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## Do Prescription Drug Ads Tell Consumers Enough About Benefits and Side Effects? Results From the Health Information National Trends Survey, Fourth Administration

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### Abstract

Direct-to-consumer prescription drug advertising (DTCA) is a major source of consumer information about prescription drugs. The present study updates 2002 U.S. Food and Drug Administration phone survey questions that found that 44% and 61% of consumers thought that DTCA did not include enough information about benefits and risks, respectively. The present study was administered by mail using a nationally representative sample, and provides a more in-depth understanding of how these beliefs relate to demographic and health characteristics.

Data collected from 3,959 respondents to the National Cancer Institute's 2011 Health Information National Trends Survey finds results similar to the 2002 survey: 46% and 52% of respondents thought that DCTA did not include enough information about benefits and risks, respectively. Respondents fell into four groups: 23% agreed that DTCA tells enough about drug benefits and risks; 41% disagreed; 18% expressed no opinion; and 18% had discordant beliefs. DTCA attitudes were negatively associated with education, income, and whether respondents purchase prescription drugs; attitudes were positively associated with whether respondents understand prescription drug information.

This study confirms that a plurality of Americans believes that DTCA does not include enough information about benefits and risks, suggesting that the educational impact of DTCA could be improved.

### Keywords

DTCA; direct-to-consumer; prescription drug; HINTS

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Direct-to-consumer advertising (DTCA) is a major source of prescription drug information for consumers in the United States (e.g., Brownfield, Bernhardt, Phan, & Parker, 2004) and impacts several health outcomes, including diagnosis and treatment (Gilbody, Wilson, & Watt, 2005; Mintzes, 2012; Niederdeppe, Byrne, Avery, & Cantor, 2013). Proponents argue that DTCA is educational, providing consumers with information they need about prescription drugs (Calfee, 2002; Holmer, 1999). Critics argue it does not convey adequate information for consumers to make informed health decisions (e.g., Hollon, 2005).

What do consumers think? Several studies have examined the utility of DTCA for consumers. Many have concluded that consumers have moderately positive attitudes about DTCA (e.g., Ceccoli & Klotz, 2013). However, some studies show that consumers have mixed attitudes toward DTCA (Young, Paterniti, Bell, & Kravitz, 2005). For instance, in a 2005 Internet survey, approximately two-thirds of participants agreed that DTCA improves consumer understanding, but only roughly half agreed that DTCA provides them with enough information to help them decide whether to ask their doctor about the drug (Polen, Khanfar, & Clauson, 2009). These results suggest that even though consumers may agree that DTCA has some utility, they may still believe that DTCA needs more information.

Some of these studies have examined demographic differences in the perceived usefulness of DTCA. For instance, survey data suggest that older adults find DTCA more useful than do younger adults (Huh, DeLorme, & Reid, 2004), and that Korean Americans (Huh, DeLorme, Reid, & Kim, 2013) and Hispanic Americans (DeLorme, Huh, & Reid, 2010) find DTCA more useful than do White Americans. Using data from a nationally representative survey conducted in 2000–2001, Ceccoli & Klotz (2013) found that non-White respondents, respondents with less education, and respondents who searched for health information online were more likely to support the increase in the prevalence of DTCA that occurred at that time. In that study, support for DTCA was not related to age, gender, insurance status, or exposure to DTCA. The authors argue that DTCA appeals to individuals with less direct access to healthcare resources.

Although these studies examined attitudes toward DTCA in general, they did not examine attitudes toward particular components of DTCA such as benefit and risk information. By law, any prescription drug ad that makes claims about the drug's effectiveness must include a "fair balance" of both benefit and risk information (Prescription Drug Advertisements, 2012). In 2002 the U.S. Food and Drug Administration (FDA) conducted a telephone survey of U.S. adults who had visited a healthcare provider in the past three months and asked them about DTCA (Aikin, Swasy, & Braman, 2004). In the FDA survey, 61% of respondents reported that DTCA does not have enough information about risks, and 44% of respondents reported that DTCA does not have enough information about benefits.

