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Communicating Risk Information in Direct-to-Consumer Prescription Drug Television Ads: A Content Analysis

Helen W. Sullivan[1], **Kathryn J. Aikin**[1], **Jon Poehlman**[2]

[1]U.S. Food and Drug Administration,

[2]RTI International

Abstract

Direct-to-consumer (DTC) television ads for prescription drugs are required to disclose the product's major risks in the audio or audio and visual parts of the presentation (sometimes referred to as the "major statement"). The objective of this content analysis was to determine how the major statement of risks is presented in DTC television ads, including what risk information is presented, how easy or difficult it is to understand the risk information, and the audio and visual characteristics of the major statement. We identified 68 DTC television ads for branded prescription drugs that included a unique major statement and that aired between July 2012 and August 2014. We used subjective and objective measures to code 50 ads randomly selected from the main sample. Major statements often presented numerous risks, usually in order of severity, with no quantitative information about the risks' severity or prevalence. The major statements required a high school reading level, and many included long and complex sentences. The major statements were often accompanied by competing non-risk information in the visual images, presented with moderately fast-paced music, and read at a faster pace than benefit information. Overall we discovered several ways in which the communication of risk information could be improved.

Keywords

direct-to-consumer; advertising; television; risk communication; prescription drug

Pharmaceutical companies use direct-to-consumer (DTC) advertising and promotional labeling to communicate the benefits and risks of prescription drugs to consumers. The industry spends billions of dollars a year on this promotion, particularly on television advertising (Kornfield, Donohue, Berndt, & Alexander, 2013). This results in several hours of DTC advertising exposure each year for the average television viewer (Brownfield, Bernhardt, Phan, Williams, & Parker, 2004). In turn, DTC advertising on television has been linked to increased prescription drug use, over-diagnosis, and over-treatment (e.g., Avery, Eisenberg, & Simon, 2012a; Niederdeppe, Byrne, Avery, & Cantor, 2013). Thus, it is important to know what information is being communicated in these ads and how it is communicated.

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The U.S. Food and Drug Administration (FDA) regulations require that prescription drug broadcast advertisements (ads), including television ads, disclose the drug's major risks in either the audio or audio and visual parts of the ad (Prescription Drug Advertisements, 2013). This disclosure of major risks is commonly known as the "major statement." The regulations also require television ads with major statements to provide consumers with information on how they can access the FDA-approved prescribing information (PI). Access could be provided through such means as a health care provider, a toll-free telephone number, a print ad, or a website ("adequate provision"). For the major statement to be useful for consumers, it should be presented in ways that make it easy for consumers to understand. This includes the language used to describe the risks, the visuals on the screen during the major statement, and the audio.

There are two broad categories of studies that have analyzed the content of DTC prescription drug television ads. First, several content analyses have examined differences between prescription drug and over-the-counter (OTC) drug television ads (e.g., Faerber & Kreling 2014; Greene, Choudhry, Kesselheim, Brennan, & Shrank, 2012). These studies conclude that, given FDA regulation of prescription drug advertising, prescription drug ads have more risk information and fewer false claims than OTC drug ads. Second, some content analyses have examined the "fair balance" of risk and benefit information in DTC television ads (Avery, Eisenberg, & Simon, 2012b; Kaphingst, DeJong, Rudd, & Daltroy, 2004; Macias, Pashupati, & Lewis, 2007). In seeking to determine whether risks and benefits are presented with similar depth and detail, these content analyses touch on issues relevant to the comprehension of the drug's risk information.

The first concern is which risks are presented. Avery and colleagues (2012b) found that by 2006–2007 all the television ads in their content analysis included serious and severe risks and most presented risks in order of severity, rather than prevalence. This is consistent with regulations for FDA-approved labeling, which mandate that the most severe risks (e.g., boxed warnings, contraindications) be presented first in the highlights section (Food and Drug Administration, 2006).

