# Barely or Fairly Balancing Drug Risks? Content and Format Effects in Direct-to-Consumer Online Prescription Drug Promotions

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## ABSTRACT

**A critical requirement of direct-to-consumer (DTC) drug promotion on the Internet is the concept of fair balance. This means that prescription drug Web sites should provide an accurate, balanced portrayal of the risks relative to the benefits of using prescription medications. However, one of the most pervasive findings in consumer research is that risk perceptions are often not aligned with the actual risk a consumer faces. This study examines the impact of certain presentation formats and types of risk information provided on a pharmaceutical Web site and the effect on consumers' perceptions of risk and fair balance. We find evidence of a bias of omission; that is, the risks of treating a health condition using a hypothetical prescription drug were perceived to be greater than the risk of**

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**inaction. Interestingly, we found no evidence that the presentation of a "black-box" warning or the warning strength affected the broader construct of fair balance. © 2008 Wiley Periodicals, Inc.**

Unlimited space, unconstrained time, and availability on demand are what the Internet provides pharmaceutical manufacturers who use direct-to-consumer (DTC) Web-based promotions. Given the relative lack of specificity in regulations of online DTC promotions, this means that pharmaceutical firms may be blessed or cursed with extensive options in both what information to provide and how to convey that information so that consumers' have an accurate perception of risk. Because there are so many options with online promotions, this medium may provide a better opportunity to achieve *fair balance* of the risks of a drug with its benefits, a legal requirement for all DTC promotions.

Yet achieving a fair balance is challenging as exemplified by the pervasive findings in consumer research that consumers' interpretations of risk are often not aligned with the actual risk consumers face (i.e., both underestimation *and* overestimation are common) (c.f., Menon, Block, & Ramanathan, 2002). This research explores the effect of some of the options available to pharmaceutical firms for Web site promotion and their effects on consumers' accurate interpretation of product risk, fair balance and choice.

Internet DTC promotions present an interesting and important context for studying risk perceptions. Their routine purpose is to provide an easily accessible source of extensive information about a drug in an on-demand, unconstrained environment. During health crises and product crises, they can become pivotal to consumers and manufacturers. For example, media coverage of the Vioxx® recall, the debates surrounding its withdrawal and subsequent black-box warnings, and consumer lawsuits attracted significant attention from the American public, inflating consumers' risk perceptions related to this and other drugs (Harris Interactive, 2004; O'Rourke, 2006). In these situations, drug Web sites could provide needed information on risks and benefits to all parties concerned with use of the product.

Indeed, this benefit/risk relationship is at the very heart of DTC online promotions. The U.S. Food and Drug Administration (FDA) requires that DTC promotions "present a fair balance between information about effectiveness and information about risk" (Food and Drug Administration, 1999, p. 2), so that a consumer receives an accurate, balanced understanding of the risks relative to the benefits of using the medication (Aikin, 2006). The adequate provision of information and the doctrine of fair balance are major considerations in the list of over thirty regulations by the FDA concerning misleading prescription drug advertising (Food and Drugs, 2000).

This "fair balance" doctrine has been studied for decades (CBS Television Network, 1984; Keown, Slovic, & Lichtenstein, 1984; Tucker & Smith, 1987). Researchers have experimentally manipulated information presentation formats in an effort to assess effects on consumer comprehension, knowledge, and product evaluations. The variables studied include the amount of risk information presented (Morris, Brinberg, & Plimpton, 1984; Morris, Ruffner, & Klimberg, 1985), specificity (Davis, 2000), and format (Morris, Mazis, & Brinberg, 1989; Wogalter et al., 2002). Results indicated that the presentation format of the advertisement could have significant effects on consumer comprehension

and memory (Morris et al., 1986). Additionally, work by Viscusi, Magat, and Huber (1986) shows a propensity for consumers to make suboptimal medical decisions when they have imperfect information on the risks and benefits of alternative options.

The study described here builds on this long stream of research and the importance of the fair balance doctrine to DTC promotion by experimentally manipulating two sources of risk information as well as the strength of risk warnings in an Internet-based DTC promotion. Since an accurate understanding of risk is critical to fair balance, we turn our attention to a particularly relevant bias—the bias of omission (Baron & Ritov, 2004; Dhar, 1997: Ritov & Baron, 1990).

