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A Wonderful Life or Diarrhea and Dry Mouth? Policy Issues of Direct-to-Consumer Drug Advertising on Television

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Over \$4 billion is being spent on direct-to-consumer advertising (DTCA) of prescription drugs. Although the greatest proportion of this media budget is spent on television, relatively few studies have investigated the key issues of DTCA on television (DTCA-TV), including fair balance, FDA regulations and if information or appeals is focused on more. This study found that emotional and rational appeals were used to a similar degree in DTCA-TV. Print tends to be more informative than TV. After developing a four-tiered classification scheme (lawbreakers, bare minimums, DTC main pack/peloton and proactives), this study found that DTCA-TV ads are not doing a good job of meeting the FDA's fair balance requirement, particularly in presenting risk information in a comprehensible manner. Today's new active healthcare consumers often want to learn what issues are important to consider when investigating drugs and how to evaluate alternative courses of treatment. Given the proportion of money spent on television, the medical industry is correct to be concerned that education does not appear more important to DTCA advertisers.

Ever since 1997 when the FDA changed its guidelines for the direct-to-consumer (DTC) broadcast advertising of prescription drugs, television advertising for this category has exploded. Pharmaceuticals have become one of the largest and fastest-growing advertising categories in the United States, accounting for around \$2.5 billion in expenditures in 2003 (Thomaselli, 2004) and \$4.45 billion in 2004 (Bittar, 2005; Hensley, 2005b). Within the overall category, individual brands of prescription drugs have substantial advertising budgets. In 2003, Pfizer spent \$100 million

annually on Viagra, and Bristol-Myers Squibb spent \$70 million on Plavix (Thomaselli, 2004).

The growth of DTC advertising (DTCA) has resulted in great interest in this category, both among practitioners and academicians. Amid criticisms about DTC, Johnson & Johnson is trying a new DTCA format for one of their brands, the Ortho Evra birth-control patch, which puts drug risk information on a more equal level creatively and in terms of ad time (Hensley, 2005a). They are urging other DTC companies to follow suit and place risks in a more prominent position, as opposed to obscuring "safety information by showing such things as a 'swirling castanet show' as risks are being discussed" (Hensley, 2005a, p. B1). Johnson & Johnson is hoping this will not only be a better way to educate and counsel

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consumers, but will also improve relations with patients, doctors and regulatory agencies.

Previously published content analyses of DTCA have focused primarily on print ads, and have largely been critical of the approaches used by advertisers (e.g., Bell, Wilkes, & Kravitz, 2000; Roth, 1996; Woloshin, Schwartz, Tremmel, & Welch, 2001). In recent years, however, the bulk of DTCA dollars have been spent on television. In 2004, \$1.5 billion (35% of total DTC media spending) was allotted to network TV alone (Bittar, 2005). However, cable is taking a bigger share of this spending and 2005 is predicted to bring a broader marketing mix (e.g., direct mail, patient education, promotions) with a smaller portion going to network TV (Bittar, 2005). Pharmaceuticals are moving away from their heavy spending on television in general. Recent industry sources have commented that some companies are rethinking their TV media allocation because of the "return on the money spent as well as a [sic] increasing public and regulatory backlash against TV ads for prescription medicines" (Hensley, 2005b, p. B1). Only recently have there been studies that investigated the content of DTCA on television (DTCA-TV; Kaphingst, Dejong, Rudd, & Daltroy, 2004).

Given that television advertising accounts for a major proportion of DTC advertising expenditures, it is somewhat surprising that there is a lack of academic policy studies focusing on the content of DTCA-TV. This article presents the results of a content analysis of television ads for prescription drugs (DTC-TV). This study had three main goals—to compare the content of DTC-TV ads with the findings of previous studies on print DTCA, to analyze to what degree the ads meet Food and Drug Administration (FDA) guidelines, and to identify what selling messages/advertising appeals are employed. This study therefore furthers our understanding of the content of DTC-TV and if it differs substantially from its print counterpart, and, if so, in what respect and to what end. This study focuses on the policy issues pertaining to the content of DTC-TV, including FDA regulation and whether the concerns about the use of emotional versus rational appeals warrant policy recommendations.

This study is particularly relevant in light of previous critiques of print DTCA alleging that such ads mislead consumers by failing to provide them with balanced information. As print advertising is generally considered superior to television in terms of its ability to communicate cognitive information, this study makes a contribution by examining the types of information conveyed by DTC-TV ads compared with their print counterparts. This study helps to fill a void in the literature by evaluating whether DTCA-TV is complying with FDA guidelines. The content and quality of DTCA is of great concern and interest to its many stakeholders—consumers, physicians, legislators, the pharmaceutical industry, and academics.

LITERATURE REVIEW

The growth of DTCA has resulted in great interest among marketers, medical practitioners, and scholars alike. Marketers have been concerned with the question of how to measure the effectiveness of DTCA, an especially interesting problem in light of the fact that consumers cannot directly purchase the advertised brands. Medical practitioners and scholars in various disciplines have been more concerned with the impact of DTCA on individual and public health, the appropriateness (or lack thereof) of pharmaceutical use resulting from DTCA, and the impact of DTCA on the doctor–patient relationship, as well as the economic impact of such ads on overall health care costs (Mintzes, 2001). Although much of this research has focused on DTC ads in the United States, scholars have also begun to examine the issue in other countries, such as New Zealand (the only country other than the United States where DTCA is permitted) and Canada. Policy makers are particularly concerned about the impact of DTCA in Canada, where the health care system is in large part state funded. Although DTC-TV ads in Canada cannot mention both the disease and the brand name in the same ad, a large number of Canadian consumers receive cross-border television signals from the United States, including DTC-TV commercials.

