ORIGINAL RESEARCH ARTICLE

Pharm Med 2010; 24 (3): 165-177
1178-2595/10/0003-0165/$49.95/0

The Changing Face of Direct-to-Consumer Print Advertising

Policy and Content Issues

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Abstract

Background: Over $US4.2 billion was spent on direct-to-consumer (DTC) advertising of prescription drugs in 2008 in the US for all media, which was down from $US5 billion in 2007. However, third quarter 2009 sales were already rebounding and faring the bad economic situation better than most other categories, according to TNS Media Intelligence data. Print DTC advertising and its regulatory environment has changed so much over the past decade that an updated, comprehensive study of its content is needed to identify current public policy concerns, including the use of emotional versus rational appeals, information content, fair balance and presentation of risk information.

Objectives: To identify the medical and drug information presented, the format of risk and benefit information, format of the brief summary, types of advertising appeals and selling messages utilized, and the degree to which DTC print advertisements were meeting US FDA guidelines.

Methods: A content analysis study of 1735 print DTC advertisements from nine popular magazines with large distribution between 2000–7, identified benefit and risk information to assess their level of fair balance and categorise each advert into one of five categories: lawbreaker, bare minimum, DTC main pack/Peloton, chase and proactive/break away. In order to assess the impact of DTC guidelines released by the FDA in 2004, advertisements were compared for the periods 2000–3 and 2004–7.

Results: Emotional rather than rational appeals were used in 55% of all adverts. From 2000 to 2003 (n = 656) there were 4 lawbreakers (0.6%), 16 bare minimums (2.4%), 631 in the DTC main pack/Peloton group (96%) and no advertisements in the proactive group. From 2004 to 2007 (n = 1079) there was 1 lawbreaker (0.1%), 51 bare minimums (4.7%), 931 in the DTC main pack/Peloton group (86.3%), 72 in the chase group (6.7%) and 24 in the proactive/break-away group (2.2%).

Conclusions: This study found that emotional appeals were used to a greater degree than rational appeals in DTC print advertisements from 2000 to 2007. While critics have expressed concerns about the overuse of emotional appeals in DTC advertisements, it should be noted that most advertisements in the sample used a combination of rational and emotional appeals, rather than just one appeal to the exclusion of the other. After developing a five-tiered classification scheme, this study found that DTC print advertisements are doing a satisfactory job of meeting the FDA's fair balance requirement, but are not doing any more than is necessary. As detailed in the results, very few are lawbreakers, slightly more do very little beyond that and the vast majority stick to what everyone else is doing. DTC advertising seems to be a 'safety in numbers' approach to communication.

Background

The content and quality of direct-to-consumer (DTC) advertising is of great concern and interest to its many stakeholders, including consumers, physicians, legislators, the pharmaceutical industry and academics. Concerns about, and support for, DTC drug advertising has increased over the past several years as the response of consumers has skyrocketed and advertising

spending continues to grow or remain strong despite the recession. A US FDA survey conducted in 2003 found that "92% of patients had asked about an advertised prescription drug, with 86% identifying the brand and 59% requesting a prescription for that drug."[1]

Over $US4.2 billion was spent on DTC advertising of prescription drugs in 2008 in the US for all media,[2] which was down from $US5 billion in 2007.[3] However, third quarter 2009 sales were already rebounding and faring the bad economic situation better than most other categories, according to TNS Media Intelligence data.[4] Between 2003 and 2008, advertisement spend in the drugs/remedy category soared 58% to $US2.2 billion, per the Publishers Information Bureau, making it second only to toiletries and cosmetics in terms of money spent buying magazine space in consumer magazines.[3] In 2007, print advertisements in newspapers declined to $US75 million from $US152 million in 2006, magazine DTC increased to $US1.76 billion from $US1.68 billion in 2006 and television (TV) also increased to $US2.87 billion from $US2.66 in 2006.[5]

Within the overall category, individual brands of prescription drugs have substantial advertising budgets. For example, the following brands each reported spending of more than $US125 million during the first 9 months of 2009: Lipitor® (Pfizer, New York, NY, USA); Abilify® (Bristol-Myers Squibb, New York, NY, USA and Otsuka America, Rockville, MD, USA); Cymbalta® (Eli Lilly, Indianapolis, IN, USA); and Advair® (GlaxoSmithKline, Brentford, UK).[6] Although more money is spent on DTC TV advertisements, and they often receive more attention because of their high visibility, a substantial portion of the DTC ad spending is in print media, magazine and newspaper. In addition, consumers are most likely to get more information from the Internet and magazines after seeing a DTC TV advertisement[7] due to their self-paced nature.

