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Literacy demands of product information intended to supplement television direct-to-consumer prescription drug advertisements

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Abstract

The US Food and Drug Administration (FDA) allows television direct-to-consumer (DTC) prescription drug advertisements that do not fully disclose drug risks if the ads include "adequate provision" for dissemination of the drug's approved labeling. This requirement can be met in part by referring consumers to multiple text sources of product labeling. This study was designed to assess the materials to which consumers were referred in 23 DTC television advertisements. SMOG assessments showed that the average reading grade levels were in the high school range for the main body sections of the materials and college-level range for the brief summary sections. The Suitability Assessment of Materials (SAM) instrument identified specific difficulties with the materials, including content, graphics, layout, and typography features. Stronger plain language requirements are recommended. Health care providers should be aware that patients who ask about an advertised drug might not have the full information required to make an informed decision.

Keywords: Literacy; Readability; Suitability; Direct-to-consumer advertising; United States Food and Drug Administration

1. Introduction

The advertising of prescription drugs to consumers has expanded remarkably over the past decade. Annual expenditures on direct-to-consumer (DTC) advertising grew from an estimated US$ 47 million in 1990 to nearly US$ 2.5 billion in 2000 [1–4]. Television advertising has become a major component of DTC advertising efforts, expanding from 13% of DTC advertising expenditures in 1994 to 60% in 2000 [3].

Under current US Food and Drug Administration (FDA) regulations, prescription drug advertisements cannot be false or misleading and must have "fair balance" in the presentation of risks and benefits [5,6]. Product-specific broadcast DTC advertisements, which mention a prescription drug's name and indication, do not have to provide complete risk information about the drug. Rather, these broadcast advertisements must include a "major statement" of the chief adverse effects and contraindications [6,7] and either (1) the "brief summary," a section that contains detailed information about side effects, contraindications, and effectiveness or (2) "adequate provision" for dissemination of the approved product labeling [5,8].

FDA guidelines suggest that broadcast advertisements can meet the adequate provision requirement by referring consumers to physicians and pharmacists and to text sources of product labeling available through a Website, toll-free telephone number, and concurrently running DTC print advertisement [7,9,10]. DTC print ads, unlike broadcast DTC ads, must include the brief summary with its detailed risk information [11]. The FDA believed that this multifaceted approach to adequate provision would allow consumers to have access to important risk information about advertised prescription drugs [6,12].

A few content analyses have assessed the characteristics of DTC print advertisements [13,14]. Consumer Reports (1996) evaluated the potential educational benefit and quality of 28 DTC print ads, examining factors such as use of medical jargon, placement of key information, comprehensiveness, and print size [15]. Prior content analyses have not systematically assessed the literacy skill levels required ("literacy demands") by text sources of product labeling (i.e., Websites, brochures, DTC print ads).

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The 1992 National Adult Literacy Survey (NALS) assessed functional literacy skills among US adults using a set of tasks that reflected the types of literacy skills that adults use in their daily lives [16]. The NALS results indicated that about 21% of US adults had low levels of functional literacy skills, while an additional 25% had marginal skills [16]. The NALS findings raised awareness in public health and medicine of the mismatch between adults' skills and the reading difficulty of many health-related materials. The main objective of this study was to evaluate the literacy demands of the text sources of product labeling referenced in a sample of DTC television advertisements.

2. Methods

2.1. Sample

We collected a sample of 23 product-specific DTC television advertisements for different prescription drugs for 22 indications in a separate content analysis [17]. To generate the content analysis sample, we videotaped six hours of programming from one of the three major television network stations (ABC, NBC, and CBS) in Boston, Massachusetts each day in February and March 2001, and identified 62 unique product-specific advertisements for 33 prescription drugs for 22 indications. We then randomly selected one drug for each indication and one ad for each drug, with the exception of allergies, for which we included randomly selected ads for both a nasal spray and a pill.