## BIAS OF OMISSION

While much media and public attention is focused on the risk of taking a particular drug, an equally important risk is the decision *not* to use a drug to treat a disease or health condition. In assessing risk, a consumer faces the choice between doing nothing and letting a disease or health condition run its course (i.e., an act of omission), or taking action (i.e., an act of commission such as taking a drug or using some other therapeutic approach). Either choice has some probability of causing harm. Research suggests that when faced with an action (i.e., commission) or a no-action situation (i.e., omission), there is "a systematic bias toward inaction in consumer decision making" (Dhar, 1997, p. 216). A bias of omission is the consumer's tendency to prefer the consequences of taking no action as compared to the consequences of taking action, even if the consequences are the same (Ritov & Baron, 1990; Spranca, Minsk, & Baron, 1991). There are psychological advantages to taking no action since doing nothing allows the consumer to remain flexible and to avoid taking responsibility for any action. It also minimizes the dissonance or regret associated with making a poor choice because there is no obvious choice outcome against which the consumer can make a comparison (Dhar, 1997; Spranca, Minsk, & Baron, 1991). Thus, a bias of omission attenuates perceptions of risk associated with the status quo and amplifies the risks associated with taking action.

Research suggests that consumers often fail to associate omissions, or a lack of action/choice, with their related outcomes (Spranca, Minsk, & Baron, 1991). This leads to an interesting situation for pharmaceutical products. While the FDA requires the major risks or side effects associated with a particular drug to be presented in fair balance with the benefits of the drug, much of the content of Internet promotions is under the control of the firm, given the relative lack of specificity of regulations. Even though pharmaceutical firms are not *required* to provide the consumer information on the effects of leaving the condition untreated, they are certainly *allowed* to provide such information. This means they have the option of explicitly identifying for the consumer the potential outcomes of an act of omission (i.e., choosing to remain untreated). Since omission bias results, in part, from the consumer's failure to consider the risk associated with no action, providing this information to consumers may reduce the bias.

Dhar (1997), however, suggests just the opposite effect. Let us assume that a decision to treat or not treat a medical condition with a prescription medication

is a function of the relative attractiveness of the potential outcome from taking a drug versus remaining untreated. The more similar the two options, the less likely the consumer is to choose one option over the other. Dhar argues that if a pharmaceutical manufacturer were to display information about the risks of remaining untreated, the consumer would face two alternatives that are more comparable in that they both have risks. Therefore, by adding information regarding the risks of remaining untreated to the Web site, the firm may actually be reducing the probability that drug therapy will be chosen.

Bias of omission is particularly important in DTC online promotions because a patient may forgo treatments for which the benefits significantly outweigh the costs. Indeed, the FDA recognizes these errors of omission when deciding how manufacturers must communicate risk to physicians and patients. The FDA's strongest level of warning for prescription drugs is known as a "black-box" warning. These designations are used with great discretion in order to not overweight risks, suggesting an underlying belief that bias of omission is even more pronounced whenever warnings of particularly severe risks are presented. For instance, in 2004, the FDA required black-box warnings about the risk of suicidal thinking in children taking antidepressants. Since then, the prescription rate has decreased by 30 percent (Williams, 2006). New research, however, suggests that using antidepressants can actually prevent suicides in children (Gibbons et al., 2006). It could be that because suicidal thinking is a black-box risk, doctors and patients have more often opted not to use antidepressants. The severe warning may have amplified errors of omission, leading to a higher actual suicide rate.

This discussion suggests that a bias of omission is likely to occur when consumers are evaluating prescription drug Web sites. Consistent with this bias:

**H1a:** Perceived risk varies systematically, such that respondents will evaluate *treating* a condition (i.e., act of commission) to be of higher risk than *not treating* a condition (i.e., act of omission); and

**H1b:** Respondents who would choose *not to treat* will perceive higher risk associated with the treatment and lower risk associated with not treating. Alternatively, those who would choose *to treat* a condition with prescription medication will report higher risks of remaining untreated and lower risks associated with the prescription drug side effects.

As suggested by Dhar (1997), there are psychological advantages to the bias of omission for consumers. Consistent with these, we predict:

**H2:** Respondents who would choose to treat the condition with prescription medication will

**H2a:** Have lower perceived flexibility in their future decisions,

**H2b:** Feel greater personal responsibility for the decision, and

**H2c:** Experience more dissonance regarding the decision than those who report that they would rather go untreated.

A bias of omission results because consumers fail to recognize the risk associated with non-action. Thus, it is possible that providing this information will attenuate the bias of omission. Yet, as argued by Dhar (1997), this information could also make the two options look more similar and, therefore, amplify the bias of omission. Thus, instead of making a directional hypothesis, the authors simply explore:

**H3:** Providing consumers with the risks associated with inaction has the potential to either amplify or attenuate the bias of omission via systematic changes in risk perception.

Finally, the strength of the risk warnings of using a medication should further bias the likelihood of nonaction and associated risk perceptions. Thus, we predict:

**H4:** The strength of the risk message will amplify the bias of omission effect so that when severe (versus moderate) risks are presented:

**H4a:** A greater number of respondents will choose not to treat the condition with a pharmaceutical drug, and

**H4b:** The differences in risk perceptions between those who choose not to treat and those who choose to treat will be greater.