Several studies have documented low health literacy rates in the United States (Parker & Ratzan, 2010) and the difficulties that individuals with low health literacy have in understanding prescription drug information (Davis et al., 2006). Previous research has raised concerns about the accessibility of DTC advertising to consumers with low health literacy (Mackert & Love, 2011). For instance, DTC television ads often use medical as well as lay language to describe risks (Avery et al., 2012b; Kaphingst et al., 2004). However, Avery and colleagues (2012b) also found that almost all ads used short sentences to describe the risks in DTC television ads for antidepressants.

Research has shown that quantitative information can increase consumers' understanding of risk and benefit information in general (e.g., Zipkin et al., 2014) and specifically in DTC advertising (e.g., O'Donoghue et al., 2014; Schwartz, Woloshin, & Welch, 2009). Qualitative labels are less useful for communication because they are open to individual interpretation (Viscchers, Meertens, Passcheir, & De Vries, 2009). However, in previous content analyses of DTC television ads, one ad in each sample included quantitative risk

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information (Kaphingst et al., 2004, Macias et al., 2007), and one content analysis found that 57% described risk prevalence with qualitative terms and 65% described risk severity with qualitative terms (Kaphingst et al., 2004).

Audio can be used in ways that increases or decreases consumer comprehension. For example, music with a fast tempo can decrease consumers' recall of ad information (Fraser & Bradford, 2013; Oakes & North, 2006). On the other hand, using both audio and visual channels (dual-modality) has been found to increase consumer understanding of drug risk information (e.g., Glinert & Schommer, 2005; Wogalter, Shaver, & Kalsher, 2014), although there is some suggestion that audio only may be better for individuals with limited literacy (Kaphingst, DeJong, Rudd, & Daltroy, 2005). Unfortunately, previous content analyses of DTC television ads found that few ads used a dual-modality approach to convey all risk information (Kaphingst et al., 2004; Macias et al., 2007).

The visual images presented during the major statement could also impede clear communication. For instance, multiple scene changes can distract consumers from important information (e.g., Hoyer, Srivastava, and Jacoby, 1984; Thomas, Fowler, and Kolbe, 2011). Previous content analyses found that almost every DTC television ad they examined presented positive (Avery et al., 2012b) or positive and neutral visual images (Kaphingst et al., 2004) during the major statement.

The previous content analyses of DTC television ads were conducted on ads that aired between 1999 and 2007. Since 2007, new drug classes, such as oncology, have been advertised on television. There have also been changes to the regulatory and industry environment, such as the enactment of the Food and Drug Administration Amendments Act in 2007, FDA's (2009) draft guidance on presenting risk information, and the publication of industry guidelines (Pharmaceutical Research and Manufacturers of America, 2008). A review by Frosch, Grande, Tarn, and Kravitz (2010) proposed guidelines for presenting risk information in DTC television ads. These guidelines suggest presenting risk information at the end of the ad with no background music and with visuals distinct from the benefit information, keeping the density and speed of the risk information similar to the density and speed of the benefit information, and including quantitative risk information. In light of these guidelines, we investigated the presentation of the major statement in current DTC television ads. We had four overarching research questions:

RQ1: What risks are presented? This included questions about the number, type, and order of risks presented.

RQ2: How understandable is the major statement? This included questions about the reading level, grammar, and use of medical terms and lay language.

RQ3: Does the major statement include quantitative information? This included questions about the use of words and numbers to relay that frequency or severity of risks.

RQ4: What are the audio and visual characteristics of the major statement? This included questions about audio characteristics such as voice-overs and background music, and issues such as speed, tempo, and pitch. This also included questions about visual characteristics,

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such as the presentation of superimposed text and the visual images during the major statement.

Methods

We obtained television ads that aired between July 2012 and August 2014 that were recorded and identified (N = 320) as prescription drug ads by Competitrack as part of its nationwide tracking of broadcast and cable television advertisements. We excluded ads that were not for branded prescription drugs regulated by the Center for Drug Evaluation and Research at the FDA (http://www.accessdata.fda.gov/scripts/cder/drugsatfda). This resulted in a sample size of 207 ads. We read the ad transcripts to determine whether the ads had major statements, and we excluded 8 ads that did not have a major statement. Of the remaining 199 ads, we identified 68 ads with unique major statements. Note that two or more ads for the same prescription drug could be in the sample if the ads had different major statements (e.g., if the drug was advertised for different indications in each ad).

