifferentiated block of text or audio (Kaphingst, De Jong, Rudd, & Daltroy, 2004), or simply "hidden in plain view" (Pitts, 2004). In addition, even when found and read, risk information often is missing key pieces of information that consumers need to evaluate drug risks, for example, explicit numeric indicators of side effect incidence

Address correspondence to Dr. Joel Davis, Professor, School of Journalism & Media Studies, San Diego State University, 5500 Campanille, San Diego, CA 92182–4561, USA. E-mail: jdavis@mail.sdsu.edu

levels (Huh & Cude, 2004). Second, the lack of specificity in current FDA regulations permits varied approaches to risk communication structure and content, which in turn has the potential to lead to consumer confusion and a reduced understanding of drug-associated risks. The FDA regulations leave it to advertisers' discretion, for example, for how to define the "major side effects"[1] to include in a risk statement, whether to include numeric levels of incidence, the order in which side effects are presented, and whether incidence levels are compared with a placebo group. FDA regulations also are silent with regard to a current DTC advertisers' practice: the use of a construct frequently referred to as qualifying language.

Qualifying language consists of text that modifies or provides additional information with regard to an explicit product claim or statement (Federal Trade Commission [FTC], 1995). This type of language was common in environmental advertising (Maronick & Andrews, 1999) and currently is being examined in the context of food-related health claims (FDA, 2006; Trumbo, 2005). An advertiser might, for example, make the claim that "Food x is great for your heart." This claim then could be accompanied by the FDA's standardized qualifying language that best reflects the state of scientific evidence supporting the claim, for example, "Although there is scientific evidence supporting the claim, the evidence is not conclusive" (FDA, 2003a). Alternatively, a food advertiser might decide to use qualifying language that the FDA approves specific to a product or category, for example, "Scientific evidence suggests but does not prove that eating 1.5 ounces per day of most nuts as part of a diet low in saturated fat and cholesterol may reduce the risk of heart disease" (FDA, 2003b). The prior examples illustrate the traditional purpose of qualifying language: to curtail the generalizability of a product claim.

Direct-to-consumer advertisers often use qualifying language in their presentation of drug-related side effects. Here, three main types of statements are commonly used, either alone or in combination.[2]

- *Severity/duration*. These statements often precede the list of side effects and note that side effects are mild or not longlasting. Lipitor, for example, states that side effects "tend to be mild and often go away," while Relpax notes, "Relpax is generally well tolerated. Side effects are usually mild and do not last long."
- *Conditional language*. Rather than using a declarative statement such as "Common side effects are . . . ," some DTC advertisers use the word "may" (often coupled with "if") as a preface to the list of side effects. Advair, for example, states, "Advair may produce side effects in some patients." while Flonaise combines "if . . . may" language with the prior approach, "If side effects occur, they are generally mild and may include. . . ."
- *Discontinuation*. Some DTC advertisers have chosen to follow the listing of side effects with a statement that refers to a low rate of drug discontinuation due to side effects. This qualifying language is typically of the form "[these] side effects

[1]FDA regulations require advertisers to communicate "major" side effects, but there is no specific definition of "major." As a result, some advertisers may present the absolute highest incidence side effects, while others may present the highest incidence side effects when compared with the placebo group.

[2]This discussion is based on our examination of side-effect reporting for a sample of 60 DTC drugs in a convenience sample of 25 DTC print ads and 35 pharmaceutical websites.

generally did not cause patients to stop taking their medicine" (Singulair) or "most patients were not bothered enough [by the side effects] to stop taking Requip." Valtrex combines severity/duration qualifying language with discontinuation language: "These side effects are usually mild and usually do not stop patients from taking Valtrex."

These examples suggest that DTC advertisers' goal for using qualifying language is the opposite of the traditional use of qualifying language. The traditional use, as illustrated in food-related qualifying language, attempts to restrict or reduce the positive aspects of a product-related statement. Qualifying language in DTC advertising, on the other hand, appears to be an attempt to make a negative statement about the drug (i.e., the listing of drug side effects) less threatening and more positive.