Over the past several years, there have been changes in how the pharmaceutical industry markets its drugs directly to consumers, how consumers perceive these advertisements and how these communications are regulated. These changes warrant renewed research attention. Self-regulation is increasingly becoming important as the government continues to threaten intervention and consumer confidence continues to decrease.[8] Specifically, consumer polls have documented a 24% drop in approval ratings of pharmaceutical companies in the past 7 years (from 73% in 1998 to 49% in 2005).[9]

The current Obama administration in Washington is continuing the trend in Bush's second term to increase the number of people monitoring DTC advertisements – to make sure the pharmaceutical industry is following the FDA guidelines. Over the past 5 years, the FDA has increased the number of people monitoring advertisements by 50–60%, according to Thomas Abrams, director of the Division of Drug Marketing, Advertising, and Communications.[6]

In 2009, the FDA issued 41 warning letters to pharmaceutical marketers, which was almost double the number from 2008.[10] The FDA has the authority to issue fines, require that a company stop running an advertisement, force a correction or even seize the product. In an interview, Abrams said "Our standards haven't changed, but we are trying to do a better job at reaching industry." He also mentioned that his staff reviewed over 70 000 pieces of promotional material in 2009.[6]

Amidst criticisms about DTC, Johnson & Johnson (New Brunswick, NJ, USA) tried a new DTC advertising format for one of their brands, Ortho Evra® birth-control patch, which puts drug risk information on a more equal level creatively and in terms of advertisement duration.[11] Johnson & Johnson urged other 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."[11] Johnson & Johnson hoped this would not only be a better way to educate and counsel consumers, but also improve relations with patients, doctors and regulatory agencies.

In addition, in 2007, the Pharmaceutical Research and Manufacturers of America released a 'DTC code of conduct' in a more organized attempt to self-regulate.[8] The three key recommendations include more of a focus on risks; more disease-awareness campaigns; and narrower targeting of specific patients.[8] Pfizer responded in 2007 to these recommendations by revamping their approach to DTC.[8] They made further changes in 2009 to their TV advertisements by devoting more time to 'warnings', using a more serious tone overall, and more real patient testimonials.[6] Overall, some industry, medical and FDA sources feel DTC advertisers are making changes for the better but still have "much room for improvement."[6] This study will try to ascertain this and identify if other pharmaceutical companies followed their lead.

The growth of DTC advertising 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 DTC advertising, 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 become increasingly concerned with the impact of DTC advertising on individual and public health, the appropriateness (or lack thereof) of pharmaceutical use resulting from DTC advertising and the

impact of DTC advertising on the doctor-patient relationship, as well as the economic impact of such advertisements on overall healthcare costs.[12] While much of this research has focused on DTC advertisements in the US, scholars have also begun to examine the issue in other countries, such as New Zealand and Canada. Policy makers are particularly concerned about the impact of DTC advertising in Canada, where the healthcare system is, in large part, state funded. While DTC advertisements in Canada cannot mention both the disease and the brand name in the same advertisement, a large number of Canadian consumers receive media from the US, including DTC advertising.

Furthermore, much of the early DTC research focused on print[13-19] with topics ranging from the content of the advertisements, whether or not DTC print advertisements meet the FDA's 'fair balance' criteria, to consumers' attention to the brief summary and its effect on patient-physician discussions. Given that is has been over 10 years since the content of DTC print advertising has been examined, this study sought to better understand the current state of magazine DTC ad content and how it has changed over the past decade in response to changing regulations. In addition, this analysis includes more extensive coding than any of the previous studies (e.g., appeals, presentation of risk information, etc.). Specifically, the aim of this study was to identify the medical and drug information presented; the format of risk and benefit information; format of the brief summary; types of advertising appeals utilized; and the degree to which DTC print advertisements were meeting FDA guidelines. The following research questions were posed:

1. What are the most common emotional and rational advertising appeals found in DTC print advertisements?
2. What medical information, including side effects and benefits, is included in DTC print advertisements?
3. How is the information about risk presented in DTC print advertisements compared with the presentation of benefit information?
4. Are DTC print advertisements meeting the fair balance criteria set forth by the FDA and further defined by previous research?

The Key Issues of Direct-to-Consumer (DTC) Advertising

DTC advertising has inspired both supporters and detractors. Supporters contend that DTC advertising helps to inform consumers about various medical conditions and makes them aware of the treatment options available to them.[20] Detractors contend that advertising, with its overtly persuasive intent, is a form of communication ill-suited to educate consumers.[21] As suggested by Joseph and colleagues[22] there are four common criticisms of DTC advertising: (i) increasing drug costs because of the need to pay for promotions; (ii) causing unsafe practices among consumers; (iii) trivializing important health decisions and shifting attention away from more pressing priorities; and (iv) that the advertisements lack objectivity. In 1991, the US General Accounting Office (GAO) prepared a list of the hypothesized outcomes of DTC advertising.[23] The possible negative outcomes identified by the GAO include the ''misleading nature of promotional materials'' and ''inability of consumers to understand technical information.'' Mintzes[20] expanded on the GAO's list to include concerns that DTC advertisements (i) may confuse patients into believing that inconsequential differences represent major therapeutic advances; and (ii) create unrealistic expectations of drugs. Other researchers are concerned about the lack of information in advertisements and potential for miscomprehension by consumers.[24] The researchers also contend that DTC advertising rarely includes suggestions about lifestyle changes or other non-pharmacological interventions.[25,26]