The sample for the present study consisted of the DTC text materials to which each of the 23 television ads referred consumers. The brand names, manufacturers, and indications for the advertised prescription drugs are listed in Appendix A. A few of the television ads referred to multiple materials of the same type (e.g., DTC print ads in two different magazines). In such cases, we randomly selected one of the materials for inclusion in the sample. We gathered 69 DTC text materials in total: one DTC magazine ad, one Website, and one mailed brochure obtained through a toll-free number for each television ad. We printed each Website in its entirety during April or May 2001, immediately after collecting the sample of television ads.

2.2. Assessment of materials

The prose literacy demands of text materials have generally been assessed with readability formulas, which provide quantitative estimates of reading difficulty [18]. We used the SMOG readability formula in this study, which Meade and Smith recommended because of its reputation for accuracy and simplicity and its widespread use in the existing patient education literature [19].

The SMOG readability formula is based on the number of words with three or more syllables found in 30 sentences. For the SMOG assessments in this study, we divided the text into thirds and then randomly selected a group of ten sentences from each third. For materials with 30 sentences or less, we assessed all of the text. We did not include brand or generic drug names in our counts, as doing so might artificially inflate the assessed score of those materials that discuss drugs that have names with three or more syllables. One researcher (KAK) conducted SMOG readability formula assessments of all materials, and we report those results here. To assess scoring reliability, a second researcher re-assessed a randomly selected 10% of the materials. Inter-rater agreement was high and statistically significant ($r = 0.87$, $P < 0.001$).

Like most readability formulas, the SMOG is based solely on writing style variables. Readability formulas, being predictive rather than diagnostic, do not identify all of the content, organization, and format factors that contribute to level of reading difficulty [18,20,21]. To examine these other factors, we also assessed the materials with the Suitability Assessment of Materials (SAM) instrument [21]. The SAM includes 22 variables organized into six categories.

(1) Content: clearly stated purpose, behavioral content, limited scope, summary/review.
(2) Literacy demand: Fry reading grade level, use of active voice/conversational style, type of vocabulary, context given first, use of headers.
(3) Graphics: features of cover graphic, illustration type, illustration relevance, explanations of tables and charts, use of captions for graphics.
(4) Layout and typography: layout features, typography features, use of subheadings.
(5) Learning stimulation and motivation: interaction between material and reader, modeling of behavior, motivation for reader.
(6) Cultural appropriateness: match in logic, language, and experience between reader and material, use of positive cultural images and examples.

A text material is given a score of 0 (*not suitable*), 1 (*adequate*), or 2 (*superior*) on each of these variables. Because some variables might not apply to certain materials (e.g., some materials might not have illustrations), overall ratings are based on the total number of points divided by the possible number of points (a percentage score). In this study, one researcher (KAK) conducted SAM assessments of all materials, which are reported below. To assess scoring reliability, a second researcher re-assessed a randomly selected 10% of the materials. Inter-rater agreement was high and statistically significant ($r = 0.88$, $P < 0.001$).

2.3. Analysis

We analyzed descriptive statistics using SPSS 10.1 for Windows (Chicago, IL).

3. Results

We separately evaluated (1) the brief summary section of each DTC text material and (2) the "main body" (i.e., the remainder of the material). We conducted separate assessments both to evaluate differences between the sections and to examine the brief summary section in detail, since it contains the comprehensive risk information.

3.1. Readability

The average SMOG reading grade levels for the main body sections of the DTC text materials were in the high school range (grades 10.5–11.6), whereas the average SMOG levels for the brief summary sections were in the college-level range (grades 13.7–14.1), as shown in Table 1. A college-level reading ability would be required for the main body sections at the upper end of the range (those sections scoring grades 13–14), while a graduate-level reading ability would be required for the brief summary sections at the upper end of the range (those sections scoring grade 17 and higher). Materials for the general public should be written at the 8th-grade level or below [22]. Only one section of one DTC text material, the main body section of a mailed brochure, met this standard with a SMOG level of grade 8.

3.2. SAM assessments

The results of the SAM assessments are summarized in Table 2 and presented below according to categories of SAM variables.

3.2.1. Content variables

The first category of SAM variables relates to content. Specifically, we assessed whether each section of a DTC text material had a (1) clearly stated purpose; (2) limited scope; and (3) review or summary of key ideas.