Although qualifying language for food-related health claims is a current focus of FDA and academic research, DTC advertisers' use of qualifying language has not received any attention. This is unfortunate, because if qualifying language does manipulate consumers' perceptions, inappropriately leading them to perceive that a drug is safer or has less risk than it does in reality, then consumers are prevented from making an accurate evaluation of risks versus benefits. This article examines this issue by presenting research that addresses the question: To what extent does the presence of qualifying language in DTC advertising lead consumers to believe that an advertised drug is safer, more beneficial, or will have a lower incidence of side effects versus perceptions of the same drug created in the absence of qualifying language?

Method

Experimental Stimuli

Stimulus materials were created in a four-step process: identification of illness conditions; creation of drug descriptions; identification, selection and, creation of qualifying language; and selection of side effects to accompany each drug description.

Identification of Illness Conditions and Creation of Drug Descriptions

Three illness conditions were selected based on their satisfaction of the following criteria: Conditions had to be common and not gender specific (to ensure the broadest application and potential interest to the study sample), and conditions had to be treatable by multiple prescription drugs (so respondents would have a real choice in evaluating the competitive appeal of the test drug). The illness conditions selected were seasonal allergies, high cholesterol, and insomnia. Descriptions of three fictitious drugs were created as a treatment for each condition, where each description reflected the characteristics and benefits of an actual drug that currently treats the condition. The drugs on which the descriptions were based follow: Allegra-D (seasonal allergies), Lipitor (high cholesterol), and Sonata (insomnia). Fictitious rather than real drug names were used in an attempt to eliminate the effects of any preexisting positive or negative biases toward the real drugs. The drug descriptions were identical across all experimental conditions, and are shown in Figure 1.

Seasonal allergy sufferers often say that congestion is their most frustrating symptom. RETYCOR is a new prescription drug that has been created to treat seasonal allergies, especially the congestion that accompanies such allergies. Retycor completely eliminates the symptoms of all seasonal allergies and because one tablet lasts a full 12 hours, symptoms are relieved for more than twice as long as the best-selling over-the-counter medication. Retycor is also specially formulated not to make you drowsy.

ULOPA is a prescription drug for lowering cholesterol. It works by blocking an enzyme that is needed by the body to make cholesterol. Thus, less cholesterol is made. For people with high cholesterol, Ulopa, along with diet and exercise, can significantly reduce cholesterol and triglyceride levels. This helps to reduce the risk of heart attack and other diseases associated with high cholesterol.

SARTARAL is a sleep aid that helps people fall asleep within 30 minutes. Importantly, Sartaral has not been shown to increase total sleep duration or decrease awakenings. As a result, even if you go to sleep late and need to wake up early, Sartaral is a sleep medicine that can work for you. Sartaral helps you fall asleep fast. And, because of the way Sartaral works, you can take Sartaral late, even after you've tried to go to sleep on your own. As long as you have four hours to sleep, you don't have to worry about waking up groggy the next day.

Figure 1. Drug descriptions used in all experimental conditions.

Selection and Creation of Qualifying Language

As stated earlier, a convenience sample of 25 DTC print ads and 35 pharmaceutical websites (for drugs different from those represented in the print ads) were examined to determine the types of qualifying language used in DTC advertising. Reflecting the outcome of this examination, three types of qualifying language, all reflecting actual DTC advertiser practice, were developed for use in the research. The statement "Side effects tend to be mild and often go away" was used in the research to represent the severity/duration qualifier. The statement, "If side effects occur, they may include . . . " was used in the research to represent the conditional language type of qualifier. The statement, "Few people were bothered enough to stop taking [name of drug]" was used to represent the drug discontinuation type of qualifier. Additionally, since DTC advertisers often combine different forms of qualifying language, all possible combinations of the three types of qualifiers were included in the research (see Table 1).