Of the 68 ads that met the study criteria, we randomly selected 50 ads as the main sample for the content analysis presented here.1 We randomly selected 10 ads to use in a pilot to refine the coding scheme. We used the remaining 8 ads (14% of the sample after refining the coding scheme) to assess inter-rater reliability between two raters. Because inter-rater reliability was high for these 8 ads (risk codes Cohen's kappa (κ) = .96; understandability codes κ = .79; audio codes κ = .92; superimposed text codes κ = .88; and image codes κ = .93), we proceeded with coding the 50 ads in the main sample. Two raters independently coded each ad, with discrepancies resolved through the use of a third rater.

We created a coding scheme based on the research questions. The codes addressed the text, audio, and visual images of the major statement (see Tables 1–5). Coders referred to the drug's PI to define each drug's risk information. They examined each drug's PI to determine the presence of a "boxed warning" (serious or life-threatening risk concepts presented in a black box at the beginning of the PI) and whether and how (by severity or prevalence) drugs were listed in the Adverse Events and Warnings and Precautions sections of the PI.

For some codes, we used objective measures rather than independent raters. Competitrack supplied general ad characteristics, such as the length of the ad and the drug class being advertised. In Table 2, the use of medical and lay language, abbreviations, number of sentences (long and overall), and words per sentence were coded using the Health Literacy Advisor (http://healthliteracyinnovations.com), and reading level was coded using Microsoft Word. For the audio characteristics in Table 3, MixMeister BPM Analyzer (http://www.mixmeister.com/download-bpmanalyzer.php) was used to code the tempo of the background music, Audacity (version 2.2.1, http://audacity.sourceforge.net) was used to code the difference between speaker and background volume, and Adobe Audition (version 7, https://creative.adobe.com/products/audition) was used to code the difference between the benefit information and major statement in volume and pitch. In Table 4, the superimposed text size was measured using a ruler (http://www.markus-bader.de/MB-Ruler/index.php).

[1]Details about the study sample can be obtained from the corresponding author.

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Results

General ad characteristics

The most common drug classes advertised were psychiatry/neurology (n = 9; 18%), pulmonary/allergy (n = 8; 16%), and metabolic/endocrine conditions (n = 6; 12%). During the time period studied, Competitrack recorded ads that ran from 1 to 8,006 times, with a median 2,115.50 times. The ads ranged from 15 to 120 seconds, with a mean of 70.20 seconds (SD = 21.74). The major statements ranged from 7 to 73 seconds, with a mean of 33.00 seconds (SD = 13.30). Most major statements (n = 47; 94%) were presented as one segment. The major statement tended to be placed toward the end of the ad (Table 1).

Risks presented during the major statement

Major statements often contained several risk concepts such as serious adverse reactions, contraindications, and common side effects. The number of risk concepts presented ranged from 5 to 42, with an average of 20.50 risk concepts (SD = 8.85; Table 1). Twenty-three of the ads (46%) were for drugs with at least one boxed warning. Of those, 20 (87%) mentioned the boxed warning first. Only seven (30%) included every boxed warning risk concept during the major statement in audio. An additional four (17%) included every boxed warning risk concept in audio or superimposed text. The remainder (n = 12; 52%) did not include one or more risk concepts from the boxed warning (11 did not include one boxed warning risk concept and one did not include two boxed warning risk concepts). When we examined boxed warning risk concepts that were missing or presented only in text, we found that they were often targeted toward health care professionals (e.g., “Health care providers should advise patients to strictly adhere to recommended instructions for use”) or referred to an indication other than the one being advertised (e.g., a boxed warning that begins “When treating patients with asthma” was not included in ads promoting a COPD indication).

Of the 48 major statements that included risks from both the Warnings and Precautions section of the PI and the Adverse Events section of the PI, 32 (67%) mentioned the risks from the Warnings and Precautions section first. Only 11 major statements had sufficient information to determine whether the risks were ordered by prevalence (i.e., had more than one adverse event included in the major statement and a PI with prevalence rates for all adverse events). Of those, 3 major statements (27%) ordered the adverse events by prevalence.