On the other side of the debate, literature that has supported the positive educational claims of DTC, includes an FDA chief, M. McClellan, who appeared in favour of DTC advertising stating, ''it has value because it informs patients.''[27] The main arguments of industry supporters include that DTC advertising helps patients to become more knowledgeable about illnesses and drugs and increases compliance (following the physician's instructions for taking medication and completing the entire regimen) which, in turn, lessens long-term problems and healthcare costs.[27]

Specifically, some think DTC advertising is particularly positive in exposing the public to side effects that were previously not publicized,[28] as well as educating consumers about common yet serious conditions that often go untreated even when effective treatments are available.[29] However, by and large, neither the potential benefits nor the potential negative consequences of DTC advertising have been proven. This underlines the need for more research in this field. Toward this end, this content analysis of DTC print advertisements will help examine the types of appeals used in magazine advertisements for prescription drugs and the types of information made available to consumers. In doing so, it can help determine if the charges leveled against DTC advertising by its critics are justified.

Rational versus Emotional Appeals

Previous print content analyses have examined whether DTC advertisements appeal primarily to the consumer's emotions or

their intellect. Parker and Delene[16] analysed print DTC advertisements and classified the types of appeals that they were using into the following categories: news/feature, problem/solution, testimonial, endorsement/authority, education and humour. They reported that problem/solution was the most popular appeal, while humour was the least used.

Bell et al.[13] conducted a content analysis of print DTC advertisements and found the most commonly used appeals were (i) claims of effectiveness; (ii) symptom control; (iii) innovativeness; and (iv) convenience. Bell et al.[13] reported in 2000 that, ''40 percent of ads used claims of innovativeness to market pharmaceuticals.'' They are critical of this finding on the grounds that, ''what is new is not necessarily better, and could even be more risky'' than older treatments. In 2000, Bell et al.[14] 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.).

Woloshin et al.[12] found that their 1998–9 sample used emotional appeals 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 were only included 13% of the time. Approximately 50% of the advertisements used 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.''[12]

Medical and Risk Information

In terms of the informational value of DTC advertisements, Wilkes et al.[19] describe the educational quality of advertisements as ''highly variable.'' Almost all the advertisements 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 advertisements 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 et al.[14] developed a more detailed classification of the types of information found in DTC advertisements. The categories identified by them include (i) condition name; (ii) misconceptions; (iii) precursors; (iv) prevalence of condition; (v) symptoms; (vi) alternative treatments; (vii) mechanism of action; (viii) success rate; (ix) supportive behaviours; (x) time to onset of action; and (xi) treatment duration. Macias and Lewis[30] used this classification with three additions (prescribing information, side effects and contraindications) for their study from the content of DTC websites. In order to remain consistent with previous literature, the present study will apply this classification to DTC print advertisements.

As was mentioned earlier, it is also important to consider how risk information is presented in relation to benefit information. For example, was it listed as text only or text and images? How big is the font size? Where is the information located on the page? How many words are devoted to each advertisement? Finally, is it written in consumer friendly language?

US FDA and DTC Drug Advertising

It is helpful to review the guidelines for broadcast, as well as print, advertising because issues like fair balance are discussed in greater depth in the broadcast documents. Adequate provision is the only item below that does not apply to print because it includes the 'brief summary' (prescribing information). However, the FDA still recommends that print advertisements include a toll-free number or website address where more information could be obtained. The FDA's 1999 Final Guidance[31] set forth the following requirements for DTC advertisements on TV:

1. *Adequate provision* for the dissemination of approved or permitted package labeling in connection with the broadcast presentation (e.g. toll-free number, website, print advertisements, publicly accessible brochures or pharmacists and physicians).
2. Are *not false or misleading in any respect*.
3. Present a *fair balance* 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*.

In the 2004 *Guidance for Industry*,[32] which focused on DTC magazine advertising, the FDA further defined consumer-friendly language to be fully understandable by the lay reader and should not contain technical, 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'. In this guidance, the FDA also recommends that the traditional 'brief summary' be replaced with an understandable, consumer-targeting format. This change

finally came about after years of criticisms that ''the volume of material, coupled with the format in which it is presented (i.e. very small print and sophisticated medical terminology) discourages its use and makes the information less comprehensible to consumers'' (FDA's 1997 *Draft Guidance*). The main changes for print advertisements were that the 'brief summary' should use 'consumer-friendly language' and 'highlights' of the key risk information.

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;[17] physical features (e.g. colour) helps distinguish text and lead to increased learning;[33] quality and quantity of risk information is important;[34] and risk information needs to be presented in the same scope, depth and detail as benefit information.[35] Related to this, Abel et al.[36] analysed 284 cancer-related DTC advertisements published in popular magazines in 2007 to examine how benefit and risk/adverse effect information is presented. They reported that approximately equal amounts of text are devoted to benefits (39.7%) and risks/adverse effects (38.2%).