Selection of Side Effects

The research focused on the extent to which qualifying language affects perceptions of side effects thought to be "more severe," as the manipulation of these types of side

Table 1. Qualifying language used in experimental conditions

Condition	Statement of side effects
1. Control	Side effects include: [names of side effects].
2. If ... may	If side effects occur, they may include: [names of side effects].
3. Severity/length	Side effects tend to be mild and often go away. Side effects include: [names of side effects].
4. Discontinuation	Side effects include: [names of side effects]. Few people were bothered enough to stop taking [name of drug].
5. If ... may and severity/length	Side effects tend to be mild and often go away. If side effects occur, they may include: [names of side effects].
6. If ... may and discontinuation	If side effects occur, they may include: [names of side effects]. Few people were bothered enough to stop taking [name of drug].
7. Severity/length and discontinuation	Side effects tend to be mild and often go away. Side effects include: [names of side effects]. Few people were bothered enough to stop taking [name of drug].
8. If ... may and severity/length and discontinuation	Side effects tend to be mild and often go away. If side effects occur, they may include: [names of side effects]. Few people were bothered enough to stop taking [name of drug].

effects would have the most profound consumer impact. Thus, the first step in the selection of side effects required that we identify consumers' perceptions of the relative severity of the side effects associated with each exemplar drug, as these drugs served as the model for the drug descriptions used in the research. We initially pretested the question, "How severe would you rate each of these side effects?" among a convenience sample of 39 college seniors. This question proved problematic, however, as there was no differentiation across side effects (almost all were rated as very severe) and many found the question vague and confusing. After discussion with members of this convenience sample, a second question, where "severity" was operationally defined as "willingness to experience," subsequently was pretested among a second convenience sample of 41 college seniors. Here, it was assumed that side effects perceived to be more severe would be those that individuals would be least likely to want to experience as a result of drug usage. This approach proved successful, and, as a result, perceptions of side effect severity in this research were determined as follows: The side effects for each of the three exemplar drugs were identified from the drug's table of adverse effects and placed in alphabetical order in list form.

A sample of 750 individuals was drawn from Syracuse University's StudyResponse Project[3] and were invited to participate in an on-line research study. Surveys using StudyResponse are anonymous and double blind. Recruited participants first were asked to read and agree to an informed consent form. Those that agreed, then were

[3]Detailed information regarding StudyResponse and the StudyResponse panel are available at http://istprojects.syr.edu/~studyresponse/studyresponse/researcherinformation.htm.

asked to complete the questionnaire. All individuals who agreed to participate were entered into a prize drawing by StudyResponse. Completed surveys were provided by 170 adults, for an overall response rate of 22.7%. The sample was slightly more female (57.6%) versus male (42.4%); tended to be aged 18 to 34 (38.8%) and 35 to 64 (58.8%); and had high school/some college (65.3%) or a college education (32.9%).

The questionnaire exposed each respondent to each of the drug descriptions, one description at a time (see Figure 1). After each description, each individual was shown the following:

> Assume that you have a problem with [name of illness condition] and are considering a prescription drug. Below, listed in alphabetical order, are the side effects associated with the use of [name of drug], a new drug designed to treat [name of illness condition]. Beside each side effect is a pull-down menu. Assuming that the drug works as promised, please use each pull-down menu to indicate how willing you would be to experience each particular side effect in order to obtain the drug's benefits. You can select any number between 1 and 9 to indicate your opinion.

Scale endpoints were "not at all willing to experience" and "very willing to experience."

The mean ratings for all evaluated side effects are shown in Table 2, which organizes the side effects so that the ratings for a side effect that pertains to more than one drug are on the same line. Two trends in the data are noteworthy. First, there is clearly a continuum of side effects: there are those consumers who are willing to endure as a function of drug use and those that are much less willing to endure. Second, it appears that willingness to endure a side effect is not drug specific. Note identical or nearly identical ratings for the side effects associated with multiple drugs, for example, abdominal pain, headache, and nausea.

This latter finding is important because it allowed us to slightly manipulate the list of side effects associated with each test drug in order to (a) eliminate duplication in side effects across drugs, (b) achieve comparability across all three drugs with regard to the range of side effects presented (especially with regard to the most and least perceived severe side effects in a side effect group), and (c) ensure comparability in the relative severity of each of the side effects in a group (for example, the most severe side effect in each group had nearly the same severity rating, as did the second side effect in each group, etc.). The outcome of this procedure was the creation of a set of three side effects and a set of six side effects for each drug, where the set of three represented the three perceived most severe side effects and the set of six included the three side effects from the prior set plus three side effects perceived as less severe. The side effects selected for each of the drugs, shown in the order in which they were presented in the research, are shown in Table 3. Note that side-effect presentation order for each drug reflects severity ratings (as shown in Table 2); that is, the side effect rated as "most severe" is presented first, the next most severely perceived is presented second, and so on.