The Key Issues of DTC-TV

DTCA has inspired both supporters and detractors. Supporters contend that DTCA helps to inform consumers about various medical conditions and makes them aware of the treatment options available to them (Calfee, 2002). Detractors contend that advertising, with its overtly persuasive intent, is a form of communication ill-suited to educating consumers (Lexchin & Mintzes, 2002). Mintzes (2001) also cites concerns about DTCA compiled by PHARMAC, New Zealand's state-owned pharmaceutical management agency, including that DTCA targets the vulnerable with emotional rather than rational information. Wolfe (2002) also states that DTCA contains powerful, emotion-arousing images and frequently fails to present balanced information on the safety and effectiveness of the products advertised. Coney (2002) cites two examples from New Zealand to illustrate her claim that "the primary purpose of DTC advertising is to appeal to emotions such as shame and anxiety about social exclusion rather than impart good-quality information, particularly evidence-based information about benefits and risks" (p. 219). Other researchers also echo concerns about the lack of information in ads and the potential for miscomprehension by consumers (Paul, Handlin, & Stanton, 2002). They also contend that DTCA rarely includes suggestions about lifestyle changes or other nonpharmacological interventions (Kravitz, 2000).

On the other side of the debate, the main arguments of industry supporters include that DTCA helps patients

become more knowledgeable about illnesses and drugs and increases compliance (the chance that they will take their medicine and go to their doctors) which, in turn, lessens long-term problems and health-care costs (Teinowitz, 2001). Specifically, some think DTCA is particularly positive in exposing the public to side effects that were previously not publicized (“DTC Has Worked Says FDA,” 2001), as well as educating consumers about common yet serious conditions that often go untreated even when effective treatments are available (“No Negative Impact,” 2001). However, by and large, neither the potential benefits nor the potential negative consequences of DTCA have been proven. This underlines the need for more research in this field. Toward this end, this content analysis of DTC-TV commercials examined the types of appeals used in TV commercials for prescription drugs and the types of information made available to consumers and provided evidence to determine if the charges leveled against DTCA by its critics are justified.

Rational Versus Emotional Appeals

Some previous print content analyses have examined whether DTCA appeals primarily to the consumers’ emotions or their intellect. Parker and Delene (1999) analyzed print DTC ads and classified the types of appeals that they were using into the following categories: news/feature, problem/solution, testimonial, endorsement/authority, education, and humor. They reported that problem/solution was the most popular appeal, whereas humor was the least used.

Bell, Kravitz, and Wilkes (2000) conducted a content analysis of print DTC ads and found the most commonly used appeals were (a) claims of effectiveness, (b) symptom control, (c) innovativeness, and (d) convenience. Bell, Wilkes et al. (2000) found that beyond the condition name and symptoms, few print advertisements gave details about the drug or medical condition (e.g., precursors, mechanism of action, etc.). They recommended that future research evaluate the secondary sources of information available to consumers (e.g., television).

Woloshin et al. (2001) found that emotional appeals were used 67% of the time and experiences perhaps being caused by medical reasons were found 39% of the time. Vague and qualitative language to describe the benefit of the medication was found in 87% of the advertisements and data about the benefit was included only 13% of the time. About 50% of the advertisements did use data to describe side effects and listed side effects that generally occurred infrequently. The authors concluded that “provision of complete information about benefits would serve the interests of physicians and the public” (Woloshin et al., 2001, p. 1146).

Recently there has been more interest in DTCA-TV (Brownfield, Bernhardt, Phan, Williams, & Parker, 2004). Kaphingst et al. (2004) questioned the educational value of the ads and their ability to achieve fair balance after

examining use of medical and lay terms, format of product information, and time consumers had to absorb benefits and risks. Although their study goes beyond the scope of previous ventures, it is somewhat limited in its scope by the level of detail used in coding benefit and risk information and in its use of a nonprobability sample drawn only from network TV programs.

In this study, we attempt to extend the literature in this area by including detailed coding of advertising appeals and benefit information as well as medical/drug information, using a probability sample that included cable stations, and comparing the content of DTC-TV ads with previous findings about the content of DTC ads in print media. In addition, this study’s sample was collected in 2003 and is an important update in a fast-moving industry (the previous two studies’ samples were collected in 2001). Identifying the types of appeals used in these ads is important for public policy about DTC because it indicates how and to what degree the ads focus on benefits as opposed to risk information. Therefore, the following research question is posed.

RQ1: What are the most common advertising appeals found in DTCA-TV?

Medical and Risk Information

In terms of the informational value of DTCA, Bell, Wilkes, et al. (2000) describe the educational quality of ads as “highly variable (p. 111).” Almost all of the ads in their study contained the name of the drug and the condition being treated, but other potential sources of information were rarely mentioned. Only 27% of the ads identified a cause or risk factor, only 12% contained information about the prevalence of the condition, and only 9% made any effort to clarify myths or misconceptions about the condition. In a different study using the same data set, Bell, Wilkes, et al. (2000) developed a more detailed classification of the types of information found in DTC ads. The categories identified by them included (a) condition name; (b) misconceptions; (c) precursors; (d) prevalence of condition; (e) symptoms; (f) alternative treatments; (g) mechanism of action; (h) success rate; (i) supportive behaviors; (j) time to onset of action; and (k) treatment duration. Macias and Lewis (2003) used this classification with three additions (prescribing information, side effects, and contraindications) for their study of the content of DTC Web sites. To remain consistent with previous literature, this study will apply this classification to DTC-TV commercials.