Methods

Sampling Procedure

We selected nine popular magazines with large distribution (circulations over 3 million and in the top five in its category) and varied US readership. The readership categories were those used in a previous print DTC study[12] – those primarily read by women (>70%) [*Better Homes & Gardens*, *Ladies Home Journal* and *Good Housekeeping*], by men (>70%) [*Sports Illustrated* and *Playboy*] and by the general population (50% women and 50% men) [*Time*, *Newsweek*, *People* and *Reader's Digest*]. A systematic sampling procedure was used to avoid seasonal differences in advertising and create a sample with equal number of issues from each magazine (some magazines have one issue a month and others have several).[12] From 2000–7, the first issue of the month was chosen from alternating months (2000/2002/2004/2006 sampled from February, April, June, August, October and December; 2001/2003/2005/2007 sampled from January, March, May, July, September and November). The sample started with 2000 because the most recent previous study[12] included advertisements up to 1999. The final sample included 1,735 magazine DTC ads. These advertisements were photocopied for coding.

Code Sheet Development

A code sheet was developed for the content analysis, using variables from previous content analyses of DTC advertising[13,30] and content analyses of advertising in general;[37] the magazine name, year, issue, ad size, brand name and pharmaceutical company were recorded. In addition, the print advertisements were coded for the following information: medical condition being treated;[30] medical information;[13] side effects; benefits; advertising appeal; general message strategy; advertising selling points;[13] and sources of additional information.[1]

Procedure and Reliability

A team of nine students coded all the advertisements. They were thoroughly trained on the code sheet, definitions and procedure. To clarify any questions and pretest the code sheet, coders used five DTC print adverts that were not drawn from the current sample. The pretest yielded few questions and high reliability (87% agreement). Confusions or problems were resolved.

Approximately 10% of the sample was coded by various pairs of coders in order to establish reliability. Inter-coder reliability was established using Cohen's Kappa. The inter-coder reliability for the coders or Kappa ranged from 0.67 (e.g. 'slice of life' appeal and duration of treatment) to 0.97 (e.g. economical and easy on the system selling points) with an overall Kappa of 0.83, which is above the minimal agreement level of 0.70 for percent agreement.[31] Any variables that were below 70% were dropped from the analysis (e.g. drug's indication and directions for use). Disagreements between the coders were resolved through discussions until 100% agreement was achieved.

Testing Fair Balance

It is difficult to empirically test if a DTC advertisement meets the FDA's definition of fair balance because the FDA does not state specific requirements. However, this study further refined a classification scheme previously used by Macias and colleagues in 2007[38] with DTC TV advertisements to shed new light

1 See appendix A for additional details in the Supplemental Digital Content 1, at http://links.adisonline.com/PMZ/A1.

on how well DTC print advertisements might or might not be meeting FDA guidelines. The five levels are as follows:

1. Lawbreakers (does not meet fair balance requirement): no side effects are listed (if benefits were included).
2. Bare minimum (this is deemed as the minimum that will not raise too many flags with FDA): some side effects are listed with little/no concern for format or scope (<20% as many words about risk information as opposed to benefit).
3. The DTC main pack/Peloton (this is defined as those who do a little more than minimum so they will not stand out and get complaints): one or more features that increase the scope or visibility of risk information (quantitative as well as qualitative information, location on page, similar or larger font, images as well as text, research results mentioned and/or >20% risk/benefit ratio).
4. Chase group (this group became obvious since the 2004 guidance and embodies those advertisements that are vigilant in providing risk information in a traditional format): four or more features that increase the scope or visibility of risk information (quantitative as well as qualitative information, location on page, similar or larger font, images as well as text, research results mentioned and/or >90% or higher risk/benefit ratio). The 'chase' group was added for the latter half of the sample to further differentiate the advertisements because of the format changes over the 8 years.
5. Proactive/break-away (safety-oriented approach):[11] this is the recent development discussed in the background section 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.

Results

Sample Description

Two magazines tied for the largest percentage (21%) of the advertisements (*Ladies Home Journal* and *Better Homes and Gardens*), followed by *Good Housekeeping* (17%), *Reader's Digest* (14%), *Time* (11%), *People* (7%), *Newsweek* (6%) and *Sports Illustrated* (2%). No DTC advertisements were identified in the sampled *Playboy* issues.

The sample was pretty evenly distributed across the years while reflecting the increasing advertising budgets – 2000 (6%), 2001 (8%), 2002 (9%), 2003 (11%), 2004 (15%), 2005 (15%), 2006 (15%) and 2007 (17%) – and across the months (ranged from a low of 7% in January to a high of 10% in March through May). Given the brief summary requirement, it was not surprising to find that the majority (59%) of the sample used a double page spread.

Medical Conditions, DTC Drugs and Pharmaceutical Companies Represented

The most frequently advertised conditions were psychiatric/neurological (20%), cardiovascular (14%), musculoskeletal (13%), allergies (12%), followed by gastrointestinal (8%) and respiratory (6%) [see table I for details]. There is a subtle waxing and waning of advertised conditions over the years with allergies and diabetes mellitus going down and psychiatric/neurological going up over the sample timeframe.