In a national survey conducted in 2001–2002, participants exposed to DTCA in the past year were asked the extent of their agreement with the statement that DTCA "did not provide information on risks or benefits in a balanced manner" (Lee & Begley, 2010). The mean for the whole sample was the midpoint of the scale; however, Hispanic participants were less likely than White participants to agree with this statement. Demographic characteristics beyond race and ethnicity were not examined.

The DTCA landscape has changed since 2002. Print readership is declining (Kohut, Doherty, Dimock, & Keeter, 2012) and the use of digital video recorders allows for fast-forwarding through television ads (Wilbur, 2008). At the same time, there has been a rise in the use of the Internet in prescription drug promotion (Liang & Mackey, 2011), an evolving area for the pharmaceutical industry and regulators (FDA, 2014). In addition to these changes in media, the publication of industry guidelines (Pharmaceutical Research and Manufacturers of America, 2008) also changed the DTCA landscape. The objectives of the present study

were to (1) gather nationally representative data on current perceptions of benefit and risk information in DTCA and (2) identify the demographic, socioeconomic, and behavioral characteristics of individuals who do and do not believe that the ads have enough information about both benefits and risks.

## Methods

### Procedure

We conducted analyses on data from the fourth administration of the Health Information National Trends Survey (HINTS 4, Cycle 1; Westat, 2012). HINTS is a survey of a probability sample of the U.S. adult population conducted by the National Cancer Institute (NCI) every few years since 2003. The survey assesses health-related knowledge, attitudes, and behaviors in the civilian non-institutionalized population aged 18 or older in the United States.

HINTS 4 Cycle 1 was a mail survey fielded from October 2011 through February 2012. Respondents were selected using a probability random sample of addresses and were mailed a survey. Spanish-language surveys were available for those who requested one. The sample was equally divided between those households in which all adults were eligible to respond and those in which the household member with the next birthday was asked to respond. Surveys were sent to 12,385 households. Eligible questionnaires were received from 3,959 respondents. Of those, 443 respondents completed a shorter version of the survey. The overall response rate was 36.7%. The survey was approved by NCI's Institutional Review Board. Additional details about the sample and sampling design are available in the survey report on methodology by the contractor (Westat, 2012).

The long version of the survey included questions submitted by the FDA regarding prescription drugs, over-the-counter drugs, FDA-regulated foods, and medical devices. The questions were cognitively tested and piloted before the survey was administered. The 443 respondents who completed the shorter survey were not included in our analysis.

### Measures

#### DTCA items.

Respondents were presented with the following two statements about DTCA and were asked whether they agreed, disagreed, or had no opinion: "Ads for prescription drugs tell me enough about the benefits of using the drugs" and "Ads for prescription drugs tell me enough about their negative side effects."

#### Prescription drug items.

Respondents were asked whether they purchased prescription drugs for themselves or anyone else (yes or no). Respondents who reported buying prescription drugs were also asked whether they thought that the directions and warnings that come with prescription drugs are easy to understand (agree, disagree, or no opinion). For this item, respondents with no opinion were excluded from detailed statistical analysis.

Because these two variables are interrelated, we combined them into one item for regression analysis. The new variable consists of three groups: (1) respondents who reported that they did not purchase prescription drugs, (2) respondents who reported that they purchased prescription drugs and agreed the prescription drug information was easy to understand, and (3) respondents who reported that they purchased prescription drugs and disagreed that the prescription drug information was easy to understand. This variable was entered into the regression analysis as two dummy variables, and the referents are shown in Table 3.

### Demographic characteristics.

All respondents were asked to report their age, gender, race, ethnicity, education level, and income level. For testing of differences in means and percentages, we regrouped income from the original dataset and the average of each income range was selected to create an interval variable with four values in thousands of dollars (i.e., \$0-\$19,999 = 10; \$20,000-\$49,999 = 34.5; \$50,000-\$99,999 = 74.5; and \$100,000 or more = 150). For multiple-logistic regression analyses, we used the original interval variable. For difference of means and percentages, education categories were assigned a number to reflect the years of education completed. The new variable had the values 6, 9, 12, 13, 14, 16, and 20, reflecting total years of formal education. For multiple-logistic regression analyses, we used the original interval variable but collapsed the lowest three educational attainment categories to eliminate empty cells, for a total of five levels.