Most of the DTC text materials either had one clearly stated purpose (*superior* rating; 34%) or several stated purposes (*adequate* rating; 52%). The ratings varied somewhat across type of material. For example, 65% of the main body sections of the mailed brochures clearly explained the purpose, whereas only 5% of the main body sections of the magazine ads did so.

Regarding the scope of the DTC text materials, 74% of the main body sections of the magazine ads provided only key educational information (*superior* rating), but a majority of the main body sections of the Websites (83%) and mailed brochures (52%) presented some nonessential information (*adequate* rating). Over half of the brief summary sections (57%) included a lot of nonessential information (*not suitable* rating), such as extensive pharmacokinetic and clinical research data that would not be of use to consumers.

Seventy-seven percent of the brief summary sections did not review or summarize any key ideas (*not suitable* rating). Most of the main body sections of the Websites (87%) and mailed brochures (61%) reviewed some key ideas (*adequate* rating). Only 5% of the materials overall reviewed most or all of the key ideas with different words and examples (*superior* rating).

Table 1
SMOG reading grade levels for a sample of direct-to-consumer (DTC) magazine advertisements, mailed brochures, and Websites

Section and type of DTC text material	SMOG reading grade level	
	Mean (S.D.)	Range
Main body sections		
DTC magazine ads ($n = 19$)[a]	10.5 (1.2)	9–13
Mailed brochures ($n = 23$)	11.2 (1.5)	8–14
Websites ($n = 23$)	11.6 (1.5)	9–14
Brief summary sections		
DTC magazine ads ($n = 23$)	13.7 (3.3)	9–22
Mailed brochures ($n = 23$)	14.1 (2.6)	10–18
Websites ($n = 23$)	14.0 (2.2)	10–17

S.D.: standard deviation.

[a] Four of the DTC magazine ads were comprised only of brief summaries, with no main body sections.

3.2.2. Literacy demand variables

The SAM literacy demand variables assess (1) readability level; (2) writing style; (3) vocabulary; (4) use of context; and (5) use of headers.

Readability level for the SAM is measured by the Fry readability formula [23], which gives slightly different results than the SMOG. Ninety percent of the materials had Fry readability scores of ninth grade or higher (*not suitable* rating). Ten percent of the materials had Fry readability scores of sixth to eighth grade (*adequate* rating); none had scores of fifth grade or lower (*superior* rating).

The writing style variable assesses use of active voice, conversational writing style, and simple sentence structure. Fifty-eight percent of the brief summary sections contained primarily passive voice text and included many sentences with long or multiple embedded phrases (*not suitable* rating). The main body sections often contained more active voice text and simple sentence structure than did the brief summary sections, and generally received either *adequate* (52%) or *superior* (43%) ratings.

Fifty-eight percent of the brief summary sections included many uncommon words and extensive unexplained medical vocabulary (*not suitable* rating). In contrast, 89% of the main body sections contained a combination of common and uncommon words and gave definitions and examples for some of the medical terms (*adequate* rating). Only 7% of the materials overall included mainly common words and explained most of the medical terms (*superior* rating).

Ninety-six percent of the materials provided contextual information prior to new facts only some of the time (*adequate* rating). Relatively few materials (3%) consistently gave contextual information first (*superior* rating).

Eighty-three percent of the materials overall placed headers before nearly all topics (*superior* rating). In contrast,

Table 2
Percentage of direct-to-consumer (DTC) magazine advertisements, mailed brochures, and Websites with "adequate" or "superior" ratings on SAM variables