The most frequently advertised brands were Nexium® (a treatment for acid reflux disease marketed by AstraZeneca, London, UK), Allegra® (an allergy drug currently marketed by sanofi-aventis, Paris, France), Lunesta® (a sleep aid marketed by Sepracor, Marlborough, MA, USA), Vioxx® (a musculoskeletal pain reliever marketed by Merck & Co., Whitehouse Station, NJ, USA, prior to its withdrawal from the US market in September 2004) and Avandia® (a diabetes treatment marketed by GlakoSmithKline, Brentford, UK).

There were five pharmaceutical companies that were represented in this sample by a substantial margin: Pfizer (15%), GlaxoSmithKline (14%), Merck (11%), Bristol-Myers Squibb (11%) and Aventis Pharmaceuticals (8%). However, there were a lot of company mergers over the latter half of our sample, which makes it difficult to categorize over this long time period.

Table I. Medical conditions targeted in sample advertisements

Medical condition	Number of advertisements	Total advertisements (%)
Psychiatric/neurological disorders	342	19.7
Cardiovascular disease	245	14.1
Musculoskeletal ailments	227	13.1
Allergies	209	12.0
Gastrointestinal conditions	142	8.2
Respiratory	99	5.7
Diabetes mellitus	83	4.8
Cancer related	76	4.4
Insomnia	60	3.5
Sexual functioning	57	3.3
Urological conditions	53	3.1
Dermatological conditions	47	2.7
Obstetrics/gynecology	36	2.1
Infectious/non-HIV diseases	33	1.9
Other	21	1.2
Tobacco cessation	5	0.3
Total	1735	100.0

Table II. General message strategy

Strategy	Number of appeals (n = 4406)	Total appeals (%)	Overall change from first 4 to last 4 years of sample
Rational/informational			
Rational/informational, general	788	17.9	–
Problem and solution (before/after presentation)	382	8.7	↑
Convenience	234	5.3	–
Demonstration of results by using the product	208	4.7	↑
Testimonial by product user	184	4.2	↓
Progress	73	1.7	↑
Endorsement by celebrity or authority	66	1.5	–
Past, present, future	23	0.5	–
Total	1958	44.4	
Emotional			
Desire to get back to normal	796	18.1	–
Slice of life	610	13.8	↓
Emotional, general	350	7.9	–
Fear	224	5.1	–
Security	114	2.6	↓
Bandwagon	84	1.9	↓
Comedy/humour	83	1.9	↑
Vanity	61	1.4	–
Sex	42	1.0	↑
Search for adventure	31	0.7	–
Too fat/too thin/less than perfect	27	0.6	–
Transfer of masculine/feminine appeal	26	0.6	↑
Total	2448	55.6	

– indicates no/little change; ↑ indicates increase; ↓ indicates decrease.

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 (45% of appeals) versus emotional strategies (55% of appeals) were used. Rational strategies were most likely to be classified as a general rational/informational appeal (18%) as opposed to a more specific appeal. The most common specific rational appeals was 'problem/solution' (9%) followed by 'convenience' (5%) and 'demonstration' (5%). Other rational appeals included 'testimonial' (4%), 'progress' (2%) and 'celebrity/authority endorsement' (2%). Noteworthy changes in rational appeals over the 8 years include an increase in problem/solution and demonstration.

The most common specific emotional strategy used was the 'desire to get back to normal' (18%), followed by 'slice of life' (14%), followed by 'general emotional classification (not otherwise specified)' (8%) and 'fear' (5%). The fifth most common was the 'security' strategy (3%). Other interesting but less commonly used emotional appeals included 'bandwagon' (2%), 'comedy/humour' (2%), 'vanity' (1%) and 'search for adventure' (1%). Additional details are presented in table II. The biggest changes in emotional appeals over the 8 years include a decrease in security appeals and an increase in both humour and sex appeals (although the latter are still rare).

Selling Points

The results for the specific selling points included in DTC print advertisements are reported in table III. The most common selling point was DTC advertisements that assured control of symptoms (38%) followed by advertisements stating the 'effectiveness' of the drug (36%). Twenty-three percent of the DTC print advertisements made specific claims about how 'convenient' the drugs were. Slightly fewer advertisements (22%) made an explicit claim of 'innovativeness'. The next most com-

mon selling points included 'prevention' (19%), 'return to normal/more active lifestyle' (18%), 'safe' (12%) and 'cure' (10%).

The 'other' category captured some important selling points that may be important to add in similar future studies, including 'relief of symptoms' (6%) [this should be a specified option under 'symptom control' for future studies], '#1 prescribed' (4%) and 'long-lasting' (3%).

Only 28% of the advertisements contained any quantitative statement with respect to their selling points. The biggest changes between time periods (2000–3 and 2004–7) were an increase of symptom control, return to more active/normal lifestyle and psychological benefit selling points and a decrease of the non-medicated selling point.

Medical Information

The second research question asked to what extent the various categories of information cues were found in DTC print advertisements (see table IV). The specific drug being promoted was named in 100% of the advertisements, and the name of the condition being treated was named in 95%. The vast majority included risk information, which included side effects (97%) or contraindications (70%).