## BLACK-BOX WARNINGS

The FDA sometimes determines that certain risks are sufficiently severe to require the manufacturer to warn health-care professionals and consumers of these risks with black-box warnings. There is a great deal of literature on warning labels (e.g., Stewart & Martin, 1994; Taylor & Bower, 2004; Zuckerman & Chaiken, 1998) and research on what types of information should be included in product warnings (e.g., Fischhoff et al., 1998). According to the FDA, black-box warnings are designed to "highlight special problems, particularly those that are serious, and to give health-care professionals a clear understanding of a potential medical complication associated with the drug" (Food and Drug Administration, 2004). While the consequences of these risks are great (i.e., death, liver failure), the likelihood of these risks is generally very small. The intent of the black box is to help healthcare professionals use the drug in a manner that maximizes benefits and minimizes risks to their patients (Food and Drug Administration, 2004).

When black-box warnings are mandated, the warning must be included as part of the "major statement" in consumer-friendly language conveying risks to the consumer (Woodcock, 2003). Even though the media often widely report the FDA's approval of a black-box warning, no explicit acknowledgement is required in DTC communications that the FDA deems the risk to be particularly severe. In other words, a DTC communication would be required to include a verbal accounting of a black-box warning but would not need to indicate graphically or

verbally that the warning is deemed a black-box event by the FDA. The choice is up to the firm, and within the Internet context, this choice is easy to implement and easy to change.

Some consumer advocates argue that black-box warnings should be openly communicated to the public explicitly as black boxes so that consumers will be more aware of these severe risks (e.g., recent action by the Illinois Attorney General and Public Citizen described in Smith, 2006). Alternatively, if a vivid portrayal of black-box warnings results in consumers overestimating the risk associated with a pharmaceutical product, a bias of omission may occur.

The literature on vivid warnings fails to provide consistent findings regarding the effects of graphical and verbal warning information on consumer perceptions (e.g., Kelley, Gaidis, & Reingen, 1989; Stewart & Martin, 1994). Given that the FDA and pharmaceutical firms are being pressured to communicate black-box risks to consumers graphically, the authors examine whether the explicit use of black-box warnings in a DTC drug promotion increases the bias of omission by inflating the perceived risk associated with the product. If the bias of omission is inflated by clearly identifying certain risks as black-box warnings then:

**H5:** A graphically displayed black-box warning will:

**H5a:** Increase perceptions of risk associated with using the prescription drug,

**H5b:** Decrease perceptions of the risks of not taking the drug, and

**H5c:** Change consumers' perception of the fair balance toward higher risk.

## STUDY

A 2 (risks of remaining untreated—present or absent) by 2 (warning strength—moderate or severe) by 2 (black-box graphic-present or not present) with control design was used to examine the above hypotheses.[1] A hypothetical product, Enfocar, for adult ADHD was used as the focus of this study. Adult ADHD is a relatively common and increasingly diagnosed condition among young adults. The use of stimulants to treat ADHD is rising fastest among young adults (versus children or adolescents) with an estimated 1.7 million adults (age 20 to 64) and 3.3 million children (age 19 or younger) reported to be using ADHD medications in 2005 (Medco Health Solutions, 2006).

Respondents were directed to a mock Web site, based on existing Web sites for actual ADHD drugs. The Web site had the brand name with its logo at the top left-hand corner, and a picture of a smiling female on a cruise ship holding a placard with the Enfocar logo at the top right-hand side. Risks and benefits associated with taking the drug, as well as the risks of remaining untreated, were

[1] Analysis of the control group did not yield insight into the issues, nor did it significantly change any results. Thus, in an effort to improve the flow of the article, we do not discuss the control group results. There are 174 subjects in the remaining analysis.

drawn from DTC drug Web sites and ADHD informational Web sites, with the latter used particularly for the effects of remaining untreated for ADHD. The risks of remaining untreated included low self-esteem, pessimistic outlooks, and greater likelihood to engage in harmful behaviors, such as smoking and drug abuse.

The strength of the risk warning was manipulated by using two risks deemed by the FDA as severe enough to warrant a black box (i.e., suicidal thinking and cardiovascular risk such as stroke, heart attack, or sudden death) and two moderate risks (i.e., anxiety and depression). When the black-box visual was used, the aforementioned risks were boxed in a thick black box with the all-caps bold heading **"FDA BLACK BOX WARNING."**

The critical sections of the Web page were clearly labeled (Vigilante & Wogalter, 2003). For example, in each condition, the first heading, bold, in all caps, and underlined was **"BENEFITS."** This was followed by the general benefits of increasing attention and reducing impulsiveness and two very specific benefits: improved academic and job performance and reduced auto accident risk. Directly below, in equivalent font size and type, was the heading "**IMPORTANT RISK INFORMATION**" that was followed by product-related risk information. In this section, the black-box warning information was either boxed or not boxed depending on the condition. Below this risk information was a hyperlink to the patient package insert, which stated "Please click here to see patient package insert." The format and content of the insert was patterned after that found in a magazine DTC ad for an ADHD drug.