Understandability of the major statement

The major statements had an average of 6.68 sentences (SD = 2.49), with an average of 15.60 words per sentence (SD = 3.79; Table 2). On average, 58.43% (SD = 24.48) of the sentences in the major statement were long sentences (i.e., 10 or more words) and 26.77% (SD = 19.94) of the sentences were complex (i.e., contained three or more commas). The major statements had an average reading level of 11th grade (M = 11.02, SD = 1.76) on the Fry grade reading level, a mean of 13.10 (SD = 2.43) on the Gunning fog index, and 49.56 (SD = 10.64) on the Flesch-Kincaid reading ease test. These three tests were highly correlated (rs = .80–.92) and suggest that the major statements, on average, require a high school reading level.

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Almost all of the major statements (n = 48; 96%) used at least one medical term (e.g., allergic reaction, blood pressure, nausea), with an average of 3.00 (SD = 1.58) medical terms used. Only seven major statements (14%) used lay language to explain the medical terms. At least one abbreviation appeared in 16 major statements (32%). Some major statements also used complex language such as passive voice (n = 16; 32%), syntactic ambiguity (n = 9; 18%; words need clarification from later words; Mohamed & Clifton, 2011), and double negatives (n = 4; 8%).

Quantitative information

None of the major statements used numerical or visual information to describe a risk's frequency or severity (Table 2). Thirty-five major statements (70%) indicated risk frequency using words like "common" or "increased." Thirty major statements (60%) indicated risk severity by using the words "serious" or "severe."

Eight major statements (16%) included comparative information. They compared the risks of the advertised drug to similar drugs, with statements such as "like most sleep medicines" and "high blood pressure has been reported with [Drug] and medicines like it."

Audio characteristics

All of the major statements were read in voice-over (Table 3). One major statement (2%) also included a woman speaking directly to the camera. Approximately half of the major statements (n = 27; 54%) were read by men; women read 23 major statements (46%). In most ads, the speaker did not change between the benefit information and the major statement (n = 31; 62%).

Eight major statements (16%) contained background noise (ambient sounds during the major statement apart from music or dialogue). All of the major statements included background music. Almost all (n = 49; 98%) included instrumental music; one (2%) included music with vocals. The average tempo was moderately fast, with 114.44 beats per minute (SD = 10.01). On average, the speaker was louder than the background noise and music, $t(49) = 12.84$, $p < .001$ (M_{diff} = 7.52 decibels, SD = 4.14, 95% CI = 6.34–8.70).

The major statement was presented at a significantly higher average speed (M = 3.17 words per second [wps]; SD = 0.30, or 190.2 words per minute) compared with the information presented before the major statement (M = 2.86 wps; SD = 0.50, or 171.6 words per minute; $t(49) = 4.44$, $p < .001$; M_{diff} = −0.31 wps, SD = 0.49, 95% CI = −0.4- −0.17). In contrast, the mean differences in volume (M_{diff} = 0.19 decibels, SD = 1.30, 95% CI = −0.18–0.56) and pitch (M_{diff} = −8.20 hertz, SD = 51.33, 95% CI = −22.78–6.39) between the major statement and the preceding benefit information were not significant, ps > .05. In addition, the speaker's emotional tone (positive/happy/upbeat vs. serious/somber) when reading the major statement was the same as the preceding benefit information in 46 cases (92%) and was rated as more serious or somber in 4 cases (8%).

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Visual characteristics

Superimposed text.—Almost all of the major statements (n = 49; 98%) included superimposed text. Of those, about half (n = 23; 47%) were rated as having good text contrast (defined as a dark color on a light background or vice versa; Table 4). The type of banner used varied: 15 (31%) used solid color banners, 15 (31%) used semi-transparent banners, 10 (20%) did not use a banner, and the remainder (n = 9; 18%) used a combination of these. The text size ranged from 2.1% of the screen to 4.4%, with an average size of 3.29% (SD = 0.56).

