

Is the Information “Fair and Balanced” in Direct-to-Consumer Prescription Drug Websites?

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This study applies the Food and Drug Administration’s (FDA’s) “fair-balance disclosure” provision to examine the content of prescription drug websites, specifically focusing on the quantity and quality of risk information. The results show that even though most prescription drug websites provide both risk and benefit information, the two types of information are presented differently. This study suggests directions for regulators to consider in writing a more specific rule to ensure that information on prescription drug websites is balanced.

Introduction

More consumers than ever use the web to find information about medical conditions and treatment options. Madden and Rainie (2003) reported that the number of people seeking health information online grew by 59% between 2000 and 2003, reaching 73 million in December 2003. In a national survey, 38% of respondents reported using the Internet as a source of information to find prescription drugs (Thomaselli & Elkin, 2003).

Off-line direct-to-consumer (DTC) prescription drug ads such as television ads increasingly refer consumers to websites for more information. However, the FDA does not require television ads to contain the “brief summary” of risk information that must be included in all other forms of DTC ads, if the ads provide consumers with alternative sources of information such as a website address (FDA, 1999). Thus, the role of an individual prescription drug website has increased in importance. More than 25 million consumers have visited a pharmaceutical product website in the past 12 months (Manhattan Research, 2004). If a website does not provide consumers with balanced information on benefits and risks, consumers may be misled.

Despite the growing importance of prescription drug websites, few empirical studies have examined them. This study analyzed the content of individual prescription drug

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websites, specifically focusing on the presentation of risk information. Risk information such as side effects and contraindications may be the most crucial piece of information that consumers will seek from a website, since it cannot be conveyed adequately by broadcast ads due to time limitations (Holtz, 1998). This research used the FDA's "fair-balance disclosure" provision to evaluate information in each website, looking at whether a site contains well-balanced information presented to facilitate understanding of the advertised drug's potential risks as well as its benefits.

DTC Prescription Drug Advertising and FDA Regulation

FDA rules require all DTC prescription drug ads that mention both the advertised brand name and the treated disease to present a fair balance of the benefits and risks associated with the drug. The ad also must convey a "brief summary" of risk information, including major and minor side effects, contraindications, and benefits (Holtz, 1998). Meeting FDA requirements for advertising in lay media, especially in broadcasting, has proven difficult. Thus, since 1997 FDA guidelines for DTC advertising distinguish between print and broadcast ads. Broadcast ads are required to include only major side effects and contraindications. The "adequate provision" guidelines allow broadcast advertisers to avoid the "major statement provision" if they can provide adequate alternative sources to access the package labeling. The most commonly used alternative information sources are toll-free telephone numbers and manufacturer-sponsored drug websites (Holtz, 1998; Wilkes, Bell, & Kravitz, 2000).

The FDA issued a new draft guidance for print advertisements in February 2004. The new guidelines focus on using language and formats that more clearly convey risk information so that the average consumer is more likely to understand it (FDA, 2004).

The FDA has not written any regulations specific to DTC prescription drug websites. If a site mentions a drug by name, however, it must meet the standards applied to print advertising (Moore & Newton, 1998).

Literature Review

Fair balance is considered one of the most important aspects of FDA's regulations, because consumers are able to make sound decisions only with a complete understanding of the advertised drug's benefits and risks (Davis, 2000). Fair balance is determined both in terms of content and the format of the information (Roth, 1996). Any ad may be considered misleading if it does not present the risk information in at least the same "scope, depth, or detail" as that of the benefit information (Kopp & Bang, 2000).

A number of researchers have examined benefit/risk information in DTC drug ads and its impact on consumer comprehension of and reactions to the advertising. Most used experimental procedures to measure consumer memory, knowledge, and attitude regarding advertised products and DTC television ads (Morris, Mazis, & Brinberg, 1989; Morris, Ruffner, & Klimberg, 1985), magazine ads (Tucker & Smith, 1987), magazine and television ads (Morris & Millstein, 1984), or magazine ads and leaflets (Morris, Brinberg, & Plimpton, 1984). These studies found that consumer perceptions of and reactions to DTC drug ads varied significantly by the inclusion of risk information and presentation format of risk and benefit information.