Experimental Conditions

The two combinations of side effects (three and six effects) and the three types of qualifying statements resulted in a 2×8 factorial design where the dimensions were

Table 2. Side effect mean severity ratings

	Mean severity rating		
Side effect	Seasonal allergy	High cholestrol	Insomnia
Upper respiratory infection	2.0		
Nausea	2.4		2.2
Abdominal pain	2.8	2.9	3.0
Anxiety	3.0		
Back pain	3.0	3.1	
Insomnia	3.1		
Upset stomach	3.3		
Agitation	3.4		
Nervousness	3.4		
Headache	3.5	3.4	3.4
Throat irritation/sore throat	4.0	4.0	
Dry mouth	6.1		
Cold and flu symptoms		3.5	
Diarrhea		3.0	
Infection		2.0	
Muscle ache		4.1	
Rash		3.3	
Dizziness			3.0
Next day drowsiness			5.6
Eye pain			3.3
Lack of energy			4.0
Prickling or tingling			5.3

Note. $N = 170$; all respondents rated all side effects. Rating scale is 1 "not at all willing to experience" to 9 "very willing to experience."

number of side effects (2 levels) and form of qualifying statement (8 levels). Note that while only three qualifying statements were created, these statements were tested alone and in combination with the others, resulting (within each level of side effect)

Table 3. Side effects associated with each drug

Drug	Three side effects	Six side effects
Retycor (allergy)	Infection, anxiety, insomnia	Infection, anxiety, insomnia, upset stomach, muscle ache, dry mouth
Ulopa (cholesterol)	Upper respiratory infection, back pain, diarrhea	Upper respiratory infection, back pain, diarrhea, rash, sore throat, prickling/tingling
Sartaral (insomnia)	Nausea, stomach pain, dizziness	Nausea, stomach pain, dizziness, eye pain, lack of energy, next day drowsiness

Table 4. ANOVA for main effects

Effect	Mean square	DF	F value	Significance
Ratings of Drug Appeal				
Number of side effects	16.09	1,653	5.47	.020
Type of qualifying language	26.41	7,653	8.98	.000
Interaction	1.02	7,653	.35	ns
Ratings of Anticipated Experience				
Number of side effects	14.13	1,653	6.09	.014
Type of qualifying language	22.76	7,653	9.81	.000
Interaction	1.85	7,653	.80	ns

Note. $N = 668$.

in seven test cells and a control cell in which no qualifying language was used. The qualifying language used within each cell in the design is shown in Table 1.

Data Collection

A sample of 3,200 individuals was drawn from Syracuse University's StudyResponse Project and was invited to participate in an on-line research study. Recruited participants were first asked to read and agree to an informed consent form, and those who agreed then randomly were assigned to one of the experimental conditions based on the last digit of their StudyResponse identification (ID) number. All individuals who agreed to participate were entered into a prize drawing by Study Response. Completed surveys were provided by 669 adults, for an overall response rate of 20.9%. The sample was slightly more female (59.8%) versus male (40.2%); tended to be aged 18 to 34 (36.5%) and 35 to 64 (61.9%); and had high school/some college (64.8%) or a college education (34.8%).

Respondents in all experimental cells viewed the same descriptions of the three test drugs, presented one at a time.[4] After viewing each drug's description and side effects,[5] two closed-ended questions probed perceptions of likelihood to request the drug and perceptions of the drug-taking experience. The questions follow:

> If you needed a prescription drug to help you with [name of illness condition], how likely would you be to ask for [name of drug] versus other prescription [name of illness condition] drugs? Please select any of the options.
>
> Think about the benefits and side effects associated with [name of drug]. How would you rate the overall experience of taking this drug? Please select any of the options.