RQ2: What medical information, including side effects and benefits, is included in DTC television ads?

RQ3: How is the information about side effects presented in DTC-TV commercials (e.g., audio only, audio plus text, text only)?

One of the characteristics that differentiate TV commercials from print ads is the limited amount of time available for the communication of ideas and information. This is particularly important in the case of DTCA, where advertisers are required to communicate the limitations, side effects, and contraindications of the advertised drugs, apart from information about the medical condition being treated. One might question whether the normal duration of a TV commercial (usually 15, 30 or 60 sec) is adequate to communicate all of this information in a comprehensible manner. Further, critics have alleged that DTC ads are imbalanced in their presentation of benefits versus warnings (including side effects, contraindications, and limitations of the drug; Kaphingst et al., 2004; Mintzes, 2002; Roth, 1996). Sometimes, DTC-TV commercials use visual, as well as verbal, elements to convey their main selling points, while presenting warnings in the form of superimposed fine print, or in the background audio track.

RQ4: What proportion of total commercial time is devoted to warning messages such as side effects, contraindications, and limitations?

In addition, it is important to better understand the relative strengths and weaknesses of the different media in presenting DTC information. This has important policy implications because of the high percentage of money being spent on DTC-TV. Macias and Lewis (2003) addressed this issue with reference to Web sites, but it is even more important that researchers undertake a comparison of print and television given that they still account for the vast majority of DTCA dollars. However, this is changing as more dollars are moving away from TV and toward other media, including the Internet, and relationship marketing techniques (Hensley, 2005b).

RQ5: How do DTC television ads compare to print ads and Web sites in terms of medical information included?

FDA and DTC Drug Advertising

In August 1997, the FDA issued a Draft Guidance for consumer-directed broadcast advertisements for drugs. The new guidelines made it much easier for pharmaceutical companies to engage in DTCA of prescription drugs on television. Advertisers were no longer required to provide the somewhat misleadingly named “brief summary,” described as “a true statement of information in brief summary relating to side effects, contraindications and effectiveness” of the drug (FDA, 1997, para. 12). Before 1997, only two types of prescription drug ads were exempt from the FDA’s brief summary requirement. These were (a) reminder ads (ads that mentioned the drug’s brand name but did not say anything about the condition treated, effectiveness, or indications),

and (b) disease ads (ads that mentioned the specific conditions that could be treated, but did not mention the drug by name).

The FDA’s 1997 Draft Guidance allowed drug companies to run DTCA in broadcast media without a brief summary, provided they fulfilled the following requirements set forth for DTCA-TV in this guidance:

1. *Adequate provision* [italics added] for the dissemination of approved or permitted package labeling in connection with the broadcast presentation (e.g., toll-free number, Web site, print advertisements, publicly accessible brochures or pharmacists and physicians).
2. Are *not false or misleading* [italics added] in any respect
3. Present a *fair balance* [italics added] between information about effectiveness and information about risk.
4. Include a thorough *major statement* conveying all the product’s most important risk information in consumer friendly language.
5. Communicate all information relevant to the product’s indication (including limitations to use) in *consumer-friendly language* [italics added]. (p. 2)

In the 2004 Guidance for Industry, which focused on DTC magazine advertising, the FDA further defined consumer-friendly language to be fully understandable by the lay reader and free of technical and scientific terms or jargon. For example, a consumer may not understand the term *contraindications* but is more likely to understand the phrase “You should not take drug X if” The latter is considered “consumer-friendly language.”

Fair balance is not specifically defined by the FDA. However, previous research has employed various definitions that are important to take into consideration. The following are qualities of fair balance that have been suggested or used in previous research—both content and format are important (Roth, 1996); physical features (e.g., color) help distinguish text and lead to increased learning (Wogalter, Smith-Jackson, Mills, & Paine, 2002); quality and quantity of risk information is important (Huh & Cude, 2004); and risk information needs to be presented in the same scope, depth, and detail as benefit information (Kopp & Bang, 2000). Given this information, the next research questions are

RQ6: Are DTC television ads meeting the fair balance criteria set forth by the FDA and further defined by previous research?

RQ7: Toward which types of additional information sources (adequate provision) do DTC-TV ads direct their viewers? In what format are these referrals made (e.g., audio only, audio plus text, text only)?

METHOD

Sampling Procedure

The commercials analyzed in this study were videotaped during the 7-day period from Monday, July 21, through Sunday, July 27, 2003. To obtain a representative probability sampling of DTC-TV commercials across all 7 days of the week, and across various day parts, programs were videotaped using a constructed week. The constructed week comprised six day parts: morning (6:30–10 a.m.), morning daytime (10 a.m.–1 p.m.), afternoon daytime (1–4 p.m.), early fringe (4–8 p.m.), prime time (8–11 p.m.) and late fringe (11 p.m.–2 a.m.). Programs were videotaped from the four major broadcast networks (ABC, CBS, FOX, NBC) and three cable networks (CNN, MSNBC, and Lifetime) in the Southeastern United States. These seven channels were chosen because they had the highest number of DTC spots from 1997 to 2003, according to VMS (a news and advertising monitoring company). A total of 156 hr of programming was taped. The coders then identified a total sample of 106 DTC-TV commercials, including repetitions of the same commercial. Repeat instances of the same commercial have been included in this analysis, as repetition is an important measure of the frequency with which consumers encounter messages for a given brand.