### Analyses

All analyses were conducted with replicated weights using SAS survey procedures in SAS 9.3. Fifty replicate weights were created by Westat using the jackknife resampling method. We examined weighted frequencies for the DTCA items as well as the cross-tabulation of the two items (Table 1). We created four groups: respondents who agreed that DTCA tells them enough about benefits and risks (DTCA agree), respondents who disagreed with both items (DTCA disagree), respondents who had no opinion about both items (DTCA no opinion), and those whose beliefs about benefits and risks were discordant (DTCA discordant; e.g., respondents may have agreed that DTCA tells them enough about benefits but had no opinion about risks).

We calculated the weighted means and percentages of the prescription drug and demographic characteristics for each of these four groups (Table 2). To assess the differences between groups, we focused on the two largest and most meaningful groups: those who agreed with both items and those who disagreed with both items. Using the analysis of maximum likelihood estimates in SAS SurveyLogistic, we tested each prescription drug and demographic variable separately to determine whether the “DTCA agree” group differed from the “DTCA disagree” group.

We then conducted a multiple-logistic regression using SAS SurveyLogistic with jackknife variance estimation to predict agreement that DTCA tells the respondent enough about benefits and risks from the prescription drug and demographic variables. We used forward stepwise equations: each equation added an independent variable based on the strength of the bivariate relationship as measured by chi-square. Best fit was recognized when the chi-

square value declined from the previous equation. *P* values were determined by analysis of maximum likelihood estimates from weighted logistic regression in which agreement or disagreement that DTCA tells enough about risks and benefits was the response variable.

## Results

As seen in Table 1, overall, only 33% of respondents agreed that DTC ads have enough information about benefits, and only 29% agreed that DTC ads have enough information about risks. Only 23% overall agreed that DTC ads have enough information about both benefits and risks. In contrast, 46% disagreed that DTC ads have enough information about benefits, and 52% disagreed that DTC ads have enough information about risks. Forty-one percent disagreed that DTC ads have enough information about both benefits and risks.

Table 2 presents the prescription drug and demographic characteristics of each group from SAS SurveyMeans and SurveyLogistic analysis. Compared with respondents in the DTCA agree group, respondents in the DTCA disagree group were more likely to be prescription drug buyers, had higher education and higher income, and were more likely to be White. Among respondents who purchased prescription drugs, respondents in the DTCA disagree group were less likely to agree that the information that comes with prescription drugs is easy to understand than were respondents in the DTCA agree group. Age, gender, and ethnicity did not differ between these two groups,  $p > .05$ .

The multiple-logistic regression model included four significant predictors (Table 3). Specifically, higher education and income reduced the odds of respondents agreeing DTCA tells them enough about benefits and risks. Respondents who agreed that prescription drug information is easy to understand were more likely to agree that DTCA tells them enough about benefits and risks than were respondents who disagreed that prescription drug information is easy to understand. Those respondents who did not purchase prescription drugs were more likely to agree that DTCA tells them enough about benefits and risks than were prescription-drug-buying respondents who disagreed that prescription drug information is easy to understand. A separate model showed that respondents who did not purchase prescription drugs and prescription-drug-buying respondents who agreed that prescription drug information is easy to understand were not significantly different from each other on attitudes toward DTCA (odds ratio = 0.97,  $p = .81$ ).

## Discussion

In a nationally representative survey, a majority of U.S. adults reported that DTCA does not include enough information about either benefits *or* risks, and a plurality reported that DTCA does not include enough information about benefits *and* risks. These results suggest that many consumers would agree with critics of DTCA and that the information about drug benefits and risks in DTCA needs to be improved to increase DTCA's public health impact. These results are similar to data collected in 2002 (Aikin et al., 2004), suggesting that attitudes about DTCA have not shifted over the last decade.