Davis (2000) also reported that consumers who viewed a less complete risk statement were more likely to recommend or purchase an advertised drug and to perceive the drug as safer. Separate benefit and risk information in a more enhanced presentation

format (e.g., large, bold print, in color) generated higher knowledge levels among consumers (Wogalter, Smith-Jackson, Mills, & Paine, 2002). In addition, several researchers have reported information deficiencies in DTC prescription drug ads, including presenting incomplete information on risk-related factors (Roth, 1996), omitting basic elements of patient-required information (Bell, Wilkes, & Kravitz, 2000), describing benefits in vague and qualitative terms without supporting data (Woloshin, Schwartz, Tremmel, & Welch, 2001), and emphasizing benefit information over risk information (Kopp & Bang, 2000).

Direct-to-consumer drug advertising on the Web has drawn the attention of researchers only recently. Moore and Newton (1998) argued that the Web has features of both print and broadcast media and its interactivity makes it very different from any other media. Unlike other traditional media, website visitors are not passively “exposed” to content because, on the web, information is not “pushed” but “pulled” by viewers. Where information is located and how it is displayed as well as how viewers browse the website, therefore, can be more important than the information itself.

Graber and Weckmann (2002) conducted a content analysis of websites for anti-depressants. They found that most websites were easily accessible through search engines and contained information useful to educating consumers about medical symptoms. They also reported few comparisons between drug efficacy and adverse effects, however, making it difficult for consumers to make rational choices about drug selection.

Macias and Lewis (2003) analyzed the content of DTC prescription drug websites and found that most provided consumers with rich information and great educational value. From the results, the authors inferred that, in general, pharmaceutical companies were conforming to FDA requirements.

These studies are a valuable first step to understanding how pharmaceutical companies use the web to promote their products directly to consumers. However, both have deficiencies. Graber and Weckmann (2002) did not specifically examine information quality of DTC websites and Macias and Lewis (2003) tested “fair balance” using only the percentages of sites containing side effects and contraindications.

Research that examines the quality as well as the quantity (or presence) of critical benefit and risk information on DTC prescription drug websites is nonexistent. The current research is designed to fill the void.

Research Questions

The objective of this study was to investigate the content of risk information and how risk information is presented on DTC prescription drug websites. While content analysis has been applied to the web environment only recently, researchers have found it to be a viable technique (see, for example, Graber & Weckmann, 2002; Macias & Lewis, 2003; McMillan, 2000). On the other hand, Preston (2003) criticized researchers who used content analysis as often making false inferences about consumer perceptions and information use based on the data. This study used content analysis therefore, to focus on objective measures of information content (i.e., what information is available), not how consumers perceive the information.

The FDA’s “fair-balance disclosure” provision and previous studies on risk information disclosure in DTC drug ads provided a basic guideline for evaluating risk information in each website. Thus, the focus was whether websites contained well-balanced information, and whether information was presented in a way that would appear to help consumers to fully understand the advertised drug’s potential risks as well as its benefits. The research questions follow.

RQ1: To what degree do DTC prescription drug websites provide risk information (side effects and contraindications) relative to benefit information?

The analysis focused on the type of risk information on DTC prescription drug websites (the homepage as well as the website as a whole), the amount of information about risks versus benefits, the relative font size of risk and benefit information, and the type and amount of risk information communicated by the types of diseases the advertised drug treats.