For respondents exposed to the risks of remaining untreated, the relevant information was presented alongside the risks of product use under the heading **"RISKS OF LEAVING ADHD UNTREATED."** The placement of these two types of risk information was counterbalanced, and the results showed no significant effects due to placement.

The participants were 194 undergraduate business students at an eastern U.S. university. Cell sizes ranged from 19 to 27 per cell. Fifty-three percent of the participants were male and the average age was 21. Thirty-five participants (18%) indicated that they had taken medication used to treat ADHD.

## Manipulation Checks

Several manipulation checks were used. First, a dichotomous "yes" or "no" scale asked whether the Web site provided the risks of remaining untreated for ADHD. In addition, respondents were asked if they noticed a boxed warning that described some of the risks associated with taking the medication. Finally, participants rated the strength of the risk warning on a 5-point scale anchored with "not at all serious" and "very serious." Strength ratings were averaged for the two moderate risks (i.e., depression and anxiety) and the two severe risks (i.e., suicidal thoughts and cardiovascular problems).

## Dependent Variable Measures

Dependent variables included consumers' perceptions of the risks of using medication to treat ADHD, the risks of leaving the condition untreated, the psychological advantages of making no choice, and perceptions of the fair balance between the risk and benefit information provided by the Web site, as well as

their choice between treatment and no treatment if they had been diagnosed with ADHD.

To measure the risks associated with taking the drug, three scales were used. The general risk of taking the prescription medication was tapped with three 5-point items which asked whether it was "very risky/not at all risky," "unsafe/safe," and "dangerous/not at all dangerous" (alpha = 0.83). To assess the general likelihood of experiencing any side effects, two 5-point items with the endpoints "no chance/certain to happen" and "not at all likely/very likely" were used (Keller, Lipkus, & Rimer, 2003; $r = 0.73$). The severity of any possible side effects was assessed with two 5-point scales with the endpoints "not severe at all/very severe" and "not serious at all/very serious" (Chandran & Menon, 2004; $r = 0.74$). In addition, the perceived likelihood of experiencing the specific moderate (i.e., depression and anxiety) or severe (i.e., suicidal thoughts and cardiovascular problems) risks listed were measured using a 5-point scale anchored by "not at all likely" and "very likely."

Measures for the risk of leaving Adult ADHD untreated mirrored the general risk measures above. Reliability estimates for these measures were acceptable: general risk (alpha = 0.91), likelihood ($r = 0.91$), and severity ($r = 0.84$).

To assess the psychological advantages of making no choice, five items were developed, based on Dhar's (1997) discussion of the preference for no choice reducing dissonance, enhancing future choice flexibility, and reducing personal responsibility. After indicating their choice to take or not take the drug on a 5-point scale, respondents indicated their level of agreement with five statements. Factor analysis and reliability analysis confirmed that three items measured dissonance [e.g., "I would be worried about the choice I made," and "I am certain it would be the right decision" (reverse coded; alpha = 0.67)]. The other two items were analyzed separately. Perceived flexibility was measured on a single 7-item scale that stated, "My decision would allow me to have more treatment options in the future." Personal responsibility was measured with a single 7-item scale that stated, "If I were harmed because of the decision I made, it wouldn't be my fault."

Consumers' perceptions of the fair balance between risks and benefit information were measured using a scale being proposed by FDA in its work on DTC advertising (Aikin, 2006). The three Likert-type items (alpha = 0.86) included "The risks and negative effects seem reasonable compared to the benefits and positive effects of the prescription medication, Enfocar," and "The benefits and positive effects of Enfocar outweigh the risk and negative effects."

## RESULTS

### Manipulation Checks

The results show that the manipulations were effective. Respondents exposed to the information about the risks of going untreated for ADHD reported higher awareness of this information ($M$s = 0.30 versus 0.89; $t = -9.89$, $p < 0.01$). Respondents indicated that the severe risks were perceived as more severe ($M = 4.58$) than the moderate risks ($M = 3.81$; $t = -11.54$, $p < 0.01$). Finally, respondents exposed to the black box reported greater awareness of a boxed

warning than those who were not exposed to a black box ($M$s = 0.21 versus 0.96; $t = -15.21, p < 0.01$).