The superimposed text was presented during 77% of the major statement (mean duration was 25.12 seconds, SD = 18.64). Federal Trade Commission regulations (Disclosures in Warranty or Guarantee Advertising, 1985) have been interpreted to mean that disclosures should be read at a speed of 108–180 words per minute (Best, 1989; Hoy & Andrews, 2004; Hoy & Lwin, 2007). The superimposed text was presented slower than this, at an average of 1.44 words per second (SD = 0.99), or 86.4 words per minute.

The majority of the major statements (n = 38; 76%) included some risk information in superimposed text, and only one (2%) included all the risk information in superimposed text. Non-risk information was also often conveyed via superimposed text during the major statement. For instance, adequate provision elements appeared during several major statements: 40 (80%) referenced a print ad, 27 (54%) referenced a toll-free number for the company or product, and 25 (50%) referenced a website for the company or product. Almost half of the major statements (n = 23; 46%) included all three of these elements. In addition, four major statements (8%) included a statement directing consumers to the FDA website and toll-free number for reporting side effects, and two (4%) included a cost promotion (e.g., coupon) during the major statement.

Images.—On average, there were 9.68 camera shots (SD = 4.97) during the major statement. The tone of the visual images was positive in 28 major statements (56%), neutral in 21 (42%), and negative in 1 (2%; Table 5). None of the major statements included visual images related to the risks, although one (2%) showed a person not feeling well. In contrast, 28 major statements (56%) included visual images related to drug benefits.

Discussion

The clear communication of risk information in DTC television ads is vital to consumers' understanding of the drug's risk-benefit tradeoff. Previous content analyses were conducted on DTC television ads from 1999–2007. Given changes in the regulatory and industry environment since these previous content analyses, we conducted a content analysis of the major statement of risk information in 50 DTC television ads that aired between July 2012 and August 2014 to determine how drug risk information is communicated. Overall we discovered several ways in which the communication of risk information still could be improved.

The major statements often contained numerous risks, with an average of 20 risk concepts in a major statement. Risks appeared more likely to be listed in order of severity rather than

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prevalence, with the most serious risks coming first for most prescription drugs with boxed warnings. Previous content analyses recorded fewer risks presented during DTC television ads (Kaphingst et al., 2004; Macias et al., 2007), suggesting that the length of the major statement has increased over time. This may be welcomed by some consumers, as evidence suggests that consumers prefer ads to contain more information about drug risks (e.g., Friedman & Gould, 2007). However, an excessive amount of risk information could result in negative consequences if consumers cannot interpret and use the information because of constraints on working memory, literacy, or information processing style (Abel et al., 2006; Day, 2006; Mitchell, Walsh, & Yamin, 2005; Wilson & Wolf, 2009). Our analysis can provide information about the number of risks in the major statement, but it cannot determine the *ideal* length and number of risk concepts therein. Which specific risks to include should be informed by both labeling and research that investigates consumer comprehension of the major statement.

The major statements required a high school reading level, and many included long and complex sentences. Almost all included at least one medical term, which may have contributed to the high reading level and complexity of the information. This is concerning given that many consumers have low health literacy (Parker & Ratzan, 2010). Although it may not be possible to avoid all medical terms when describing drug risks, care should be taken to avoid complex language and present the information in the clearest manner possible. Presenting fewer risks may also help eliminate long, complex sentences and therefore increase understanding of the risks presented.

None of the major statements included quantitative information. Instead, qualitative labels such as “common” were used. This is similar to previous content analyses (Kaphingst et al., 2004; Macias et al., 2007), which suggests that DTC marketing has yet to embrace the inclusion of quantitative information, notwithstanding calls for this information to be included in DTC television ads (e.g., Frosch et al., 2010). Because research supports the use of quantitative information (West et al., 2013), one way to improve the major statement may be to replace qualitative labels with quantitative information.

Despite published recommendations (Frosch et al., 2010), the major statements were often accompanied by moderately fast-paced music, and the risk information was also read at a faster pace than the benefit information. These audio characteristics can make it difficult for consumers to understand the risk information, especially for older adults (Fraser & Bradford, 2013; Oakes & North, 2006; Wingfield & Tun, 2001). Advertisers may consider presenting the major statement at a slower pace to increase consumer understanding.