Category/variable	Magazine ads		Mailed brochures		Websites	
	Main body ($n = 19$)[a]	Brief summary ($n = 23$)	Main body ($n = 23$)	Brief summary ($n = 23$)	Main body ($n = 23$)	Brief summary ($n = 23$)
Content						
Clearly stated purpose	100	83	100	70	91	78
Limited scope	100	52	96	35	100	43
Summary included	26	13	83	13	87	43
Literacy demand						
Reading grade level	16	13	9	0	9	13
Writing style	100	52	91	30	96	43
Vocabulary type	100	48	96	35	96	43
Context given first	100	96	100	100	100	100
Use of headers	26	96	96	100	100	100
Graphics						
Cover graphic[b]	100	100	100	0	100	100
Illustration type[b]	88	75	91	100	100	100
Illustration relevance	42	13	96	4	100	13
Directions for graphics[b]	N/A	0	63	93	75	87
Explanatory captions[b]	100	82	70	81	65	78
Layout and typography						
Layout	100	30	100	61	100	83
Typography	95	100	91	78	100	100
Use of subheadings[b]	75	14	43	17	17	27
Learning stimulation and motivation						
Interaction with reader	32	48	87	39	91	48
Subdivision of text	100	74	96	30	100	39
Cultural appropriateness						
LLE[c] match	100	48	96	35	100	43
Use of positive images[b]	100	100	96	N/A	95	100

[a] Four of the DTC magazine ads were comprised only of brief summaries, with no main body sections.
[b] These variables did not apply to all materials. Values in table are percentages of applicable materials.
[c] LLE: Logic, language, and experience.

61% of the main body sections of the magazine ads did not include any headers (*not suitable* rating).

3.2.3. Graphics variables

The graphics variables assess (1) the features of the cover graphic; (2) type of illustrations; (3) relevance of illustrations; (4) use of explanations for figures; and (5) use of captions with graphics.

Of those materials with cover graphics, 91% had cover graphics that attracted attention and/or seemed friendly (e.g., characters smiling) (*adequate* rating). No cover graphic met both of these criteria while also clearly conveying the material's purpose (*superior* rating).

Among those materials with illustrations, 93% included photographs rather than line drawings, which are preferred, or included illustrations that showed unfamiliar objects (*adequate* rating). Few materials (7%) included primarily line drawings of familiar objects (*superior* rating) or photographs of unfamiliar objects (*not suitable* rating).

Ninety percent of the brief summary sections and 58% of the main body sections of the magazine ads either did not have any illustrations or had only technical illustrations (*not suitable* rating). Almost all of the main body sections of the Websites (100%) and mailed brochures (96%) included non-technical illustrations for some of the key messages (*adequate* rating). Only one material contained non-technical illustrations for most of the key ideas (*superior* rating).

Sixty-three percent of the materials that included tables, charts, or graphs gave some explanations for these figures (*adequate* rating). Very few of the materials (7%) provided directions on how to use the figures with examples (*superior* rating). Thirty percent of the materials provided no explanations for figures (*not suitable* rating).

Fifty percent of the materials with graphics included mostly brief captions, which did not fully explain the graphics (*adequate* rating). Twenty-eight percent of the materials did contain mainly explanatory captions (*superior* rating); 22% contained no captions (*not suitable* rating).

3.2.4. Layout, typography, and subheading variables

Layout ratings are based on eight criteria: (1) placement of illustrations adjacent to relevant text; (2) consistent layout; (3) use of visual cueing devices (e.g., boxes) to highlight key content; (4) adequate white space; (5) effective

use of color; (6) line length of 30–50 characters; (7) high contrast between type and paper; and (8) use of nongloss or low-gloss paper. Sixty percent of the DTC text materials had both favorable and unfavorable layout features (*adequate* rating). On the positive side, many of the materials had good contrast between type and background; effective use of color; and placement of illustrations adjacent to relevant text. On the negative side, many of the materials had line lengths greater than 50 characters; a lack of visual cues to highlight key content; and a lack of white space, especially in the brief summary sections. The brief summary sections of the magazine ads often had especially crowded layouts.

Typography ratings are based on four criteria: (1) use of both uppercase and lowercase type for text; (2) type size of at least 12 point; (3) use of typographic cues to indicate key content; and (4) no use of all uppercase letters for long headers or running text. Seventy-eight percent of the materials had both favorable and unfavorable typography features (*adequate* rating). The materials generally used both uppercase and lowercase type in the text, which is a positive feature. Common negative features were small type; lack of typographic cues (e.g., bold type) to indicate key content; and use of all uppercase letters for long headers or running text.