[4]We did not test for comprehension of the drug benefits or for prior exposure to the actual drugs on which the descriptions were based. We assumed that through random assignment to experimental cells, levels of comprehension and prior exposure should not be significantly different across cells. Additionally, it was assumed that random assignment should result in the number of respondents currently taking a drug for each of the described conditions to be equivalent across cells.

[5]Qualifying language in each experimental cell was the same for all three drugs.

The first question is labeled "Appeal," while the second is labeled "Experience." Both questions used a nine-point response scale, where lower numbers indicate more positive attitudes. The scales for each of the prior questions, respectively, were: "extremely likely to request/extremely unlikely to request" and "extremely pleasant/extremely unpleasant." Following the two closed-ended questions, three open-ended questions asked respondents to estimate the frequency of occurrence for the three most severe side effects, these being the three side effects common to both the three-side-effect and six-side-effect experimental conditions. Side effects were listed in the order in which they appeared in the statement of side effects. Directions were as follows:

> In the spaces shown, please tell us your guess of the percent of [name of drug] users who will have each of these side effects after taking the drug. You can type any number between 1 (meaning 1 person in 100 will have the side effect) and 100 (meaning 100 people out of 100 will have the side effect).

Results

Calculation of Summary Measures

Responses were examined to determine if summary measures could be created. The first analysis determined whether responses to the same question across the three drugs could be combined into a single summary measure. Cronbach's alpha was computed for the Appeal and for the Experience measure. Given a high alpha (.72 for Appeal; .77 for Experience), an overall Appeal and an overall Experience measure were calculated by averaging the responses to the three individual Appeal and three individual Experience questions. The second analysis determined whether summary measures could be calculated for estimates of side-effect incidence, given that the lists of side effects were constructed so that there would be comparability across drugs, for example, that the most severe side effect for each drug would have nearly the same severity rating, as would the second and third listed side effects. Cronbach's alpha was computed for the most severe, next most severe, and third most severe side effects. Given a high alpha for side effects at the same severity level (.80, .83, and .85, respectively), three summary measures were computed: Incidence Most Severe (the average of incidence ratings of the first named side effect), Incidence Second Severe (the average of incidence ratings of the second named side effect), and Incidence Third Severe (the average of incidence ratings of the third named side effect).

Test for Main Effects

ANOVA was conducted for the two scale measures: Appeal and Experience. Both measures displayed a similar pattern: the number of side effects and the type of qualifying language used were statistically significant, and there was no interaction between the two factors (see Table 4). An examination of the mean scores within each factor indicated that, overall, drugs accompanied by three side effects were seen as more appealing ($\text{Mean}_{\text{three side effect}} = 4.3$, $\text{Mean}_{\text{six side effect}} = 4.6$) and as providing a better experience ($\text{Mean}_{\text{three side effect}} = 4.5$, $\text{Mean}_{\text{six side effect}} = 4.8$) than drugs accompanied

by six side effects. The significant main effect of Number of Side Effects motivated us to conduct separate analyses for the three-side-effect and six-side-effect groups. For both analyses the research focused on answering three questions:

- When compared with the control group, to what extent does qualifying language affect perceptions of drug appeal and the drug-using experience?
- If qualifying language does affect perceptions of drug appeal and the drug-using experience, how can this effect be explained?
- If qualifying language does affect perceptions of drug appeal and the drug-using experience, are some forms of qualifying language more effective than others in fostering positive drug perceptions?

Three-Side-Effect Condition

The mean scores for the Appeal and Experience measures for each individual experimental cell in the three-side-effect condition are shown in Table 5. Individual *t* tests were used to compare control group means with the means of each of the seven experimental groups. In all cases, qualifying language affected perceptions of drug appeal; drugs with side effects presented with qualifying language always were rated as more appealing than those in the nonqualifying language control condition. Anticipated quality of experience, however, was not always influenced by the presence of qualifying language. As shown in Table 5, Condition 2 (“if ... may”) and Condition 3 (severity/length) were not significantly different from the control. All remaining conditions were significantly different, where the anticipated experience in using the drug always was rated more positively from the control condition.