Over half of the advertisements (57%) in the sample mentioned the symptoms of the condition being treated, 32% talked about precursors to the condition and almost a third had some mention of how the drug worked (i.e. mechanism of action). An example of this was an advert for the antidepressant drug Zoloft® (Pfizer), which had a schematic diagram explaining the causes of depression, and explained how Zoloft® remedies the problem.

The DTC print advertisements in the sample reported the prevalence of the various medical conditions (8%). While 22% of the advertisements mentioned supportive behaviours, such as diet and exercise and 19% mentioned alternative treatments; only 10% of the advertisements in the sample made any mention of what might happen if the condition was not treated through medication.

Table IV also indicates whether or not each piece of medical information generally increased, decreased or stayed about the same between the two time periods of the sample. It is helpful to know this for each piece of information since information content is related to a common criticism of DTC as well as a potential overall goal to educate the consumer. The most dramatic changes include an increase in including symptoms (37–70%) and precursors (10–45%).

The brief summary was most often included on a full second page (65%) with 16% of the advertisements only using an additional half page and 13% using more than a full page. Not surprisingly, 76% of the advertisements used a font that was 7 point or smaller. Because this sample spanned both before and after the 2004 Guideline,[32] which recommended the brief summary be presented using 'highlights' in 'consumer-friendly language', it is helpful to see that 30% of the advertisements used this format between 2000–3 and 58% used it between 2004–7 with an additional 12% before 2004 and 8% after using a combination of 'prescribing information' (traditional brief summary form) and 'consumer-friendly highlights'. Therefore, the remaining 55% of advertisements before 2004 and 38% after used only the 'prescribing information' as the brief summary. Anecdotally, some advertisements in the second half of the sample began including comments like ''no advertisement can replace a conversation with your physician'' or ''important drug safety information to consider.''

Presentation of Risk and Benefit Information

Research question (3) asked about the format of risk information presented in DTC print advertisements compared

Table III. Selling points used

Selling point[a]	Number of uses	Total advertisements (%) [n = 1735]
Symptom control	661	38.1
Effective	623	35.9
Convenience	406	23.4
Innovative (drug is new or a breakthrough)	388	22.4
Prevention	333	19.2
Allows for more active lifestyle/normal lifestyle	310	17.9
Safe	216	12.4
Cure	174	10.0
Psychological benefit	168	9.7
Quick acting	158	9.1
Nonmedicated	141	8.1
Nonaddictive	83	4.8
Powerful	77	4.4
Reduced mortality	57	3.3
Natural	57	3.3
Easy on system	40	2.3
Dependable	21	1.2
Social	16	0.9
Economical	6	0.3
Portion of selling points with quantitative statement	484	27.9

a There may be more than one point per advertisement.

with the presentation of benefit information. This deals specifically with risk information in the advertising copy as opposed to the brief summary. Risk information was more likely to be presented in text only (96%) as opposed to text and images compared to benefit information (65% text only). The vast majority (83%) of the risk information was presented in a font size very similar to the benefit information. However, the majority of the risk information was presented on the bottom (69%) or middle (31%) of the page. While 85% of the risk information was presented in solely qualitative terms (e.g. dry mouth may occur), 11% of the advertisements used both qualitative and quantitative language (e.g. a 2% chance of dry mouth).

'Consumer friendly language' was used to a similar degree for both risk (77% before 2004 and 93% after) and benefit information (83% before and 97% after). They both listed research results to a similar degree – 76% (risk) versus 68% (benefit) of the advertisements mentioned no supporting research results and 20% (risk) versus 24% (benefit) of the advertisements mentioned research results without identifying the source. Finally, on average, risk information was communicated in 73 words between 2000 and 2003 and 98 words from 2004 to 2007. Benefit information was presented in 69 words from 2000 to 2003 and 87 words from 2004 to 2007.

Fair Balance

Using the classification scheme described in the method section, from 2000 to 2003 (n = 656) there were four lawbreakers (0.6%), 16 bare minimums (2.4%), 631 in the DTC main pack/Peloton (96%) and no advertisements in the proactive group. From 2004 to 2007 (n = 1079) there was one lawbreaker (0.1%), 51 bare minimums (4.7%), 931 in the DTC main pack/Peloton (86.3%), 72 'chase' group (6.7%) and 24 advertisements in the proactive/break-away group (2.2%).

Discussion

This study provides an important update and deeper look into the content of print DTC drug advertisements. It also made important discoveries about how well DTC print advertisements

Table IV. Medical information

Type of medical information	Number of uses	Total advertisements (%) [n = 1735]	Overall change from first 4 to last 4 years of sample
Medical condition			
Condition name	1648	95.0	–
Symptoms	991	57.1	↑
Precursors	547	31.5	↑
Clarification of misconceptions	264	15.2	↑
Prevalence	143	8.2	–
Treatment			
Drug name	1735	100.0	–
Side effects	1674	96.5	–
Contraindications	1222	70.4	↑
Mechanism of action	536	30.9	↑
Supportive behaviours	387	22.3	↑
Alternative treatments	330	19.0	↑
Treatment duration	315	18.2	–
Time to onset of action	270	15.6	↑
Result of no treatment described	169	9.7	↑
Success rate	164	9.5	–
Directions for medication use	[a]	[a]	
Indication of drug and medical limitations	[a]	[a]	

a Variables dropped for low reliability.