Sample Description

Allergies and gastrointestinal disorders (such as acid reflux disease) were the two most frequently targeted conditions (with 23.6% of the ads each). Psychiatric and neurological disorders (such as depression and ADHD) were the next most frequent, accounting for 15.3% of the ads. To a lesser degree, the following conditions were also found—cardiovascular disease, dermatological conditions, sexual functioning, musculoskeletal ailments, urological conditions, and cancer-related ailments. Prevacid (which treats acid reflux disease) was the most frequently advertised brand, accounting for 15.1% of all ads in the sample. The next most frequently advertised brand was Zoloft (an antidepressant) (10.4%), followed closely by Ambien (a sleep aid), Nexium (a treatment for acid reflux disease), and allergy drugs Clarinex and Singulair. Other drugs included in the sample were Plavix, Procrit, Strattera, Allegra, Detrol LA, Elidel, Ortho Evra, Viagra, Lamisil, Remicade, Retin-A-Micro, and Zocor. When evaluating this sample, it is important to note that the sample was drawn from TV ads airing in the Southeastern part of the United States during the summer. This might have influenced the number of allergy ads present in the sample. The majority (70%) of the ads did not list the pharmaceutical company, but of those that did, the most common were Merck (8%), Astra Zeneca (7%), and Pfizer (6%).

The largest proportion (33%) of the ads were on ABC, followed by CBS (17%), Lifetime (15%), NBC (12%), CNN

(11%), MSNBC (7%), and Fox (5%). Contrary to popular belief, most ads were during the afternoon day part (1–4pm; 31%), followed closely by early evening (4–8 p.m.; 29%), then prime time (8–11 p.m.; 15%), morning (6:30–10 a.m.; 14%), and finally morning daytime (10 a.m.–1 p.m.) and late fringe (11 p.m.–2 a.m.), both with 6% of the sample. Sixty-two percent of the sample were 60-sec ads, 23% were 30-sec ads, and 14% were 15-sec ads. Although there is a common impression that the majority of DTC TV ads are during the evening news, this was actually not the case in this sample. Soap operas contained the highest percentage of the sample (25%), followed by the national/local news (15%), news/magazine shows (14%), talk shows (12%), dramas (5%), and situation comedies (4%). Finally, the “other” category contained another fourth of the sample and indicates the importance of new genres of programming, including game shows (e.g., *Jeopardy*), reality shows (e.g., *Big Brother 4*), courtroom shows (e.g., *Judge Judy*), and movies.

Code Sheet Development

A code sheet was developed for the content analysis using variables from previous content analyses of DTCA (Bell, Kravitz, et al., 2000; Macias & Lewis, 2003) and content analyses of television advertising in general (Stewart & Furse, 1986). The telecast date, channel, day part, program type, program name, ad length, brand name, and pharmaceutical company were recorded. In addition, the commercials were coded for the following information: medical condition being treated (Bell, Kravitz, et al., 2000); medical information (Bell, Wilkes, et al., 2000; Macias & Lewis, 2003); side effects, benefits, advertising appeal, general message strategy, advertising selling points (Bell, Kravitz, et al., 2000); and sources of additional information.¹

Procedure and Reliability

The coding was done using two separate sets of coders at two large research universities for a total of five coders. To maintain the integrity of the research protocol, the training was done synchronously at both universities through a teleconference. To clarify any questions and pretest the code sheet, coders used five DTC-TV commercials that were not drawn from this sample. The pretest yielded few questions and high reliability (87%, using percentage agreement between all five coders). Confusions or problems were resolved.

Approximately 85% of the sample was coded by two coders to establish reliability. Intercoder reliability was established using both Cohen’s kappa and percentage agreement. Cohen’s kappa ranged from 0.49 (e.g., quick-acting

¹Additional detail about the coding procedure can be obtained from the first author.

selling appeal or time to onset of action) to 1.00 (e.g., desire to get back to normal or lifestyle appeals), with an overall average of .86, and percentage agreement ranged from 92% (e.g., general emotional appeals and vignettes) to 100% (e.g., economical and easy on the system selling points) with an overall average of 98%. These averages are above the minimal agreement levels for Cohen's Kappa (.75 or above) and 80% for percentage agreement (Riffe, Lacy, & Fico, 1998). Any variables that were below the Cohen's kappa cutoff of 0.75 were dropped from the analysis (e.g., alternative treatments, mechanism of action). Disagreements between the coders were resolved through discussions until 100% agreement was achieved.