## Bias of Omission

H1a predicted that the risks associated with treating a condition (i.e., act of commission) would be perceived to be greater than the risks of not treating the condition (i.e., act of omission). The results supported this prediction. Participants reported higher levels of general risk ($M = 3.34$ versus 3.05; $F = 10.62, p < 0.01$) and perceptions of severity ($M = 3.57$ versus 3.19; $F = 21.07, p < 0.01$) for treating the condition with a prescription drug versus not treating the condition. Perceptions of the likelihood of experiencing negative health effects did not differ.

H1b predicted that respondents who would choose not to take the drug would perceive that there was a higher risk from using the drug and a lower risk for not treating the condition. The opposite was predicted for those who would choose to take the drug. To test this hypothesis, a series of GLM models were run on the three measures of risk (i.e., general risk, severity, and likelihood) for treating the condition and not treating the condition. GLM provided greater robustness given the variations in cell size. The first three GLM models assessed effects on the three risk measures from taking the drug (i.e., general risk, severity, and likelihood of experiencing negative side effects) based on the respondent's choice to use the drug or leave the condition untreated. Twenty-nine respondents indicated that they would choose not to take the drug while 89 would choose to use Enfocar.[2] Respondents choosing not to take the drug had significantly higher general risk scores ($M = 3.93$ vs. $3.11, F = 35.54, p < 0.01$), felt that the risks were more severe ($M = 4.02$ vs. $3.41, F = 16.40, p < 0.01$) and that the side effects were more likely to occur ($M = 3.64$ vs. $3.15, F = 9.89, p < 0.01$) than those choosing to take the drug. The second three models examined the effects on the three risk measures for remaining untreated. Respondents choosing not to take the drug felt the risks of remaining untreated were lower ($M = 2.71$ vs. $3.12, F = 3.79, p = 0.054$), and that the negative effects of remaining untreated were less severe ($M = 2.95$ vs. $3.30, F = 3.12, p = 0.08$), but there were no differences between the two groups regarding the likelihood of negative effects from remaining untreated.

Taken together, the results provide strong support for H1a and H1b. In general, consumers perceived the risks of treating to be greater than the risks of doing nothing. Additionally, risk perceptions varied systematically with the choice. We find a strong effect (i.e., eta-squareds ranging from 0.08 to 0.24), indicating that those choosing to treat the condition with prescription drugs perceived the risk of the drug to be lower than those who chose not to treat the condition. We also find evidence that the perceived risks of remaining

[2] The respondents' choice to use or not use the prescription drug was measured with a 5-point, "definitely would take" to "definitely would choose not to treat" scale. The responses were dichotomized, so that those respondents indicating that they "definitely" or "probably" would take the prescription medication were coded as choosing to treat the condition (i.e., act of commission; 89 participants) and those that indicated that they "probably" or "definitely" would remain untreated were coded as choosing not to treat the condition (i.e., act of omission; 29 participants). The remaining participants chose "not sure," the midpoint of the scale.

untreated were higher among those who chose to treat than those who chose not to treat the condition, albeit this effect is not as strong (largest eta-squared = 0.03).

H2 predicted that consumers who would choose to treat the condition with prescription medication would a) have lower perceived flexibility in their future decisions, b) feel greater personal responsibility for the decision, and c) experience more dissonance regarding the decision than those who report that they would rather go untreated. Findings support these predictions. Participants who reported that they would choose to take the prescription drug to treat the condition reported lower levels of flexibility ($M$ = 3.88 versus 4.63; $F$ = 6.16, $p < 0.05$), higher levels of responsibility ($M$ = 3.88 versus 2.75; $F$ = 10.65, $p < 0.01$), and higher levels of dissonance ($M$ = 3.61 versus 2.99; $F$ = 7.98, $p < 0.01$) than their counterparts.

## Effects of Leaving the Condition Untreated

H3 stated that providing consumers with risks associated with inaction has the potential to either amplify or attenuate the bias of omission. In order to help control for Type 2 errors, we used three MANOVA models to test the effects of the three manipulations: presence or absence of risks of remaining untreated, the warning strength (i.e., moderate vs. severe), and presence or absence of a black-box warning. The first model examined the effect of the manipulations on the risk of treating the condition (i.e., the general risk, severity of side effects, and general likelihood of experiencing side effects). The second model used the likelihood of experiencing specific side effects (e.g., depression, anxiety, suicidal thoughts, and cardiovascular problems). The last one examined the risks of remaining untreated (i.e., general risks, severity of negative outcomes, and likelihood of negative outcomes).

The MANOVAs showed no main effects of the presence or absence of untreated ADHD risks in any of the models. However, there was a significant interaction between providing risk information for leaving ADHD untreated and the warning strength on the likelihood of experiencing the side effects ($F$ = 7.30, $p < 0.01$). As shown in Figure 1, the pattern of results suggests that the likelihood of side effects is greatest when no information is provided on the risk of remaining untreated and the warning strength is moderate ($M$ = 3.6 versus $M$s = 3.04 to 3.22; $t$s = 2.16 to 3.33; $p$s $< 0.05$).