Type of risk information was operationalized as either “general information” or “specific information.” If a website presented a general statement such as “for more information, see your doctor” without specific information on side effects and other risks, it was considered “general information.” If a website provided statements regarding specific side effects or other risks (e.g., the most common side effects are stomach and muscle pain), it was considered “specific information” (Morris, Mazis, & Brinberg, 1989). The different drug types were based on the categorization used by Roth in his 1996 research: (1) drugs used on a repeated basis (short-term periodic use); or (2) drugs used on a maintenance basis (long-term use).¹

RQ2: What steps were taken to improve ease of access to risk information on the website?

For this research question, the focus was the location of risk information on the website. Is it on the homepage or another page? How deep is the information located in terms of the site structure? Information on a homepage is available to all visitors to a site while information on other pages can be accessed only by those who go to those pages. In addition, the number of options available to consumers seeking risk information (e.g., a main navigation button, a text link in a body text, search engine, etc.) was used as a measure of ease of navigating the website to access risk information.

RQ3: How complete is the risk information?

There is neither a commonly accepted definition nor a consensus on a methodological approach to assess completeness of risk information. The FDA does not specify an objective measure of “complete” risk information (Holtz, 1998). To answer RQ3, therefore, the researchers defined “complete risk information” as presenting numeric descriptors. Websites that did not provide numeric descriptors of the level of risk were considered to provide “incomplete information.”

Method

Sample

A sample was drawn from the “Top 200 Prescriptions for 2000 by Number of US Prescriptions Dispensed” (<http://www.rxlist.com/top200.htm>; Source: Scott-Levin,

¹Originally, Roth used a third category, “drugs used occasionally (short-term unlikely repeat occurrence).” For this study, however, we collapsed the two short-term categories into one after consulting with a physician.

Newton, PA). Then, the researchers used several popular search engines to find stand-alone brand websites. Among the top 200 prescriptions, 140 ultimately were eliminated: 73 did not indicate any specific brand names, listing only the name of main ingredients of prescribed drugs (e.g., acetaminophen); 54 prescriptions did not have their own stand-alone brand websites; 11 sites were intended only for health care professionals; one (“Baycol”) had been withdrawn from the market; and one (“Serzone”) was updating its website.

Taken in the context of the total number of prescription brands with stand-alone websites, the final sample of 60 is not small. Bell, Wilkes, and Kravitz (2000) reported 101 different prescription drug brands in their study of DTC print ads and Macias and Lewis (2003) identified 90 DTC prescription drug websites as of March 2001. Based on the population size defined by Macias and Lewis, this study’s sample includes two-thirds of the entire population.

Coding

The coding scheme was developed based on the FDA’s fair-balance criteria and previous studies on risk information disclosure. The code sheet is available from the authors.

All websites analyzed were archived in January 2002 using ‘Grab-a-Site’ software from BlueSquirrel.com. ‘Grab-a-Site’ allows the researcher to capture all pages and image files included in a website and save them to a local disk so they may be viewed as they appeared when initially accessed. This is a crucial procedure in web content analysis, given that a website changes constantly (Weare & Lin, 2000). The archived websites were analyzed by the first author; another coder independently reanalyzed a subsample of 20 sites to ensure coding reliability. The overall coefficient of reliability for nonmetric variables was 89.6%, which is above the minimal 80% level suggested by Riffe, Lacy, and Fico (1998). Individual percentages of agreement also met the 80% standard except for one variable, “location of risk information—FAQ page,” which was dropped from the analysis.

Pearson’s correlation coefficient was used to check the reliability of metric measurement variables such as number of words of information and number of steps to a risk information page. The average Pearson correlation coefficient was 0.81–0.99 for number of words in risk information and 0.67 for number of words in benefit information.

Using the standards for reliability measures suggested by Neuendorf (2002) and Ellis (1994), we found that the correlation coefficient for number of words in benefit information indicates relatively low reliability. Perhaps the lower reliability is related to differences in the ways the words were counted. The words in benefit information, often presented in animation or an image file, were hand-counted. The words in risk information, which usually were presented in a text format, were counted using the “word count” option in Microsoft Word.