Testing Fair Balance

It is important to further research's understanding of how fair balance can/should be defined and to begin to understand to what degree advertisers are meeting fair balance requirements. Therefore, this study proposes and implements a new classification scheme for fair balance. The sample ads were placed into one of these four categories using a post hoc analysis procedure of the variables coded in this study (and previously found to be reliable). The four levels are

1. *Lawbreakers*: Ad does not meet fair balance requirement; no side effects are coded (if benefits were included).
2. *Bare minimum*: This is deemed as the minimum that will not raise too many flags with the FDA; some side effects are listed with little/no concern for format or scope. Several variables were considered to identify the "bare minimums." They had to spend less than 10% of time on risk information (the amount of time spent on side effects was divided by the length of the ad) and no features were added to increase the visibility of the risk information (quantitative as well as qualitative information, voiceover and superscript, and/or research results mentioned).
3. *The DTC main pack/peloton*: This is defined as those who do a little more than the minimum so they will not stand out and get complaints. Such ads include one or more features that increase the scope or visibility of risk information (quantitative as well as qualitative information, voiceover and superscript, research results mentioned and/or more than 10% of ad time spent on risk information).
4. *Proactive (safety-oriented approach; Hensley, 2005a)*: This is the recent development discussed earlier that Johnson & Johnson introduced in March 2005 for its Ortho-Evra birth control patch, which presents risk information in a similarly creative format as benefit information. Because this is a new format introduced after our sample was collected, it

is not represented here. The "proactive" group was not expected nor explicitly coded because the issue developed after this study's sample was selected and coded. The authors asked the coders if they remembered any ads with this distinct creative format. Although this is not a method for which the reliability could be checked, the format is so distinct we felt comfortable that the coders would remember these ads apart from the traditional format.

RESULTS

Advertising Appeals

RQ1 asked what the most common advertising appeals were in DTC-TV ads. For the purposes of coding, this was then divided further into general message strategy and advertising selling points.

General message strategy. There was both a distinct difference in the specific types of general message strategies used as well as the extent to which rational (59.7% of appeals) versus emotional strategies (40.3% of appeals) were used. Rational strategies were most likely to be classified as a general rational/informational appeal (74.5%), as opposed to a more specific appeal. "Slice of life" was the most common (51.9%) specific appeal used, followed by "problem/solution" (33.0%), demonstration of results (19.8), and testimonials by a product user (18.9%).

The most common specific emotional strategy used was the "desire to get back to normal" (64.2%), followed by comedy/humor (22.6%), and "search for adventure" (11.3%). The third most common was the general emotional classification (not otherwise specified; 19.8%). Other interesting but less commonly used emotional appeals included bandwagon (3.8%), fear (2.5%), vanity (.9%) and sex (.9%). Additional details are in Table 1.

Selling points. The results for the specific selling points included in DTC-TV ads are reported in Table 2. More than half of the ads (53.8%) promised the advertised medication could help return the viewer to a more "normal" or active lifestyle. Almost half of the ads (44.3%) assured relief of symptoms. A quarter of the ads mentioned the possibility of prevention. Only 12.3% of the DTC-TV commercials made any explicit claims of innovativeness. Fewer DTC-TV ads (21.7%) made specific claims about how effective the drugs were. Interestingly, only 21.7% of the DTC-TV ads in this sample contained quantification of their selling points.

Medical Information

RQ2 asked to what extent the various categories of information cues were found in DTC-TV ads. RQ3 compares

TABLE 1
General Message Strategy

	%
Rational/Information Strategies	
Rational/informational, general	74.5
Slice of life	51.9
Problem and solution (before/after presentation)	33.0
Demonstration of results by using the project	19.8
Testimonial by product user	18.9
Progress	3.8
Convenience	2.8
Endorsement by celebrity or authority	0.9
Past, present, future	0.0
Emotional Strategies	
Desire to get back to normal	64.2
Comedy/humor	22.6
Emotional, general	19.8
Search for adventure	11.3
Bandwagon	3.8
Security	2.8
Transfer of masculine/feminine appeal	2.8
Fear	2.5
Vanity	0.9
Sex	0.9
Too fat/too thin/less than perfect	0.0

Note. *N* = 106.

TABLE 2
Selling Points Used

Selling Point	%	Print ^a
Allows for more active lifestyle/return to more normal lifestyle	53.8	6
Symptom control	44.3	41
Prevention	25.5	16
Quantitative statement	21.7	—
Effective	21.7	57
Nonmedicated	14.2	14
Innovative (drug is new or a breakthrough)	12.3	41
Safe	9.4	11
Psychological benefit	8.5	11
Cure	7.5	3
Nonaddictive	4.7	5
Powerful	3.8	9
Social	3.8	3
Convenience	2.8	38
Quick acting	2.8	6
Economical	0.9	5
Reduced mortality	0.0	7
Dependable	0.0	4
Natural	0.0	7
Easy on system	0.0	3

Note. There may be more than one point per ad; therefore percentages may add up to more than 100%.

^aData are from "The educational value of consumer-targeted prescription drug print advertising," by R. A. Bell, M. S. Wilkes, & R. L. Kravitz, 2000, *Journal of Family Practice*, 49, p. 1092–1098.

DTC-TV to DTC print ads (as identified by Bell, Wilkes, et al., 2000). The results pertaining to these questions are presented in Table 3. The specific drug being advertised is

named in 98.1% of the ads, and the name of the condition being treated is named in 86.8%. As required by the FDA, all of the ads in which the condition is named also contain disclosures of side effects. The ads in which the condition is not named are 15-sec reminder ads, and FDA regulations do not require that side effects be disclosed.

A little more than half the ads (57.5%) in the sample mentioned the symptoms of the condition being treated (compared to 60% of print ads in Bell, Wilkes, et al., 2000), and 52.8% had some mention of how the drug worked, that is, mechanism of action (compared to 36% of print ads in Bell, Wilkes, et al., 2000). An example of this is an animated ad for the antidepressant drug Zoloft, which has a schematic diagram explaining the causes of depression and explaining how Zoloft remedies the problem. More than a third of the ads (35.8%) mentioned the drug's indications and the medical limitations of usage, and 27.4% of the ads gave some idea of how the medicine was to be taken (neither reported by Bell, Wilkes, et al., 2000).