There were also significant interactions between the presence or absence of untreated ADHD risks and warning strength on the specific risks associated with treatment (Wilks' lambda = 3.65, $p < 0.01$). Figure 2 graphically presents these interactions. The perceived likelihood of experiencing depression ($F$ = 3.76, $p < 0.05$) was highest when the risk of ADHD was absent and the warning strength was moderate ($M$ = 3.79). The presence of the ADHD information negates this effect; that is, when the ADHD information is present, the effect of having the moderate risk information is significantly lower ($M$ = 3.25; $t$ = 2.32, $p < 0.05$). However, when the warning strength was severe, the likelihood estimates were similar across the ADHD risk information conditions ($M$s 3.40 and 3.45). The same pattern of results was found for the likelihood of experiencing suicidal thoughts ($F$ = 6.45, $p$ = 0.01). When a moderate warning was provided, the likelihood of experiencing suicidal thoughts was significantly higher when the risk of untreated ADHD was not

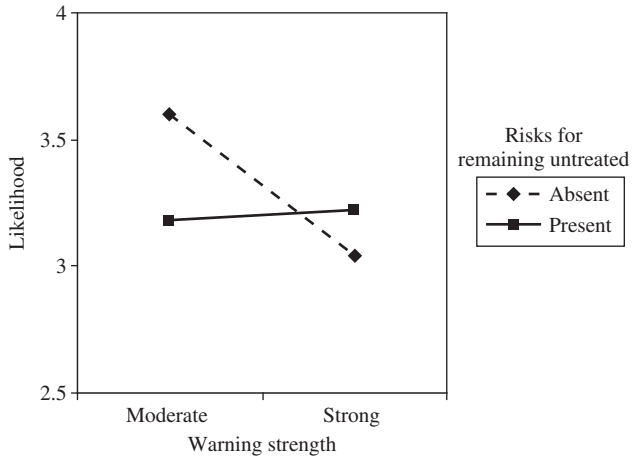


**Figure 1.** The influence of providing risk information on remaining untreated and warning strength on the general risk of treating with drugs.

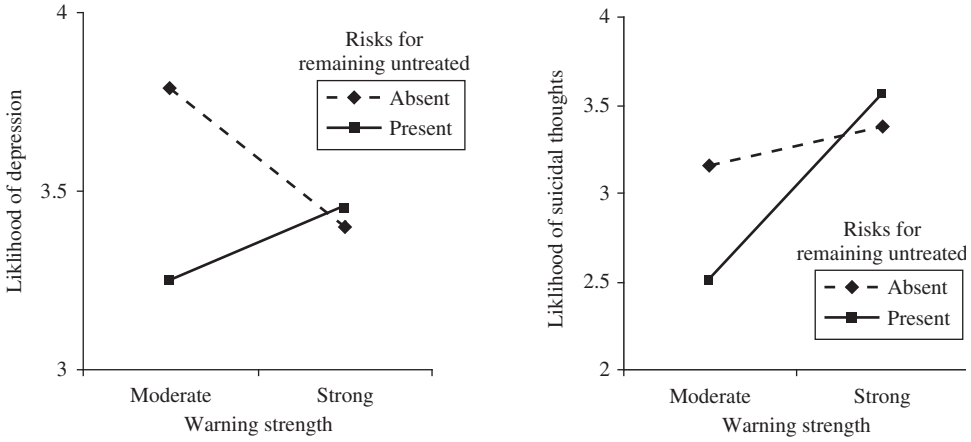


**Figure 2.** The influence of providing risk information on remaining untreated and the warning strength on the likelihood of specific side-effect risks.

presented versus when those ADHD risks were present ($M = 3.16$ versus 2.51; $t = 2.73, p < 0.05$). Again, when the warning was strong, there were no statistical differences between the presence or absence of the risks of untreated ADHD.

In sum, these results show partial support for H3. Under a moderate warning, the absence of untreated ADHD risks resulted in higher perceptions of the likelihood of depression and suicidal thoughts. Providing these risks significantly reduced those risk perceptions. The reasons for the differences by warning strength are unclear but are discussed later.

## Effects of Warning-Strength Manipulation

H4 predicted that the strength of the warning would moderate the bias of omission effect. In H4a, we predict that the more severe the risk warning, the greater

the likelihood that the respondent would choose not to treat the condition with a prescription drug. In the moderate risk condition (i.e., depression and anxiety), 9 respondents chose not to take the drug and 54 chose to take Enfocar, while in the severe risk condition, 17 respondents chose not to take the drug and 34 chose to treat with Enfocar. Chi-square showed a statistically significant difference ($\chi^2 = 6.04$, df $= 1, p = 0.01$), supporting H4a.