Results

The medical conditions treated by the drugs in the sample varied greatly from general allergy symptoms to various mental illnesses (see Table 1). Among 26 different conditions, the highest proportion of drugs treated depression followed by allergy and menopause/osteoporosis. Almost two-thirds of the sample (62%) included maintenance drugs taken continuously for a long time. The balance was categorized as short-term, repeat-use drugs.

TABLE 1 Medical Conditions Treated by the Drugs in the Sample ($N = 60$)

Categories	N	%
Depression	8	13.4
Allergy medicine	5	8.3
Menopause/osteoporosis	5	8.3
Heartburn	4	6.7
Asthma	4	6.7
Birth control	4	6.7
Diabetes	4	6.7
High cholesterol	3	5.0
Other	23	38.2
Total	60	100.0

Inclusion and Presentation of Risk Information

Fair balance of each website was measured in two ways: what type of information appears on each website and the ways in which consumers could access the information. First each website was examined to learn if it had both risk and benefit information, how well-balanced the amount of risk and benefit information was, and how specific the risk information was. All but one website provided both risk and benefit information somewhere on the website. Among the homepages, however, only about one-half (48.3%) presented both risk and benefit information; one-third presented only benefit information. Less than one-fifth (18.3%) had neither risk nor benefit information (see Table 2).

In terms of the type of risk information, all of the websites had specific risk statements about contraindications and side effects somewhere on the site. Homepages were somewhat less likely to adhere to this measure of fair-balance provision, however; 2 out of 29 homepages presented only general risk information and did not include numeric indicators of the level of risk.

When a website had both risk and benefit information, the amount of risk information on the homepage as measured by the number of words appeared to surpass the amount of benefit information. The average number of words in risk statements on 29 homepages was 114 compared with 72 words in benefit statements. The range in the number of words for risk statements was from 22 to 481 and from 4 to 318 for benefit statements. The number of words in risk information outnumbered the number of words in benefit statements by an average ratio of 1.6 to 1.

TABLE 2 Inclusion of Benefit and Risk Information

	Homepage		Whole website	
	N	%	N	%
Benefit only	20	33.3	1	1.7
Both	29	48.3	59	98.3
Neither	11	18.3	0	0.0
Risk only	0	0.0	0	0.0
Total	60	100.0	60	100.0

TABLE 3 Comparison of Font Sizes of Benefit and Risk Information ($N = 29$ Homepages With Both Benefit and Risk Information)

	<i>N</i>	%
Benefit information in a bigger size	14	48.3
Same	15	51.7
Risk information in a bigger size	0	0.0
Total	29	100.0

Almost one-half (48.3%) of the websites with both risk and benefit information, however, presented benefit information in a larger font size than risk information (see Table 3). Prominent benefit information, therefore, was more likely on the homepages of prescription drug websites than prominent risk information. This comparison of font sizes demonstrates that the number of words is not an ideal single measure of fair balance. Presenting benefit information in Flash movies or graphics may decrease the likelihood that risk information presented in small-size, plain-text format will draw a site visitor's attention (Lang, Borse, Wise, & David, 2002; Van Schaik & Ling, 2003).

Comparison of Risk Information Between Drug Usage Types

To compare risk/benefit information inclusion rates between the two drug usage types, a chi-square analysis was conducted. The results (see Table 4) showed that the inclusion rate of both risk and benefit information on the homepage was significantly different between different drug usage types. Difference of proportions tests revealed that long-term and short-term use drugs differed significantly in the inclusion of both benefit and risk information and in presenting no information at all (at the $p < 0.05$ level). The rate of including both risk and benefit information was higher for short-term, repeat-use drugs. All of the 11 websites that included neither risk nor benefit information fell into the "long-term, maintenance-use" drug category.