The DTC-TV ads in the sample reported the prevalence of the various medical conditions (16%) to a slightly higher degree than print ads (12%) as found in Bell, Wilkes et al. (2000). Although 19.8% of the ads did mention supportive behaviors, such as diet and exercise (compared to 24% in Bell, Wilkes, et al., 2000), only 7.5% of the ads in the sample made any mention of what might happen if the condition were not treated through medication (not measured in Bell, Wilkes, et al., 2000).

Presentation of Risk Information

RQ3 asked in what format (audio, text, or both) the side effects information was presented in DTC-TV ads. Of the 106 ads in the sample, 92 ads (86.8%) contained some form of disclosure. Out of these ads that included disclosure, almost all of them (97.8% or 85% of the entire sample) disclosed side effects solely in the voice-over audio portion of the ad, whereas the remaining 2 ads (2.2%) had the disclosure in both the voice-over as well as in text form.

As television commercials are by nature limited in their time, one of the concerns that critics of DTCA have raised is that advertisers do not achieve a fair balance in their presentation of persuasive brand claims and their presentation of disclaimers (e.g., Coney, 2002). Thus, RQ4 asked what proportion of total commercial time is devoted to disclaimers such as side effects, contraindications and limitations of effectiveness. From the data, one can see that the average 60-sec DTC-TV spot contains less than 8 sec devoted to disclaimers (13% of the total ad time), 30-sec ads had 4.4 sec of side-effects disclaimers (15% of total ad time), and most of the reminder 15-sec spots devote literally no time to such disclosures. This is because, as noted earlier, reminder spots that do not make any explicit references to the condition being treated do not have to make any references to side-effects.

TABLE 3
Medical Information

	TV	Web ^a	Print ^b (2000)	χ^2 (TV vs. Web)	χ^2 (TV vs. print)
Medical condition					
Condition name	86.8%	97%	95%	5.991*	2.194**
Clarification of misconceptions	5.7%	21%	9%	10.442***	1.222
Precursors	5.6%	74%	27%	98.526***	21.164***
Prevalence	16.0%	66%	12%	50.273***	1.227
Symptoms	57.5%	84%	60%	16.736***	.199
Treatment information					
Alternative treatments	— ^c	63%	29%	44.269***	4.224*
Mechanism of action	— ^c	83%	36%	20.432***	9.456**
Success rate	2.8%	23%	9%	19.042***	4.452*
Supportive behaviors	19.8%	69%	24%	48.019***	.812
Time to onset of action	2.8%	52%	20%	62.488***	17.710***
Treatment duration	17.9%	50%	11%	22.772***	3.512
Side effects	86.8%	94%	—	3.256	—
Contraindications	8.5%	80%	—	102.647***	—
Drug name	98.1%	—	—	—	—
Directions for medication use	27.4%	—	—	—	—
Drug's indication & medical limitations	35.8%	—	—	—	—
Result of no treatment described	7.5%	—	—	—	—

Note. Each site could potentially have numerous pieces of information; therefore, percentages do not add up to 100.

^aData are from "A content analysis of direct-to-consumer (DTC) prescription drug Web sites," by W. Macias & L. S. Lewis, 2003, *Journal of Advertising*, 32, p. 43–56.

^bData are from "The educational value of consumer-targeted prescription drug print advertising," by R. A. Bell, M. S. Wilkes, & R. L. Kravitz, 2000, *Journal of Family Practice*, 49, p. 1092–1098.

^cVariable dropped for low reliability.

* $p \leq .05$. ** $p \leq .01$. *** $p \leq .001$.

Comparison of DTC TV to Print

To summarize and answer RQ5, there were five pieces of medical or drug information that were found to be present to a (statistically significant) higher degree in print ads (as found by Bell, Wilkes, et al., 2000) than in TV ads: condition name, precursors, success rate, time to onset of action, and alternative treatments. It should be noted that the difference in condition name is primarily a result of "reminder" TV ads not requiring the condition name. There was only one variable that was present in TV to a higher degree (statistically significant)—mechanism of action.

Fair Balance

It is difficult to empirically test whether a DTC ad meets the FDA's definition of fair balance because the FDA does not state specific requirements. However, this study collected several pieces of data and developed a classification scheme that sheds new light on how well DTC television ads might or might not be meeting FDA guidelines. Using the classification scheme described in the Method section, there were two lawbreakers (1.9%), 11 bare minimums (10.3%), 93 in the DTC main pack/peloton (87.7%), and no ads in the proactive group.

Fourteen percent of the sample did not disclose side effects. Given that 12% of sampled ads do not list bene-

fits (reminder ads are not required to list side effects), there were still two advertisements that listed benefits but did not list side effects. This is a clear violation of the FDA's fair balance requirement. Beyond this, 85% of the side effects were listed with a voice-over only and 1% included both superscript and a voiceover, compared to 71% of benefits presented as voice-over only and 17% as voiceover and superscript. In all cases the superscript was large enough to be readable. Side effects were presented for an average of 6.3 sec. The mean ad length was 46.3 sec. Therefore, 40 sec were spent on benefits, creative execution, and additional information (e.g., where to find additional drug information). The vast majority of the ads (90%) placed the risk information in the middle or end. Only one ad included quantitative information about risks. Finally, only five (4.7%) of the ads included research information pertaining to risks.