– indicates no/little change; ↑ indicates increase; ↓ indicates decrease.

are meeting FDA requirements for fair balance and presentation of risk information. These issues are important for the advertisers, members of the health community and public policy makers to understand because of the implications for the health and welfare of US consumers. 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 TV. For example, a drug may not work as well as portrayed or 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 presented in DTC advertisements and some areas where they are improving. DTC advertisers have received increasing criticism for this type of advertising and it is important to verify if the criticisms are empirically supported.

This study found that emotional appeals were more common than rational appeals in DTC print advertisements. Although direct comparisons are not possible because of methodological differences, this pattern is generally supported in previous literature.[19] While critics have expressed concerns about the overuse of emotional appeals in DTC advertisements, it should be noted that most DTC print advertisements in the sample used a combination of rational and emotional appeals, rather than just one appeal to the exclusion of the other. The copy of the advertisement often communicated the rational appeal and the visual conveyed the emotional appeal.

It is interesting to see that a majority of the rational appeals did not fit previously defined classifications whereas emotional appeals were more likely to be classified as a 'desire to get back to normal' or a 'slice of life'. This indicates that the type of rational strategy DTC advertisements use is less likely to fit traditional advertising categories. It seems clear from the number of 'celebrity/authority' appeals and 'testimonials' that associating a human face with the drug can be an important strategy, which has also recently been cited by industry as an increasing trend.[6] While it did not seem unusual to see a heavy use of the 'desire to get back to normal' appeal, it was surprising to see that fear appeals were used more often than most other emotional appeals. Fear appeals were more commonly employed for cardiovascular and gastrointestinal conditions. Our study found a high degree of 'problem/solution' appeals as has been a general finding in the literature.[17]

The top selling points identified in Bell et al.[13] were also the most common found in our study (i.e. 'effective', 'symptom control', 'innovative' and 'convenient'). In addition, when looking at the slight changes in selling points used over the course of our sample, it indicates that there have been only subtle changes in regards to the benefits DTC print advertisements communicate to consumers.

One of the most common criticisms of DTC advertisements is that they are more focused on selling than education. This study has added some crucial pieces of information to help resolve this conflict. Even though the new FDA print guidelines were not released until the latter half of our sample, a large portion of the advertisements between 2000 and 2003 were already presenting both benefit and risk information in a 'consumer-friendly' manner; this percent did go up after 2004. This study also found that DTC print advertisements during the time period studied were formatting some advertisements in ways that makes the risk information more easily understood and recognized including: quantitative in addition to qualitative descriptors; using 'consumer-friendly language'; placing risk information in the middle of the page; and using a similar number of words to describe risks as were used for benefits. The dramatic increase in consumer-friendliness was apparent in the brief summary. DTC magazine advertisers really made improvements since the 2004 FDA Guidance in making the brief summary layout, in particular, greatly improved. Since the 2004 FDA *Guidance for Industry*,[32] DTC magazine advertisers have made improvements to the layout, in particular, to the brief summary section. The advertisements that use highlights and consumer-friendly language are exponentially more inviting to read and easier to understand for the layperson. These are positive findings about the way that medical information is being presented.

Our findings are not congruent with a 2005 article that stated ''the quality and tone of drug advertising is getting worse, not better.''[9] DTC print advertisements do seem to be improving but at a slow pace and somewhat constrained range. It is possible that many of the criticisms of DTC are based on changing perceptions and expectations by the public and policy makers rather than the actual change in the content and form of DTC drug advertisements. The pharmaceutical industry and DTC advertising may benefit from some positive public relations effort.

There were not any obvious attempts at disease awareness campaigns. This practice would be seen as educational while not brand specific. Public service announcements could be utilized to educate the public about how to read and comprehend the complicated DTC advertisements. Research continues to show that consumers have a hard time understanding the information, particularly side effect information, which may often (approximately 50%) 'scare them off' or cause them to not want to take a prescription drug.[3] Psychological literature has a long history of showing that people are not very good at making representative judgements or about how likely an event is to affect them.[39]

The type of medical information presented also indicates the advertisements are improving in terms of educational content. All 15 categories of medical or treatment information increased (9) or stayed the same (6) over the 8 years of this sample. The two most dramatic being symptoms and precursors, which indicate the desire to educate the consumer about the condition the drug is intended to treat. The inclusion of symptom information also coincides with the most common benefit selling point of 'symptom control'. It was also encouraging to see a higher degree of supportive behaviour and alternative treatments being included. These have the potential to help the consumer avoid being medicated for a condition using, as an example, 'diet and exercise' instead for some common conditions such as diabetes and cardiovascular disease. Some advertisers have also commented that newspapers, magazines and the Internet "allow deeper communication with consumers than TV, particularly on drug features and risks."[40]