On the other hand, the presence of risk/benefit information in the entire website was not significantly different by drug type (Pearson chi square = 0.63, $p = 0.43$). Also, type of risk information and font size of risk information were not significantly different between different drug types (for homepages, Pearson chi square = 1.66, $p = 0.20$; for the whole website, Pearson chi square = 1.60, $p = 0.21$).

Ease of Access to Risk Information

Ease of access to information was operationalized as the location of risk information and the number of navigation options available to website visitors. As shown in Table 5, all but one website presented risk information in package inserts in either HTML or PDF format. The second most likely location for risk information was the "About" page, which provides general descriptions about the drug, including what conditions it can treat, how it works, and how to take the drug. Ninety percent of websites had risk as well as benefit information on the "About" page.

About one-half of websites had risk information in the Frequently Asked Questions (FAQ) section. Only 38.3% of websites had a separate risk information page. The average number of places with risk information within a website was 3.3, including package inserts; the number ranged from 1 to 5.

TABLE 4 Chi-Square Analysis of Risk/Benefit Information Inclusion Rate by Drug Type for the Homepage ($N = 60$)

	Drug type					
	Short term		Long term		Total	
	<i>N</i>	%	<i>N</i>	%	<i>N</i>	%
Benefit only	7	30.4	13	35.1	20	33.3
Both	16	69.6	13	35.1	29	48.3
Neither	0	0.0	11	29.7	11	18.3
Risk only	0	0.0	0	0.0	0	0.0
Total	23	100.0	37	100.0	60	100.0

Chi square = 10.41 ($df = 2, p < .01$).

Benefit information was available in almost all of the 5 places (4.8 average) considered in a website. All but 11 websites had benefit information available on the homepages, separate benefit information pages, the “About” pages, the FAQ pages, and on-line package inserts.

The number of steps from the homepage to risk information was 2.0 on average. The range was from 0, which meant there was detailed risk information on the homepage, to 4, which meant the viewers had to click four different links or buttons to reach detailed risk information. About three quarters of websites (76.6%) had risk information within two steps from the homepage. In websites that had a separate risk information page, the average number of steps to go to this specific page was 2.1.

On the other hand, the number of steps from the homepage to benefit information was 0 in all but 11 websites because specific benefit information was on the homepages. Even when there was no benefit information on the homepage, the information was accessible within the distance of one click.

The number of ways to find risk information averaged 1.8 and ranged from 1 to 5. The most frequently available navigational tool to find risk information (35% of the sample) was a direct link button on inside pages (any pages other than the homepage). Only 8% of homepages had direct link buttons. Around one-third provided a text link on inside pages or a search engine (30.0%). Over a quarter of websites (26.7%) did not have any navigational tools for consumers to use to find risk information.

TABLE 5 Location of Risk Information ($N = 60$, Multiple Choice)

Location	<i>N</i>	%
Package inserts	59	98.3
“About” page along with benefit	54	90.0
FAQ page	31	51.7
Homepage	29	48.3
Separate risk information page	23	38.3

In contrast, all 60 websites provided some type of navigational options to find benefit information. All but three of the analyzed websites provided a direct link button on the homepage to a benefit information page: among these three websites, one had a direct text link to benefit information from the homepage and two had a direct link button on inside pages.

An ANOVA was conducted to examine whether the ease of locating risk information differed between the two drug usage types. The number of places within a website with risk information varied significantly between drug usage types ($F = 3.98, p = .05$). There were more places to find risk information for short-term repeat-use drugs (mean = 3.57) than for long-term use drugs (mean = 3.08).

Completeness of Risk Information

The last research question asked how complete risk statements were. The results showed that more than three-quarters of websites did not provide numeric descriptors for the incidence level of each side effect other than the information that appeared in package inserts (see Table 6). Information completeness significantly differed between drug usage types (Pearson chi square = 6.74, $p < .01$). Long-term use drugs were more likely to present incomplete risk information than short-term use drugs.