Adequate Provision

Through the "adequate provision" requirement, DTC-TV advertisers are required to refer the viewer to other sources of information. RQ6 asked which sources of information the consumer was being referred to. Of the 106 commercials in the sample, 105 (99.1%) contained a Web address, 103 (97.2%) provided a toll-free phone number, and 97 (91.5%) made reference to a print ad in a specific magazine.

Eighty four of the ads (79.2%) also instructed the viewer to consult a health care provider for more information. Eighteen of the ads (17.0%) supplied this information solely in visual format (usually through a text super), and the remaining 87 ads (82.1%) reinforced the text super with a voice-over.

DISCUSSION

This study has begun to fill a gap in the DTCA literature that has lacked scholarly research—content of DTC-TV advertisements. Due to the large proportion of DTC advertising dollars spent on TV, this is an important endeavor. Although only a first step in better understanding DTC-TV ads, this study has made some important discoveries about how well DTC-TV ads are meeting FDA requirements for fair balance, risk information, and adequate provision. In addition, the comparisons made between DTCA in print and on TV indicate their relative strengths and weaknesses. These issues are important for the health community to understand because they are often in contact with patients who have been exposed to these ads. By understanding the content, physicians and health practitioners should be better able to explain that the drug and its side effects may not always be exactly as portrayed on television. An example might be that a drug may not work as well as portrayed or that side effects may not be as “common” as the patient assumes. Health public policy makers also need to be aware of these research findings because they indicate potential problems with the content of DTC-TV ads.

This study found that rational appeals were slightly more common in DTC-TV ads. Although critics have expressed concerns about the overuse of emotional appeals in DTCA, it should be noted that most DTC-TV ads in the sample used a combination of rational and emotional appeals rather than just one appeal to the exclusion of the other. There were some interesting differences in the degree to which drugs targeting different conditions used particular appeals. For example, drugs targeting gastrointestinal conditions such as acid reflux disease tended to use humorous appeals (e.g., exaggerated vignettes about consuming an acid-producing dinner). Humor was also used for ads targeting urological functions (e.g., ads for Detrol with the jingle “Gotta go, gotta go, gotta go right now!”) and sexual functioning (e.g., Viagra ads).

“Slice of life” appeals were used more for drugs targeting cardiovascular, OB-GYN conditions, and allergies (e.g., a woman overcoming her allergies to spend a day on the farm with her boyfriend’s family). Fear appeals were used for drugs targeting cardiovascular problems, infectious non-HIV diseases, and cancer. The “desire to return to normal” appeal was used for many conditions, with more explicit instances found in ads for drugs to treat chemotherapy side effects (e.g., Procrit) and psychiatric conditions (e.g.,

ads for the attention deficit disorder drug Strattera and the antidepressant drug Zoloft). There is probably a connection between the type of condition targeted and the appeal used, although it is beyond the scope of this study to explore this issue in detail. For example, it appears as if humorous appeals were used for ads targeting conditions that are either potentially embarrassing (e.g., bladder control and erectile dysfunction), or where patients may tend to minimize the seriousness of the problem (e.g., treating acid reflux as merely an exaggerated form of heartburn).

Two notable and interesting differences between the selling points used in print (as measured by the Bell, Wilkes, et al., 2000, study) and those used on TV help shed light on the emotional/rational debate. Lifestyle claims were much more common on TV than in print ads (53.8% vs. 6%). This may lend credence to the criticism that “with TV, dancing couples and other happy images are what people remember—not the cautionary voiceover” (Bittar, 2002, p. 27) and show that emotional appeals are more common on TV. Second, effectiveness claims were less common on TV than in print (21.7% vs. 57%). Again, this indicates that TV uses more emotional appeals where print uses more rational appeals. This is logical given the relative strengths of each medium. Again, the medical conditions were examined in relation to the use of selling points and many of the results are logical (e.g., allergy drugs use a “symptom control” message).

The two most common criticisms of DTC-TV ads is that they are more focused on selling than education. This study has added some crucial pieces of information to help resolve this conflict. In addition to the aforementioned findings on appeals, this study has found that print appears to be more focused on medical information. There were five pieces of information that appear to a greater degree in print (as documented by Bell, Wilkes, et al., 2000; condition name, precursors, success rate, time to onset of action, and alternative treatments.) and there was only one piece of information found to a great degree on TV (mechanism of action). Mechanism of action is much easier to explain using visual animation and auditory explanation, making this a natural for TV. Overall, these results support that print is the more educational of the two forms of DTC. Some advertisers have also commented that newspapers, magazines, and the Internet “allow deeper communication with consumers than TV, particularly on drug features and risks” (Hensley, 2005b, p. B1). This is further supported by additional analyses reported in Table 3 showing statistical comparisons between results from Macias and Lewis (2003) for the Web and this study’s TV sample. All but two pieces of medical information were present to a greater extent ($p \leq .001$) on the Web than in TV.

In addition, DTC-TV ads for certain medical conditions included particular pieces of medical information to a greater or lesser extent. For example, cardiovascular, allergy, and sex drugs were less likely to include

information on symptoms; cardiovascular drugs were more likely to include prevalence data; alternative treatments were discussed to a greater degree for dermatological and cardiovascular drugs; side effects were less likely to be included for sexual functioning drugs, supportive behaviors were discussed more in ads for dermatological, cardiovascular, and OB-GYN drugs; misconceptions were clarified more commonly in dermatological and sexual functioning ads; and what might happen if no treatment were undertaken was included more in cardiovascular drug ads. Of these findings, two things seem particularly important—the lack of information on side effects for drugs treating sexual function, and the greater likelihood of cardiovascular drug ads to include more, key information to educate the consumer.