H4b predicted that the presentation of severe risks would result in a stronger bias of omission. For the moderate risk condition, GLM models showed that respondents who chose not to treat the condition had significantly higher perceptions of general risk, severity, and likelihood of side effects than those who chose to treat (all $p$s $< 0.05$, $R^2$ ranging from 0.07 to 0.12). For the severe risk condition, the analysis revealed evidence of bias of omission in that the respondents who chose not to treat the condition had significantly higher perceptions of general risk, severity, and likelihood of side effects than those who chose to treat (all $p$s $< 0.05$, $R^2$ ranging from 0.07 to 0.26). Comparing the two warning strength conditions, the most striking difference in effect sizes was the impact of bias of omission on the general risk assessment. For those exposed to the moderate warning, the $R^2$ was 0.12, while for those exposed to the severe warning, the $R^2$ was doubled at 0.26. This provides support for H4 in that more severe risks inflated bias of omission.

## Effects of the FDA Black-Box Warning

H5a through H5c examined how the FDA's black-box designation may communicate certain severe risks. Specifically, the presence of a black-box graphic and designation was expected to increase consumers' risk perceptions, decrease perceptions of the risk of not taking the drug, and change the balance between benefit and risk information.

H5a was explored using two $2 \times 2 \times 2$ MANOVAs using the three general risk measures and the likelihood of the four specific risks of taking the drug as the dependent variable sets. There were no main effects of the black-box manipulation for either model. However, the interaction of the black-box treatment with the warning strength affected risk perceptions for the specific risks mentioned in the stimuli (Wilks' lambda $= 2.46, p < 0.05$). Under moderate warning, the results showed that consumers perceived that depression was more likely to occur when the black box was present ($M = 3.69$) versus when there was no black-box warning ($M = 3.26$; $F = 4.56, p < 0.05$). In the severe warning condition, similar results were found for the risk of suicidal thoughts. The presence of an FDA black-box warning resulted in higher perceptions of the likelihood of experiencing suicidal thoughts ($M$s $= 3.71$ versus 3.23; $F = 4.63$, $p < 0.05$).[3] Together, these findings suggest that the black-box warning format can impact specific perceptions of the likelihood of experiencing specific side effects of using the prescription medication. These findings offer limited support for H5a.

H5b predicted that the presence of a black-box warning would decrease the perceived risk of remaining untreated. A $2 \times 2 \times 2$ MANOVA examined the effects of the manipulations on the three perceived risks of remaining untreated

[3] To test the effect of specific risks, only the effects on the associated moderate (i.e., depression or anxiety) or severe (i.e., suicidal thoughts or cardiovascular risks) items were included.

(general risk, severity of negative outcomes, and likelihood of negative outcomes). None of the main effects or interaction effects were statistically significant (all Wilks' lambda's $> 0.97$; all $p > 0.20$). Thus, H5b is not supported in that there is no main effect of a black-box warning, nor does the black box interact with other manipulations to affect the perceived risks of remaining untreated.

Finally, H5c predicted that the black-box warning would result in a shift in consumers' perception of "fair balance" so that they will perceive that the risks and negative effects outweigh the benefits and positive effects of the drug. Using the single fair-balance measure, a $2 \times 2 \times 2$ ANOVA showed no main effects or interactions (all $p > 0.24$). Thus, H5c was not supported.

## DISCUSSION AND IMPLICATIONS

A recent Pew survey showed 37% of Americans searched the Internet for information on prescription or over-the-counter drugs (Fox, 2006). With such use likely to increase in the future, understanding the interpretations that consumers make of drug risks and benefits in this environment is paramount. With limited regulatory guidance on precisely what online DTC promotions should provide, pharmaceutical firms have the freedom to decide how to best communicate risks and benefits yet still provide the required fair balance. Herein, the authors explored specific options: the presence or absence of the risks of going untreated and the graphic presentation of black-box warnings. These effects were examined under both moderate and severe warning conditions. The results support and extend the work in the DTC arena, while also extending prior empirical work demonstrating the effect of biases related to healthcare decision making on the part of consumers (Ritov & Baron, 1990). While limited to just one population, one drug, and one Web site, this study provides evidence that a bias of omission (i.e., inflating the risks of action and attenuating risks associated with inaction) can occur in the Internet DTC context. Health experts are concerned that an unintended consequence of risk communications is that consumers may not reach out and use medications that could treat conditions. Given that a bias of omission was demonstrated in this research, that concern seems well-founded.