Seventy-five percent of the materials with lists contained lists with more than seven items and no subheadings (*not suitable* rating). Twenty-five percent only had lists with seven or fewer items (*adequate* rating). None of the materials included lists that were chunked into groups of five or fewer items by subheadings (*superior* rating).

3.2.5. Learning stimulation, motivation, and cultural appropriateness variables

These last sets of variables assess whether a material (1) interacts with the reader; (2) provides motivation through subdivision of the text; (3) matches the logic, language, and experience of the target audience; and (4) shows positive images of the target audience.

A majority of the main body sections of the Websites (70%) and mailed brochures (61%) presented questions or problems for consumer response (*superior* rating). Thirty-six percent of materials overall had a question-and-answer format (*adequate* rating). Fifty-five percent of the brief summary sections and 68% of the main body sections of the magazine ads did not include any interactive features (*not suitable* rating).

Eighty percent of the main body sections and 61% of the brief summary sections of the magazine ads subdivided the text somewhat (*adequate* rating on the motivation variable). In general, the text of the brief summary sections of the Websites (61%) and mailed brochures (70%) did not appear to be subdivided (*not suitable* rating). A few materials of each type had text that was subdivided into small parts (*suitable* rating).

In terms of logic, language, and experience, 58% of the brief summary sections were more appropriate for health care providers than consumers—that is, they focused on clinical information, included extensive unexplained medical vocabulary, and were addressed to physicians (*not suitable* rating). The majority of the main body sections of the magazine ads (63%) and mailed brochures (61%) were an intermediate match for consumers (*adequate* rating), while 65% of the main body sections of the Websites were a good match (*superior* rating).

Finally, when materials contained images of patients, these images were generally positive (*superior* rating; 70%). Only 3% included mainly negative images (*not suitable* rating), while 27% included a mixture of positive and negative images (*adequate* rating).

3.2.6. Overall SAM scores

As shown in Table 3, we rated 95% of the main body sections as *adequate* and 61% of the brief summary sections as *not suitable*. These results mean that consumers could use the main body sections with some assistance, but that the majority of the brief summary sections were not appropriate for consumer use.

Table 3
Overall SAM scores for a sample of direct-to-consumer (DTC) magazine advertisements, mailed brochures, and Websites

	Magazine ads		Mailed brochures		Websites	
	Main body ($n = 19$)[a]	Brief summary ($n = 23$)	Main body ($n = 23$)	Brief summary ($n = 23$)	Main body ($n = 23$)	Brief summary ($n = 23$)
Raw SAM scores (%)[b]						
Mean	51.5	34.8	56.9	31.9	56.0	40.1
S.D.	7.2	15.2	8.5	12.9	6.7	16.8
Range	39–62	15–60	38–71	17–53	44–68	15–68
Number in each SAM category[b]						
Superior	0	0	1	0	0	0
Adequate	18	11	21	6	23	10
Not suitable	1	12	1	17	0	13

S.D.: standard deviation.

[a] Four of the DTC print ads were comprised only of brief summaries, with no main body sections.

[b] Raw SAM scores (percentage scores) are classified as follows [21]: (a) 0–39, not suitable; (b) 40–69, adequate; (c) >70, superior.

4. Discussion

FDA guidelines currently allow broadcast DTC advertisements that do not fully disclose all of a prescription drug's risks if the ads include "adequate provision" for dissemination of the drug's approved labeling. The FDA has suggested that ads can meet this requirement by referring consumers to physicians and pharmacists and to text sources of product labeling (Website, toll-free telephone number, and concurrently running DTC print advertisement). Such DTC text materials are therefore important sources of risk information for consumers.

We assessed the main body and brief summary sections of 69 DTC text materials using the SMOG readability formula. All of the materials except one had SMOG grade level scores for both sections above the maximum eighth-grade level recommended for materials intended for the general public [22]. The average readability scores of the materials were substantially above that level. In fact, a college-level reading ability would be needed to read the average brief summary section. These findings suggest that most consumers would be unable to understand risk information contained in the brief summary sections.