Table 5. Mean ratings and significance versus control for three side effect groups

		Measure				
				Incidence		
Group	(N)	Appeal	Experience	Most severe	Second severe	Third severe
1. Control	(45)	5.5	5.4	19.3	24.3	27.3
2. If ... may	(46)	4.7[a]	4.8	15.9	19.4	25.2
3. Severity/length	(50)	4.3[a]	4.9	20.7	23.4	31.1
4. Discontinuation	(43)	4.5[a]	4.5[a]	9.6[b]	13.0[b]	14.9[b]
5. If ... may and severity/length	(44)	4.1[b]	4.4[a]	12.5[a]	15.7[a]	21.1
6. If ... may and discontinuation	(39)	3.9[b]	3.9[b]	12.3[a]	15.9[a]	21.0
7. Severity/length and discontinuation	(38)	4.0[b]	4.2[b]	11.9[a]	16.2[a]	19.8[a]
8. If ... may and severity/length and discontinuation	(42)	3.5[b]	3.8[b]	10.5[b]	14.3[b]	18.6[a]

[a]Significant *t* value of $p < .03$.
[b]Significant *t* value of $p < .001$.

Table 6. Mean ratings and significance versus control for six side effect groups

		Measure				
				Incidence		
Group	(N)	Appeal	Experience	Most severe	Second severe	Third severe
1. Control	(42)	5.7	5.9	18.4	23.3	25.3
2. If ... may	(44)	4.7[b]	4.9[b]	11.9	15.3[a]	20.7
3. Severity/length	(40)	4.7[b]	4.9[b]	17.0	22.4	28.9
4. Discontinuation	(37)	4.8[a]	4.9[b]	13.1	16.6	17.5[a]
5. If ... may and severity/length	(40)	4.4[c]	4.7[b]	10.7[a]	13.1[b]	18.4
6. If ... may and discontinuation	(41)	4.3[c]	4.8[b]	16.9	22.9	28.0
7. Severity/length and discontinuation	(42)	4.0[c]	4.2[c]	12.2	15.0[b]	18.1
8. If ... may and severity/length and discontinuation	(36)	4.2[c]	4.0[c]	12.6	14.2[b]	20.1

[a]Significant t value of $p < .05$.
[b]Significant t value of $p < .01$.
[c]Significant t value of $p < .001$.

All forms of qualifying language therefore increase drug appeal, but only some forms improve perceptions of the drug usage experience when side effects are composed of three severe side effects. An examination of the anticipated frequency of side-effect occurrence provides insights into how qualifying language may influence the latter measure. The trend across estimates of side-effect frequency in all cells is remarkably consistent. Consumers believe that more severe side effects will occur less frequently and, consistent with this belief, they estimate that less severe side effects will occur more frequently. With this belief in mind, anticipated pleasantness of the drug-using experience is heightened when qualifying language reduces the estimate of side-effect occurrence, especially the more severe side effects. As seen in Table 6, ratings of the drug using experience are only more positive (versus the control) in those cases where the qualifying language reduced the anticipated occurrence of the most- and second-most-severe side effects.

Duncan's multiple comparison range test (Duncan, 1955) was used to determine which, if any, types of qualifying language were significantly more effective than others in encouraging positive attitudes toward a drug.[6] With regard to Appeal, Duncan's test confirmed the initial t tests, in that all variations of qualifying language significantly improved drug appeal versus the control group. Beyond these comparisons with the control, Duncan's test found that a combination of qualifying language was more effective than single types in promoting positive drug attitudes. Condition 8, which used all three types of qualifying language, was significantly

[6]The minimum significance level for the Duncan test was $p = .05$.

better than Conditions 2, 3, and 4 in fostering positive drug appeal. Duncan's test also was used to determine which, if any, types of qualifying language were significantly more effective in leading respondents to believe that they would have a pleasant drug-usage experience. Similar to the prior Appeal measure, combinations of qualifying language were more effective than single approaches: Condition 8 was again significantly better than Conditions 2, 3, and 4; Condition 6 was significantly better than Conditions 2 and 3; and Condition 7 was significantly better than Condition 3.