Almost all the major statements included superimposed text; however, its use may not have aided consumers’ understanding of the risk information. First, the superimposed text could be difficult to read. Second, we found that only one ad used both audio and visual channels to convey all risk information. Use of the dual-modality approach has not increased since previous content analyses were conducted (Kaphingst et al., 2004; Macias et al., 2007), despite research findings and the FDA’s (2010) consideration of this practice. The finding that the majority of major statements included some risks in super-imposed text suggests that these ads can be accommodated for dual-modality presentations for all the risks. Finally,

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many ads used the superimposed text during the major statement to convey non-risk information. The effects of presenting non-risk information during the major statement is unclear, with one study showing a decrease in risk retention (Wogalter et al., 2014) and another study not finding a significant effect on risk retention (Aikin, O'Donoghue, Squire, Sullivan, & Betts, 2016). Given that the presence of non-risk information is unlikely to *increase* consumers' understanding of the risk information, it would be prudent to avoid it during the major statement.

In keeping with previous content analyses (Avery et al., 2012b; Kaphingst et al., 2004), we found that about half of the ads contained positive visual images during the major statement, 42% contained neutral visual images, and none of the visual images were risk-related. As a result, the visual images shown during most major statements do not reinforce the risk information. In addition, the number of camera shots suggests that the major statement often includes multiple scene changes. Because this can distract consumers from important information (e.g., Sullivan, Boudewyns, O'Donoghue, Marshall, & Williams, in press; Thomas et al., 2011), decreasing the number of scene changes in future ads may improve the communication of risk information.

The study had some limitations. First, content analyses cannot tell us how consumers respond to, or comprehend, these ads. Quantitative studies with consumers that investigate characteristics of the major statement would give additional insight into how well the major statement is understood. Second, we looked at one snapshot in time; changes in advertising and regulation over time could lead to shifts in how the major statement is presented in DTC television ads. Third, for some of the audio, visual, and health literacy questions, we relied on tools for objective coding. These codes depend on the accuracy of each tool. On the other hand, some of the codes were subjective and therefore open to coders' biases. We attempted to address this concern by double-coding each variable.

The use of objective measures for healthy literacy-related codes raises a methodological consideration for future research. To effectively communicate to a lay audience, words should be used that are familiar to the audience, and any specialized terminology should be defined in plain language (Adams & Bruck, 1993; Redish, Felker, & Rose, 1981). While the concept is well-documented, there is a dearth of literature and resources available to effectively measure and define jargon, especially when multiple coders are making a determination. The software program employed in this study provided the advantage of having an objective way to measure and code jargon within the major statement. However, the trade-off was the loss of the subjective expertise of a skilled coder who may be able to better determine whether a term was truly jargon in the context in which it was applied. More research is needed to create a measure of jargon that is both objective and flexible enough to account for contextual factors, as well as evolving terms that may not be included in a static database.

Another methodological issue in need of future research is the measurement of audio characteristics. A review of literature failed to identify any established approach for coding audio. Given a lack of an established methodology, we sampled short segments of sound that featured uninterrupted speech or background sound and then used the objective audio

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measures to determine the characteristics of these samples. Future research would be aided by validated, standardized methods to capture and measure audio.

Our findings provide a view of the current DTC television environment for consumer research to build upon. The findings from this study will benefit future and ongoing studies that address the communication of information in DTC television ads. These currently ongoing studies include examinations of (1) the amount of risk information in DTC television ads (FDA, 2015a), (2) the presentation of superimposed text in DTC television ads (FDA, 2016a), (3) including quantitative information in DTC television ads (FDA, 2016b), and (4) how audio characteristics of DTC television ads affect older adults and the hearing-impaired (FDA, 2015b). This content analysis also shows there is a need for more research on the role of literacy in DTC advertising.