While many studies criticized the ability of DTC print advertisements to convey enough and the right kind of information,[17,19] few studies have specifically examined if DTC print advertisements meet the FDA's fair balance requirement. Given the vague nature of this requirement, this study employed its own specifications of five specific levels of fair balance: lawbreaker, bare minimums, DTC main pack/Peloton, chase group and proactive group. The results show that the vast majority of DTC print advertisements are doing what the FDA recommends and there is an indication that these advertisements are trending to the more consumer-friendly nature, possibly to avoid further government regulation. However, they continue to approach DTC advertising with a 'safety in numbers' approach and do not appear to do more than what the FDA recommends. From 2000 to 2003 four advertisements were found to be 'breaking the law' and 2% were just barely doing enough to stay off the FDA radar. The vast majority (96%), were in the DTC main pack/Peloton category. There were no advertisements in the proactive group. There was a subtle improvement from 2004 to 2007 when there was only one lawbreaker, 5% bare minimums, 86% in the DTC main pack/Peloton group, 7% in a newly formed 'chase' group and 2% in the proactive/break-away group. It seems that DTC advertisers still tend to follow the status quo. It is possible that in the absence of more specific guidelines from the FDA, the industry looks to its competitors for examples of what to do. If this data were graphed, it would look similar to a naturally occurring bell curve and indicate a propensity towards mediocrity for DTC advertisers. There are at least two ways to interpret this 'c-average' approach: (i) average may be considered ok; or (ii) average is not good enough and DTC needs more leadership and self-regulatory success.

Johnson & Johnson tried to present risk information more prominently and creatively in the 2005 Ortho Evra® advertisement and the industry has tried to develop its own self-regulating guidelines,[8] but neither of these approaches have had as much impact as the 2004 FDA guidelines.[34] Although our study only found a small percentage in the proactive group, these changes in the industry may indicate a trend towards following Johnson & Johnson's encouragement to do better.[11]

From 2000 to 2003 there were five warning letters issued by the FDA for DTC magazine advertisements.[10] One of these letters was for a drug categorized in the sample of this study as a 'lawbreaker'. Although the warning letter was issued for the same advertisement, it was printed in a different magazine than the one we found it in. The other four DTC advertisements that this study identified as not meeting the fair balance requirement were not issued warning letters. This indicates that the FDA is doing a fairly good job of 'catching' some, but not all, of the lawbreakers. One of these four advertisements was classified as a lawbreaker in this study; the other three advertisements did not disclose side effects as required. As was mentioned in the introduction, the FDA has recently increased the monitoring and issuing of warning letters.[6]

Future Research and Limitations

Although this research has furthered what was known about DTC print advertisements, there is still much that needs to be learned. Future research needs to examine what the consumers take away from the communication. This may shed further light on what fair balance should be and how DTC advertisers need to meet it. Future research should investigate the impact of 'consumer-friendly' language and various formats for risk, and brief summary information on comprehension. Informal comments from some of the study's coders may indicate a related area of future research to be the format of the ad itself. Several coders indicated that the traditional format of DTC, which presents benefit and then risk information, makes it easier to distinguish the difference and, hence, understand the information. This is in contrast to Johnson & Johnson's 2005 idea to present the information in similar creative manners. Researchers need to better understand how to most effectively present risk information so it is both attended to and understood by the consumer.

Another question for future research is whether consumers are seeking out more detailed information from the Web after seeing a print ad for a drug. If they are not, the concern that

DTC advertising does not fully educate the consumer and may cause patient-physician problems (because of misconceptions etc.), is somewhat validated. Also, given Johnson & Johnson's move to change the presentation of risk information, it is important for future research to track whether or not other DTC advertisers become 'proactive'. Given the complicated nature and high degree of information that needs to be communicated for pharmaceuticals, an integrated marketing programme is highly desirable. However, future research needs to more fully understand the entire process that consumers undergo to learn about a drug and medical condition. Do they see a TV advertisement, go to a magazine for more information and finally to the Web to answer any lingering questions? If not, how can DTC advertisers better educate the consumer? Finally, as was seen in this study, the FDA guidelines are vague, subjective and difficult to apply and test. One could argue that no DTC advertisement can educate to the level that opponents desire. Alternatively, does it make more sense to evaluate an entire DTC campaign as opposed to one advertisement? While this study adds one more piece to the DTC puzzle, there is much we still need to understand.

As with all studies, this one has its 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 print advertisement. However, understanding the content that 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 that are lacking from the FDA, but also to begin a research dialogue about other possibilities.

Conclusions

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 healthcare. Previously, many consumers relied heavily on their physician to prescribe the appropriate course of action to treat any illness or condition.[41] In today's new active healthcare, 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.

Acknowledgements

The authors would like to thank the graduate and undergraduate students from the University of Georgia who helped with data collection and coding and who were key to the success of this project.

No sources of funding were used to assist in the preparation of this study. The authors have no conflicts of interest that are directly relevant to the content of this study.

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