Individuals with higher education, individuals with higher income, and those more likely to purchase prescription drugs were more likely to believe that DTCA does not include enough

information about both benefits and risks. These individuals may be more motivated to search for detailed prescription drug information (i.e., those who purchase prescription drugs) or more able to search for detailed prescription drug information (i.e., those with higher education and income; Ramanadhan & Viswanath, 2006). They also may be more skeptical of DTCA in general (DeLorme, Huh, & Reid, 2009; Joseph, Spake, & Finney, 2008).

In addition, individuals who said they had difficulty understanding other prescription drug information also reported that DTCA does not include enough information about both benefits and risks. Past research has shown that people who are less confident in their ability to search for health information are less satisfied with their health information searches, their health care, and their own health and well-being (Rakovski et al., 2012). Thus, these individuals seem dissatisfied with the information they are receiving about prescription drugs from multiple sources, which may reflect a more general dissatisfaction with their overall health care.

Although we found an association between race and attitudes toward the benefit and risk information in DTCA, this association was not significant when other factors, such as educational attainment, were taken into account. This is in contrast to other studies that examined the relation between race and attitudes toward the usefulness of DTCA in general (e.g., Ceccoli & Klotz, 2013). This could reflect a change over time; many of the studies showing differences across race or ethnicity were conducted several years ago. It could also reflect a difference in the sample or question wording. Given the lack of clarity surrounding the relation between DTCA and demographics (Huh et al., 2004), additional research is needed on whether and how demographic groups respond differently to DTCA (Mukherjee, Limbu, & Wanasika, 2013).

The advantage of including DTCA-related items on the HINTS was the ability to gather responses from a large, nationally representative sample. However, this limited our ability to ask in-depth questions about DTCA. The questions we asked were limited to agreement or disagreement, so we cannot tell how strongly respondents felt. Also, we were not able to probe what kind of DTCA respondents were thinking of when they answered these questions: were they thinking of DTCA overall, or were they focused on television, print, or online advertising? Different media allow different amounts of information to be presented; therefore we might expect to see different responses depending upon the media format.

Further we do not know how respondents' exposure to, or familiarity with, DTCA, may have affected our results. Ad spending increased from 1998 to 2006, only to decline from 2006 to 2012 (Ad Age, 2011; Cegedim Strategic Data, 2013; Kornfield, Donohue, Berndt, & Alexander, 2013). However, DTCA spending in 2012, approximately \$3.4 billion, was higher than in 2002, and spending on internet promotion increased during this time. Moreover, across this time period there was an increase in the number of DTCA promotional pieces submitted to FDA (as required by FDA regulations that state that prescription drug advertising and promotional labeling must be submitted when it is first disseminated; Kiester, 2007, 2012). Although exposure to DTCA remains high (e.g., Alperstein, 2014; Kantar Media, 2013) it is possible that some participants were relying on their impressions

of DTCA they had seen in the past rather than more recent advertising. These findings should be replicated and expanded upon in a survey focused on consumers' attitudes regarding DTCA.

Another limitation is that these results cannot tell us what *kind* of information respondents think is lacking in DTCA. Individuals may not be looking simply for more benefits and risks to be listed, but rather for more contextual information about the benefits and risks already presented in the ads. Consumers may be looking for information about the duration, likelihood, or magnitude of the drug's benefits and risks (Young et al., 2005). For instance, one study found that the majority of participants agreed it was very or extremely important for clinical trial data to appear in ads (Schwartz, Woloshin, & Welch, 2009). Indeed, several studies support the inclusion of simple quantitative information about drug benefits and risks in DTCA to improve consumer understanding (e.g., O'Donoghue et al., 2013; Schwartz, Woloshin, & Welch, 2007; Schwartz et al., 2009). Another possibility is that consumer understanding of risk information could be improved by focusing on serious and actionable risks and including a disclosure that not all risks and side effects were presented. Although this would provide less information overall, it may provide consumers with more useful information (Disclosure Regarding Additional Risks in Direct-to-Consumer Prescription Drug Television Advertisements, 2014). Future research should further investigate what information about drug benefit and risks in DTCA would be most useful for consumers. Until these issues are addressed, it appears that many consumers continue to find DTCA lacking in important information.