Six-Side-Effect Condition

The mean scores for the Appeal and Experience measures for the six-side-effect condition are shown in Table 6. As with the three-side-effect conditions, *t* tests were used to compare mean scores of the control group with each of the experimental groups. In all cases, qualifying language affected perceptions of drug appeal and perceptions of the pleasantness of the drug-using experience. Drugs with side effects presented with qualifying language always were rated as more appealing than the control, and these drugs also were more positively rated with regard to the anticipated pleasantness of the drug-using experience.

The reason for more positive perceptions in the presence of qualifying language is less clear in the context of six versus three side effects. The trend in estimates of side-effect frequency is internally consistent across the three most severe side effects and is consistent with the three-side-effect condition; that is, consumers believe that more severe side effects will occur less frequently and that less severe side effects will occur more frequently. Unlike the three-side-effect condition, in the six-side-effect condition more positive ratings of drug appeal and anticipated experience were not *always* accompanied by a reduction in estimates of the most severe side effects' frequency of occurrence. Directionally, however, the results are consistent with the pattern displayed in the three-side-effect condition. A reduction in at least one side effect's anticipated frequency of occurrence did happen in five of the seven experimental conditions.

As with the individual cells in the three-side-effect condition, Duncan's multiple comparison range test was used to determine which, if any, types of qualifying language were significantly more effective than others in encouraging positive attitudes toward a drug. With regard to Appeal, Duncan's test confirmed the initial *t* tests: All variations of qualifying language significantly improved drug appeal versus the control group. There was no significant difference, however, within the experimental conditions; no pair of comparisons displayed a statistically significant difference. Duncan's test also was used to determine which, if any, types of qualifying language were significantly more effective in leading respondents to believe that they would have a pleasant drug-usage experience. Duncan confirmed the initial *t* tests where all experimental conditions significantly improved attitudes versus the control. Paired comparisons of all experimental conditions showed that condition 8 was the strongest; it was significantly better than conditions 2, 3, 4, and 6 in fostering the expectation of a positive drug-usage experience.

Discussion

Direct-to-consumer (DTC) advertisers currently have the option of using one or more types of qualifying language when presenting drug-related side effects. The research clearly demonstrates that three common types of qualifying language when

used independently, and especially in combination, have a profound effect on the likelihood to request a drug and the anticipated positive experience of using a drug. In almost all cases, the presence of qualifying language made individuals say that they would be more likely to request a drug and to believe that using a drug would be a more pleasant experience versus these same attitudes in the absence of qualifying language. It appears that qualifying language may exert its influence by reducing individuals' estimates of the likelihood of experiencing specific side effects, typically side effects considered more severe.

Beyond the significant impact of qualifying language on drug perceptions and estimates of side-effect frequency, two additional results of the research are noteworthy. The first is related to the number of side effects listed. The six-side-effect condition contained the three side-effects from the three-side effect condition plus three side effects perceived to be less severe (than the common set of three). Nevertheless, the significant main effect Number of Side Effects, where drugs with three side effects were rated more positively than drugs with six side effects, may indicate that drug-related perceptions may be influenced more by the number of side effects reported than by the perceived severity of the side effects reported. This assumption that the absolute number of side effects is an important factor (especially if, as in this research, the additional side effects are believed to be less severe) fits well with the second additional research finding. This finding relates to how individuals estimate levels of side effect incidence. Individuals believe that more severe side effects are less likely to occur and that less severe side effects are more likely to occur. Thus, the presence of additional but less severe side effects in the six-side-effect condition may have caused people to believe that they were likely to experience at least one of the less severe side effects, consequently reducing drug appeal and lessening perceptions of a pleasant drug-using experience.

Policy Implications

The findings have implications for how "fair balance" is evaluated in DTC advertising as well as for regulations governing how side effects are reported.

The FDA regulations (FDA, 2005) require all DTC ads that name both the advertised drug and the illness treated by the drug to present a fair balance of the drug's risks and benefits. Fair balance in DTC advertising is of critical importance because consumers are able to make sound decisions about drug use only if they can accurately weigh drug benefits against drug risks. Fair balance with regard to the content of risk information has been evaluated in terms of whether risk information is or is not present (Mascias & Lewis, 2003), the number and types of side effects reported (Davis, 2000), and the presence or absence of numeric levels of incidence (Huh & Cude, 2004). The research findings indicate that these approaches to evaluating fair balance may not be sufficient. Consider the following side effect statement; assume that it is placed in an easy to find location in a DTC ad and that it states the most common (i.e., major) side effects associated with drug use:

> Relapanax is generally very well tolerated. Side effects tend to be mild and often go away in a short time. If side effects do occur they may include: nausea, upset stomach and diarrhea. It is important for you to know that few people were bothered enough by these side effects to stop taking Relapanax.