DTC ads are prevalent on television (Kornfield et al., 2015) and advertisers are also posting these television ads online (Muncy, Iyer, & Eastman, 2014). One way that DTC advertising affects health care is by encouraging consumers to ask their health care provider about the drug. Consumers may use the information in advertising to decide whether to have this discussion. Good, accurate information enables consumers to make informed choices about when (and when not) to seek treatment. It is imperative that these ads provide an accurate, fairly balanced communication of the product's characteristics. The increased regulatory and industry focus on the communication of risk information since 2007 may have led to an increase in the number of risks presented in DTC television ads, without a corresponding increase in the accessibility of this information. Thus, our results suggest an unintended consequence of a focus on risk completeness without an accompanying focus on understandability. Recommendations for improving the communication of risk information (e.g., Frosch, 2010) have yet to be heeded. In particular, our research suggests a need to consider further the ordering of risks within the major statement (prevalence versus severity), the health literacy levels of ads, lack of quantitative information in presenting risks, and the competing effects of multiple visuals when conveying critical information.

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Table 1

Risks presented during the major statement ($N = 50$).

	Mean	Standard deviation
Ad length in seconds	70.20	21.74
Major statement length in seconds	33.00	13.30
Length of ad after major statement in seconds	9.00	4.49
Number of risk concepts	20.50	8.85
	n	%
At least one boxed warning in PI	23	46
Boxed warning listed first in major statement	20	87
Every boxed warning in audio	7	30
Every boxed warning in audio or superimposed text	4	17
Major statement included risk concepts from Warnings and Precautions and Adverse Events sections of PI	48	96
Warnings and Precautions listed first	32	67
Adverse Events ordered by prevalence[a]	3	27

Note. PI = Prescribing information.

[a]Out of 11 major statements that had more than one adverse event in the major statement and had a PI with prevalence rates for all adverse events.

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Table 2

Understandability of the major statement and inclusion of quantitative information ($N = 50$).

	Mean	Standard deviation
Number of sentences	6.68	2.49
Words per sentence	15.60	3.79
% Long sentences (10 or more words)	58.43	24.48
% Complex sentences	26.77	19.94
Number of medical terms	3.00	1.58
Reading level		
Fry grade reading level	11.02	1.76
Gunning fog index	13.10	2.43
Flesch-Kincaid reading ease test	49.56	10.64
	n	%
At least 1 medical term	48	96
Used lay language to explain medical terms	7	14
At least one abbreviation	16	32
Passive voice	16	32
Syntactic ambiguity	9	18
Double negatives	4	8
Risk frequency or severity numbers or visuals	0	0
Risk frequency words	35	70
Risk severity words	30	60
Comparative information	8	16

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Table 3

Audio characteristics of the major statement ($N = 50$).

	Mean	Standard deviation
Background music tempo (beats per minute)	114.44	10.01
Difference between speaker and background volume (decibels)	7.52	4.14
Difference between benefit information and major statement		
Speed (words per second)	−0.31	0.49
Volume (decibels)	0.19	1.30
Pitch (hertz)	−8.20	51.33
	n	%
Spoken in voice-over	50	100
Spoken direct-to-camera	1	2
Spoken by a man	27	54
Spoken by a woman	23	46
Change in speaker from benefit information to major statement		
No change	31	62
Contained background noise	8	16
Contained background music	50	100
Instrumental music	49	98
Music with vocals	1	2
No change in emotional tone	46	92
Emotional tone more serious/somber in major statement	4	8

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Table 4

Visual characteristics of the major statement: superimposed text ($N = 50$).

	Mean	Standard deviation
Size (percent of screen)	3.29	0.56
Duration (seconds)	25.12	18.64
Speed (words per second)	1.44	0.99
	n	%
Super-imposed text during major statement	49	98
Good text contrast[a]	23	47
Banners[a]		
Solid color	15	31
Semi-transparent	15	31
No banner	10	20
Combination of banner types	9	18
Content		
Some risk information in superimposed text	38	76
All risk information in superimposed text	1	2
Print ad reference	40	80
Toll-free number for company/product	27	54
Website for company/product	25	50
MedWatch statement	4	8
Cost promotion	2	4

Note.

[a]Percentage denominator = 49 major statements with superimposed text.

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Table 5

Visual characteristics of the major statement: images ($N = 50$).

	Mean	Standard deviation
Camera shots	9.68	4.97
	n	%
Visual image tone		
Positive	28	56
Neutral	21	42
Negative	1	2
Risk-related visual images	0	0
Benefit-related visual images	28	56
Visual images showing person not feeling well	1	2