Discussion and Implications

This study examined the content of DTC prescription drug websites, specifically focusing on risk information such as side effects and contraindications. As a whole, most prescription drug websites provided both risk and benefit information, reaffirming Macias and Lewis's (2003) findings. When the analysis shifted to how the information was presented, however, the results suggested an imbalance between risk and benefit information. Only one-half of the sample presented both types of information within the homepage. Also, about one-half presented risk information in a smaller font size than benefit information. Thus, pharmaceutical companies could make greater efforts to ensure that not only their websites but also their homepages provide consumers with well-balanced information.

If critical information is not on the homepage, its location influences how likely consumers are to find it (Moore & Newton, 1998). The number of steps from the homepage to risk information was 2.0 on average, and about three-quarters of websites had risk information within two steps from the homepage. Given that basic benefit

TABLE 6 Completeness of Risk Information ($N = 60$)

	Short-term drugs		Long-term drugs		Total	
	<i>N</i>	%	<i>N</i>	%	<i>N</i>	%
Complete risk information	8	34.8	3	8.1	11	18.3
Incomplete risk information	15	65.2	34	91.9	49	81.7
Total	23	100.0	37	100.0	60	100.0

Chi square = 6.74 ($df = 1, p < .01$).

information was available in about 82% of the analyzed homepages and more detailed benefit information was always available in a first-tier page, most websites seemed to make benefit information more available than risk information.

In terms of navigational options, benefit information also was more accessible than risk information. While most websites had a direct link to benefit information in the main navigational button set on the homepage, only 8% of websites provided the same tool for risk information. Furthermore, over a quarter of websites did not have any navigational tool for consumers to use to find risk information. Considering the nature of the web as a “pull” medium, any new regulations specific to the web should be written taking into consideration this interactive aspect in its fair-balance criteria.

Sheffet and Kopp (1990) proposed that the nature of the disease and the frequency of treatment affect a drug manufacturer’s likelihood of using DTC advertising. They suggested that drug manufacturers are more likely to reach consumers and disseminate information through DTC advertising in the short-term-use drug market, where new consumers constantly enter and leave and have low product knowledge and therefore seek information. By extension, one also might expect short-term-use prescription drug websites to provide more information than sites for long-term-use drugs. In fact, both risk and benefit information were more likely on the homepages of short-term-use drugs. In addition, risk information was more complete for short-term-use drugs than for long-term-use drugs.

Though preliminary, this study identified important issues for online DTC prescription drug advertising and regulations. It suggests that in an interactive environment such as the web, how information is presented and accessed can be as important—if not more important—as the information content itself. In addition, this study demonstrated the value to researchers and regulators of treating the homepage as a separate piece of marketing communication as well as a part of the entire website. As Moore and Newton (1998) suggested, if the impact of a drug site’s homepage is comparable with that of a print/broadcast advertisement, regulators should write a more specific rule to ensure that a drug website’s homepage is substantially balanced.

Although most homepages had more risk information than benefit information in terms of the number of words, differences in the way information is presented suggest that benefit information would be more likely than risk information to draw visitors’ attention. A limitation of content analysis, however, is that it cannot demonstrate how consumers perceive and interact with a website. Research with consumers is needed to learn the impact of different presentation formats upon consumers.

Further research also is needed to examine the impact of the location of risk information relative to benefit information within a webpage. In many homepages, benefit information was either at the top of the page, the center, or both, while a usual place for risk information was at the bottom of the page. Vigilante and Wogalter (2003) reported that consumers were more likely to see a prominent link to risk information near the top of a homepage or on a second-level page than to see it near the bottom of the homepage.

In addition, future researchers should examine DTC prescription drug websites using a sample based on advertising spending. An advertising-based sample might be more practical and it would be interesting to compare the results from different sampling schemes.

It is becoming more important to understand how consumers use and comprehend DTC ad-provided information in different media environments and to reexamine the fair-balance provision in the new interactive media context. This study provides a meaningful step in this direction.

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