A notable feature of this study is its use of the SAM instrument [21], which complements the readability formula by identifying specific text features that might increase reading difficulty. The SAM results reported here highlight specific features of DTC text materials that could be changed to make these materials more suitable for consumer use, including the following factors.

(1) Content: clearly stating the purpose of the material, limiting the scope to essential consumer information, and summarizing key ideas.
(2) Literacy demand: use of active voice, simple sentence structure, common words, and explanations and definitions for medical terms.
(3) Graphics: use of line drawings, illustrations for all key messages, how-to directions for figures, explanatory captions, and cover graphics that illustrate a material's purpose.
(4) Layout/typography: shorter line lengths, more white space, larger type, use of visual and typographic cues to indicate key content, and chunking lists into groups of five or fewer items.
(5) Learning stimulation/motivation: greater subdivision of the text and more interaction with the reader through posing questions and problems for reader response.
(6) Cultural appropriateness: greater match between materials and consumer audience.

We found some consistent patterns across the three types of materials (i.e., DTC magazine ads, mailed brochures, and Websites). Both the SMOG and SAM results indicated that the brief summary sections would be particularly difficult for readers. One major reason for this, in our opinion, is that these sections are often derived from the full package insert, which is written for physicians. As a result, a number of the brief summary sections we examined included many unexplained medical terms and extensive pharmacokinetic and clinical research data. Our findings are consistent with those of previous materials assessment studies, which have found the use of medical jargon, tiny print, long sentences, and difficult vocabulary in many brief summaries [15,24].

The main body sections for the three types of materials also shared many similarities. Almost all of these sections had a clearly stated purpose. In contrast to the brief summary sections, most of the main body sections limited the scope to essential consumer information, used more lay vocabulary, had a more suitable writing style and layout, and matched the logic, language and experience of consumers. This is likely due to the more promotional nature of the main body sections compared to the brief summary sections.

We also observed some differences across material type. For example, fewer main body sections of the DTC magazine ads included a summary, relevant illustrations, or interaction with the reader compared to the main body sections of the other materials. Fewer of the brief summary sections of the DTC magazine ads included graphics and had an adequate or superior layout compared to the brief summary sections of the other materials. These patterns are likely due to the greater space constraints of the magazine format. The main body sections of the DTC magazine ads were generally comprised of one or two magazine pages, whereas the brief summary sections were often comprised of only one page.

The Website format had some unique considerations. For these assessments, we printed all of the Websites on a color printer, a resource that might not be accessible to many consumers. Many of the Websites required a high-speed connection to use effectively; attempts to download some of the Websites or move between Website pages using a 56K dial-up modem were very slow. The location of the brief summary information was not always obvious on the Websites, making it necessary to move through a series of links or to consult the site map to uncover it. Therefore, accessing information on the Websites required resources and Website knowledge that consumers might not have, issues that are important to examine in future studies.

The limitations of this study should be considered in interpreting the results. We assessed the materials using the SMOG and the SAM rather than directly examining consumer comprehension. Some researchers have argued that medical terminology may artificially inflate readability formula scores [25]. To partially address this concern, we excluded brand and generic drug names from the SMOG assessments. In addition, Morris et al. found that readability estimates for the same material could vary widely depending on the readability formula used [26]. Even so, Meade and Smith found that commonly used readability formulas (e.g., SMOG, Fry, Fog, and Flesch) all had very high, positive correlations with each other when used to assess a sample of health education materials [19].

Furthermore, although the SMOG readability formula was validated by testing comprehension of adult periodicals in a college student population [27], it has not been validated with patients using educational materials developed for their medical conditions [20]. Likewise, the SAM has not been validated with a patient population [21]. Therefore, a critical next step is to assess more directly consumer comprehension of DTC text materials. A future study expanding on our results might be to test directly consumer comprehension of text materials and examine the correlation between these comprehension scores and the SMOG and SAM results. Such a study could validate the use of the SMOG and the SAM in future studies designed to assess the literacy demands of these materials. Still additional studies could be conducted to compare results using different direct and indirect methods to assess various types of prescription drug information [28].