Findings from this study also suggest that a bias of omission (i.e., choosing to take no action) provides predicted psychological advantages because it results in less dissonance, leaves the consumer with a feeling of greater flexibility in future choices, and allows the patient to minimize personal responsibility for the decision. Stewart and Martin (2004) propose that the effectiveness of disclosures is based on how well consumers understand and use the information and should take into account individual differences such as consumer goals and knowledge. For example, a risk-averse and a risk-seeking individual may have different goals when it comes to utilizing disclosure information, thereby resulting in different comprehension and use of product information (Stewart, Folkes, & Martin, 2001). The findings from this study indicate that dissonance reduction appears to function indirectly as a goal for consumers when processing message-relevant information, thereby confirming the work of Dhar (1997). Additional research should examine the role that product familiarity plays in moderating the strength of the cognitive advantages resulting from a bias of omission. Increasing product familiarity through educational messages may

subsequently increase goal-relevant knowledge, thereby attenuating any preexisting bias (Kozup, Burton, & Creyer, 2006).

The findings related to the inclusion or exclusion of risks associated with inaction, however, are complex. Although it is the manufacturer's choice whether to provide this information in DTC Web site promotions, it offers an interesting scenario in which to test theory. The interactions found herein confirm the basic premise that risk perceptions depend on much more than simply providing accurate information about risks to consumers. Obviously, the interpretation of these interactions is speculative, but it does suggest that other factors impact the ability to clearly communicate drug-related risks. For example, consumers' estimates of the general likelihood of side-effect risks as well as the likelihood of specific adverse risks depends on the presence or absence of information about remaining untreated and the relative strength of the warning. In this study, it is not possible to examine what processes are driving these results. It could be that consumers make side-by-side comparisons when both the risks of treatment and of remaining untreated are presented, resulting in one of these two risk sets providing an "anchor" against which the other risk set is compared. Alternatively, consumers may have more experience with moderate risks (such as anxiety and depression) than severe risks (such as suicidal thoughts and cardiovascular problems) making it easier to envision their occurrence and therefore perceived to be more likely (Schwartz, 2004).

Graphically highlighting the black-box warning on a DTC site had little impact on consumers. Bold graphical highlighting and labeling of black-box risks did not affect consumer fair-balance ratings and modestly affected consumer risk perceptions. Graphic black-box warnings would not seem to result in consumers forgoing "the benefits of a product because disclosures cause them to underestimate its benefits relative to competitive alternatives or overestimate the risk of using the product," a situation in which "the consumer is not well served" (Stewart & Martin, 2004, p. 188). However, it also did not produce different perceptions of risk, meaning that the risk warnings, whether black-boxed or not, are processed similarly. Thus, it would appear that the addition of black-box warnings as desired by consumer advocates may not achieve any benefit over nonboxed warnings. Several reasons could explain the negligible impact of a graphic black-box warning. First, DTC Web sites are replete with information, potentially resulting in information overload (Scammon, 1977). Consumers could have ignored the black-box warning and gravitated toward other pieces of information they found more salient. Perhaps greater effort should be placed on educating the public about black-box warnings. Based on prior research in the area of warning noticeability, perhaps alternative mechanisms should be constructed to increase the prominence of black-box warnings on cluttered Web sites in order to increase consumer attention (e.g., color, callouts, pop-ups; Wogalter et al., 2002).

Finally, this study is the first to directly measure the fair-balance concept. Interestingly, none of the manipulated constructs (i.e., warning strength, black-box graphics, risks associated with leaving the condition untreated) had an effect on consumer perceptions of fair balance. There are at least two reasons this could occur. First, since the construct has not been directly assessed in previous works, it could be that the measure itself needs refinement and development. Given these measures are those under consideration by the FDA, this may provide some insight into that decision. Alternatively, it could be that

fair balance is a more robust concept than is risk perception, so that only very large changes in the underlying product risks or benefits have an effect on consumer perceptions of fair balance. Given the critical nature of this construct on policy, scale development and testing may be a fruitful research avenue.

An interesting extension of the current work would be to examine the impact of counter-risk information in both a print and television setting. While stricter guidelines for those media are in place and enforced, a reevaluation of DTC Internet promotions is a frequent topic of interest to both researchers and policymakers. Lastly, a potential opportunity for research would be to examine perceived credibility of various types of prescription information presented in a DTC Web site versus those presented in more traditional media outlets.

While using the Internet to promote prescription drugs provides the advantages of unlimited space, unconstrained time, and availability on demand, the use of this medium may also provide challenges to pharmaceutical companies. Providing more information does not necessarily lead to more accurate risk perception. Providing more definitive warnings, such as black-box warnings, as advocated by many may not differentially affect the consumer's risk/benefit judgments. Examining the content and formatting of DTC advertising on the Internet raises many interesting and important practical and theoretical questions for future research.

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