Taken at face value, one would assume that this statement is a good presentation of side effects and provides adequate fair balance. After all, it is placed where it is likely to be seen, it is written in consumer-friendly language, it names the most common side effects, and it provides important additional information on severity and drug discontinuation. The results of this research indicate, however, that the assumption that this statement provides fair balance would be incorrect. The statement, in fact, does not contribute to fair balance—the presence of qualifying language actually increases consumers' positive perceptions of the drug and reduces estimates of how likely they would be to encounter specific side effects. In other words, statements that communicate side effects with qualifying language actually contribute to the "benefit" not "risk" side of the fair balance equation. In light of this situation, we recommend that future revisions of FDA regulations explicitly prohibit the use qualifying language in DTC advertising as this language appears to provide little, if any, consumer benefit. The elimination of qualifying language from side effect reporting does not, however, prohibit DTC advertisers from discussing the severity, length, or discontinuation aspects of their drug's side effects.

Qualifying language in the context of DTC advertising is, we believe, inherently misleading because it contains terminology that is vague and open to multiple interpretations, for example, "mild," "usually," and "short time." Qualifying language ceases to be misleading (and actually ceases to be qualifying language at all) however, when it becomes a statement of fact supported by explicit data. Thus, while we recommend the regulatory elimination of the types of qualifying statements used in this research, we do believe that DTC advertisers should be allowed to discuss side effect severity, duration, and discontinuation when this discussion includes explicit numeric support. An advertiser could say, for example, "The most common side effects were headache (3%) and stomach ache (2%). Side effects generally did not last for a long time. All side effects disappeared within two weeks. Very few people (1%) stopped taking [name of drug] due to these side effects."

Finally, as illustrated in the prior statement, the inclusion of numeric data in the presentation of side effects also would address one additional research finding. The results show that consumers evaluate the relative severity of side effects and apply this evaluation to the belief that more severe side effects will occur less frequently and that less severe side effects will occur more frequently. This belief may or may not be true, given the specific circumstances of a particular drug. As a result, the inclusion of numeric information would stop consumers from making incorrect assumptions as to the likelihood of experiencing a particular side effect or making incorrect assumptions regarding drug discontinuation.

Limitations and Further Research

We believe that the consistency in the research findings provides a sound basis for the prior policy recommendations. Nevertheless, additional research that addresses the limitations of the current research and issues raised by this research would be very helpful in providing additional support for the recommendations as well as additional insights into how consumers process risk information in DTC advertising.

Generalizations from the current research are limited to risk statements that are predominantly composed of side effects perceived to be more rather than less severe. This is not a significant problem with the policy recommendations, as it is unlikely that DTC advertisers would need to use qualifying language with side effects

perceived to be relatively nonsevere. Research that provides insights into the relationship between qualifying language and a broader range of side effects would, however, aid in a fuller understanding of the effects of qualifying language. Generalizations of the research also are limited by the types of drugs selected. As with the side effects themselves, additional research that focuses on an expanded range of illness conditions, particularly severe conditions, would provide important insights.

Additional research also might explore several questions raised by the outcomes of the research. The current research was designed to uncover the relationship between qualifying language and subsequent drug perceptions. Beyond demonstrating the effect of qualifying language, some insights were provided into the process by which qualifying language exerts its influence. Additional research, specifically designed to explore the psychological processes by which this language works, would be very beneficial. Along these lines, the research focused on the effect of qualifying language on perceptions of drug risk. It is possible, however, that there is a relationship not only between qualifying language and perceptions of risk, but also between qualifying language and perceptions of drug benefits. Additional research specifically designed to determine the nature of this relationship would be of great value.[7]

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[7]We thank an anonymous reviewer for raising this issue.

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