This study supports previous findings (Kaphingst et al., 2004) that DTC TV ads are not doing a good job of meeting the FDA's fair balance requirement. Given the vague nature in which this requirement was written, this study employed its own specifications of four specific levels of fair balance—lawbreakers, bare minimums, DTC main pack/peloton, and proactive group. The results do not invoke much confidence in the state of DTC-TV ads at the time the sample was drawn. Two ads were found to be “breaking the law” and 10% were just barely doing enough to stay off the FDA radar. The vast majority (88%) were in the DTC main pack/peloton. It seems that DTC advertisers find safety in numbers and tend to follow the status quo. It is possible that in the absence of specific guidelines from the FDA, the industry looks to its competitors. However, this may be changing with the bold, new move of Johnson & Johnson presenting risk information more prominently and creatively in the ad. Although our study did not find anyone in the proactive group, J & J has recently introduced a new form of DTC advertising that puts the risk information in an equally prominent position. They are encouraging others to make a similar move to keep good industry relations and avoid stricter requirements (Hensley, 2005a).

In addition to the short amount of time spent on risk information, this research also found that the format was overwhelmingly voice-over. Although voice-over disclosures are possibly more comprehensible than fine-print text disclosures alone, the relatively short duration of these disclosures suggests that advertisers have probably used accelerated speech rates to try to minimize the time spent on these statutorily required parts of the ads. Unless the FDA establishes more specific guidelines for fair balance, this issue is subject to interpretation.

During 2003 (the time of this study) there was only one warning letter issued by the FDA for a broadcast ad included in the study's sample (as indicated at www.fda.gov/cder/warn/). It was issued to Lamisil on August 29, 2003, and included three charges: overstatement of Lamisil's efficacy, minimization of risk, and unsubstantiated superiority claim (Murphy 2003). Essentially, the letter

details how the “ads' strong visuals (as well as voiceovers and background music) and claims and weak SUPERS combine to give a misleading picture of the efficacy of Lamisil. . . . “distract from and may make it difficult for consumers to adequately process and comprehend risk information” (Murphy, 2003, pp. 2–3). This indicates that the FDA is doing a fairly good job of “catching” some but not all of the lawbreakers. This was one of the ads this study found to be lawbreaker. The fact that another ad did not disclose side effects as required indicates that the FDA is not able to monitor all DTC ads on TV.

A comparison between the medical and drug information included in print ads (as reported by Bell, Wilkes, et al., 2000) and this study's TV ads indicates that print is better at communicating more information than TV (print had higher levels of clarifying misconceptions, precursors, symptoms, success rate, supportive behaviors, and onset of action whereas TV had higher levels of condition name, prevalence, and duration of treatment). The greater degree to which medical information was included in print ads supports the contention that print media have the ability to communicate more, detailed information. However, given that a larger percentage of DTC ad dollars is spent on TV than in print, policy makers should be concerned about whether or not consumers are getting the level of information they need. Another consideration is what the goal of the DTC ad is. Television is better at creating awareness and can direct consumers to other sources for more detailed information (i.e., print or the Web). Therefore, if the TV ads are supposed to drive consumers to print ads or the Web for more information, policy makers or future research needs to determine if this is actually happening. Or are some/many consumers simply getting all their information from TV (which is a poorer source of detailed medical information)?

Advertising a prescription drug to consumers is quite different from advertising a bathroom cleaner or even an automobile. Regardless of whether it is a high- or low-involvement product, the average consumer does not even have a knowledge structure about pharmaceutical products within which to place the information gleaned from advertising. Consumers are increasingly becoming active participants in their own health care. Previously, many consumers relied heavily on their physician to prescribe the appropriate course of action to treat any illness or condition. Today's new active health care consumers need to learn what issues are important to consider when investigating drugs and how to evaluate alternative courses of treatment. Health professionals must remain informed about these sources of information to answer the questions that result.

FUTURE RESEARCH AND LIMITATIONS

Although this research has furthered what was known about DTC ads on TV, there is still much that needs to be learned.

Future research needs to examine what the consumers take away from the communication (comprehension and memory). This may shed further light on what fair balance should be and how DTC advertisers need to meet it. Do differing rates of speech affect message comprehension? Does it matter if details like adequate provision and side effects are presented in two modalities versus only one?

Finally, although this study's results document the content of DTCA-TV and indicate how it is doing according to FDA guidelines, future DTC research needs to apply and develop more theory-based models and information to move the area forward. Dual-processing theory may be helpful in understanding how information from multiple modalities (printed and spoken) is processed and potentially remembered better. As is indicated in this study, this is an important issue given the format in which risk information is often provided (printed and spoken). In addition, Risker (1996) discusses several models, including health belief, consumer decision, and information processing models, that have been employed in general health decision making and information search literature but not specifically in DTC research. Some of these theories may be appropriate given our findings that DTC-TV ads feature a combination of education and entertainment.

As with all studies, this one has limitations. These limitations primarily relate to the nature of content analysis and its descriptive purpose. This study cannot determine what consumers take away from a TV commercial. However, understanding the content consumers are exposed to is an important first step in this research area. In addition, some may disagree with the classification scheme utilized here to further define to what degree DTC advertisers are meeting fair balance. It represents one viewpoint and is intended to further this area by not only providing additional details lacking from the FDA, but also to begin a research dialogue about other possibilities.

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