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**Table 1.**

Weighted percentage of respondents by beliefs about DTCA.

	“Ads for prescription drugs tell me enough about the benefits of using the drugs”			
“Ads for prescription drugs tell me enough about their negative side effects”	Agree	Disagree	No opinion	Total
Agree	23.16%	4.18%	1.84%	29.18%
Disagree	9.04%	41.07%	1.50%	51.61%
No opinion	0.71%	0.95%	17.54%	19.21%
Total	32.91%	46.21%	20.88%	100.00%

*Note.* N = 3,959. Respondents who refused to answer either question or did not provide codeable responses ( $n = 67$ ) or who completed a short form of the survey that did not include these questions ( $n = 443$ ) were considered missing data.

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Table 2.

Weighted values (means and percentages) and standard errors (SE) for prescription drug and demographic characteristics by beliefs about DTCA.

Variable	DTCA agree (n = 780)		DTCA disagree (n = 1486)		Prob. > $\chi^2$	DTCA no opinion (n = 544)		DTCA discordant (n = 472)	
	Value	SE	Value	SE		Value	SE	Value	SE
% Buy prescription drug	67.9	3.7	79.0	1.9	.003	56.2	4.1	77.3	3.6
% Agree prescription drug information is easy to understand <sup>a</sup>	92.8	2.0	65.5	2.0	<.001	88.0	2.9	70.6	4.1
% Male	50.8	2.8	45.7	1.7	.18	56.3	3.5	46.1	3.7
% Asian	6.2	1.6	4.0	1.2	.36	6.6	2.3	5.7	1.5
% Black	17.2	2.8	10.6	1.6	.07	12.6	2.8	9.8	2.2
% White	73.3	2.9	81.6	2.0	.04	78.6	3.6	81.6	2.5
% Hispanic	12.2	0.9	9.4	1.6	.31	16.7	4.4	13.2	2.8
Mean age in years	46.2	1.3	48.6	0.7	.14	43.2	1.5	45.6	1.2
Mean years of education	13.4	0.2	14.5	0.1	<.001	13.2	0.2	14.7	0.2
Mean income (\$)	57,318	2,616	67,808	2,025	<.001	59,726	3,093	73,338	2,618

Note. Respondents were categorized as agreeing, disagreeing, or having no opinion that DTCA tells them enough about benefits and risks. If they agreed that DTCA tells them enough about benefits but not enough about risks or vice versa, they were categorized as ‘DTCA discordant.’

<sup>a</sup>This question was limited to respondents who said they bought prescription drugs (N = 2,796). P values were determined by analysis of maximum likelihood estimates from weighted bivariate logistic regression in which agreement or disagreement that DTCA tells enough about risks and benefits is the response variable.

**Table 3.**

Weighted multiple-logistic regression of agreement that DTCA tells enough about benefits and risks.

Data Summary		MLE	Wald $\chi^2$	Pr > $\chi^2$	Odds-ratio point estimate
Number of unweighted observations	1,869				
Sum of weights	108,811,597				
Fit Statistics					
<b>Analysis of Maximum Likelihood Estimates (MLE) and Odds Ratio Estimates</b>					
Parameter					
Intercept		0.59	5.38	.02	-
Educational attainment (1–5)		-0.09	7.24	.01	0.91
Income ranges (1–6)		-0.08	4.45	.03	0.92
“Do you agree that the directions and warnings that come with prescription drugs are easy to understand?” (0 = do not purchase prescription drugs or disagree; 1 = agree)		1.90	25.76	<.001	6.66
“Do you buy any prescription drugs for yourself or anyone else?” (0 = no, 1 = yes)		-2.03	25.35	<.001	0.13

Note. The probability modeled is DTCA = 1 (agree that DTCA tells enough about benefits and risks).