An additional study limitation was that the examined materials were not a random sample of all available DTC text materials. It should be noted, however, that 10 of the 23 prescription drugs represented in our sample were ranked among the top 50 drugs for 2001 retail sales [29]. In addition, the materials we examined related to 22 different indications. For these reasons, we do not believe that a study involving a random sample of available materials would change our major conclusion that DTC text materials are inadequate for consumers with low or marginal literacy skills.

The FDA has addressed the issue of readability of print prescription drug advertisements in the context of fair balance in the presentation of risk and benefit information [30]. With respect to the brief summary sections of DTC print advertisements, a draft guidance issued by the FDA in March 2001 commented that information drawn from the package insert might be difficult for consumers to understand [31]. Under this draft guidance, the agency allowed the use of approved patient labeling, which often uses simpler language, to meet the brief summary requirement, but only if it comprehensively addresses the drug's most serious and common risks [31]. However, not all prescription drugs have approved patient labeling that meets this standard. Development of suitable patient labeling for more prescription drugs would be one method of increasing the usefulness of the brief summary sections of DTC text materials for consumers.

Our results clearly indicate that the FDA needs to take further steps to ensure the use of consumer-friendly plain language in the main body and brief summary sections of DTC text materials. Materials that are too difficult cannot actually inform consumers about the risks and benefits of a prescription drug. True "adequate provision" of this information means using plain and consumer-friendly language.

4.1. Practice implications

The results of these SMOG and SAM assessments indicate that text materials intended to supplement DTC television advertising (i.e., DTC print advertisements, Websites, mailed brochures) would not be useful to many consumers. The brief summary sections, which provide comprehensive risk information, are particularly difficult. A college-level or even graduate-level reading ability would be required to understand many of the brief summary sections we examined. The results of the SAM assessments suggest specific areas for improvement for the developers of these materials. Some critical areas include limiting the scope to essential consumer information; increasing the use of active voice, simple sentence structure, common words, and explanations and definitions for medical terms; illustrating key messages with line drawings; using more white space, larger type, and cues to indicate key content; increasing reader interaction; and developing consumer-appropriate materials. Based on the results presented here, health care providers need to be aware that patients who approach them about a prescription drug as the result of DTC advertising might not have the full information required to make an informed decision about the drug. Hence, counseling regarding risk information is particularly critical in any conversation that health care providers have with patients about an advertised drug.

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Appendix A

Brand name, manufacturer, and indication for the 23 prescription drugs for which materials were included in this assessment.

Brand name	Manufacturer	Indication
Actonel	Aventis & Proctor and Gamble	Osteoporosis/bone strength
Allegra	Aventis	Allergies
Ambien	Searle	Insomnia/sleep difficulties
Detrol	Pharmacia & Upjohn	Overactive bladder
Diflucan	Pfizer	Yeast infection
Imitrex	GlaxoWellcome	Migraine headaches
Lamisil	Novartis	Nail infection/nail fungus
Meridia	Knoll Pharmaceutical Co.	Overweight/weight loss
Nasacort AQ	Aventis	Allergies
Ortho Tri-cyclen	Ortho McNeil	Birth control
Paxil	Smith-Kline Beecham	Social anxiety disorder

Appendix A (*Continued*)

Brand name	Manufacturer	Indication
Prevacid	TAP Pharmaceuticals	Acid reflux
Procrit	Ortho Biotech	Anemia related to chemotherapy
Remicade	Centocor	Rheumatoid arthritis
Sarafem	Eli Lilly and Co.	Premenstrual dysphoric disorder (PMDD)
Serevent	GlaxoWellcome	Chronic obstructive pulmonary disorder (COPD)
Singulair	Merck	Asthma
Tamiflu	Roche	Flu/influenza
Valtrex	GlaxoWellcome	Genital herpes
Vaniqa	Bristol-Myers Squibb	Facial hair growth
Vioxx	Merck	Osteoarthritis
Wellbutrin SR	GlaxoSmithKline	Depression
Zocor	Merck	High cholesterol/ heart disease

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