6-1-2010

Prescription drug brand Web sites: Guidance where none exists

Lewis Glinert

Follow this and additional works at: http://pubs.lib.umn.edu/innovations

Recommended Citation
http://pubs.lib.umn.edu/innovations/vol1/iss1/8

INNOVATIONS in pharmacy is published by the University of Minnesota Libraries Publishing.
Prescription drug brand Web sites: Guidance where none exists

Lewis Glinert, Ph.D.; Linguistics Program, Dartmouth College

Key Words: Prescription drugs, Internet and health, Advertising, Regulation, Communication, Discourse Analysis, Navigation, Usability, WWW, Web

ABSTRACT
This paper applies insights from linguistics and discourse analysis to prescription drug brand Web sites, with special reference to the 100 top-selling drugs. Such sites give the outward appearance of being a place to go for straightforward information about a specific brand. In reality, they present a confused mix of brand information, health information and hype, muddled organization, and poor indication of authority, creating an imbalance between benefit and risk content. In so doing, they breach the letter and spirit of the regulations governing direct-to-consumer advertising, which the FDA has by default applied to such Web sites but which were not designed for this special type of discourse. The many communicative difficulties proven to be caused by Web sites in general, in particular for the elderly and less literate, also pose ethical problems. A rethinking of the verbal and visual design of these drug sites is needed -- and new regulatory guidance, for which this paper offers recommendations. At stake is not just the quality of health information at brand drug sites but also their credibility.

Introduction
More American consumers have been visiting the Internet than their doctors to obtain information about their health, according to a study published in 2007. Indeed, a Pew Internet report of 2009 found that even for a specific health or medical problem, 57% of US adults searched online for assistance. Use of the social media is a fast-growing part of this picture: the 2010 Prevention Magazine Annual Survey reported that 60% of online health information seekers had used social media. Regarding online health-seeking by minorities, research is scanty, but Hispanics were found to favor Internet and broadcast advertising while Anglos preferred health Websites such as WebMD. As for prescription and over-the-counter medications, 33% of US adults searched online for information about them in 2009, as against 19% in 2002.

A Google search for information on almost any well-known prescription drug <xx> during 2009 and the first half of 2010 would have listed as first (non-sponsored) the company-sponsored so-called 'official' brand site, <xx>.com. Accurate figures or estimates for visits to <xx>.com sites were not available to us at time of writing, but according to a 2005 Accenture survey 22% of those surveyed sought facts on medications at brand Web sites, and the 2010 Prevention Magazine Survey noted that 42% of respondents reported seeing an ad that connected to a site of this kind. The fact that manufacturers were 'paying for placement' suggests that they were generating considerable traffic, and a study found that brand sites were the most effective form of pharmaceutical marketing and were highly effective at generating new patient starts and refills. At the same time, the Pharma industry appears to see the function of these sites as to 'both educate consumers and build relationships between brands and their target audiences', as one marketing agency executive has summarized it, but with the editorial content or other useful information serving to bring users back to visit the brand.

This paper argues that 'official' brand sites pose serious communicative and ethical problems, which regulators have failed to address, and proposes a set of guidelines, using insights from linguistics and discourse analysis.

The credibility that users have been attributing to Internet health information has been consistently high. According to a Pew Internet report of 2002, 72% of health-seekers said you can believe all or most online health information, and 69% said they had not seen any wrong or misleading health information on the Internet. At the same time, 47% of health seekers had rejected information from a site that appeared to be promoting a product or was just too commercial. A Pew report of 2006 records that three-quarters of American Internet health seekers said they checked source and date “only sometimes,” “hardly ever,” or “never” , while some two thirds thought they could tell if a medical site is from a credible source prior to clicking on the search result according to a 2009 Manhattan Research report. Compared to broadcasting and print, the Internet may now be perceived as a more credible source of prescription drug information, perhaps because it hosts substantial high quality content -- although few would list the Internet as more trusted than their physician. However, the recent rise of user-generated social media has generated mixed judgments: the 2010 Prevention Magazine Survey found that 58% of users regarded such sources of health information as trustworthy.
A step toward greater credibility in on-line information for medications occurred on June 21, 2010, when, with no fanfare, Google introduced a policy ensuring that the first hit you would now be seeing (right after any sponsored x.com links) would be a link to a National Institutes of Health (National Library of Medicine) site with objective and more specific information such as "side effects." The new feature was developed in partnership with NIH, who in turn license this data from The American Society of Health-System Pharmacists, which creates and maintains the data.

In the early days of the Web, the FDA was inclined to regard on-line product information as labeling, and advised that "a good test for [firms seeking to utilize the Internet] would be to say, 'Would I send the information I’m putting on the Internet out on hard copy?'" However, following solicitation of opinion in 1998/9, the FDA postponed issuing guidelines in view of the uncertainty as to where the Internet was headed and how it would be used. At time of writing, the FDA still appears to view the situation as it was depicted by Marilyn Moberg and colleagues at that time: "As a hybrid of print and electronic communication [and of labeling and advertising], Internet-provided information about a pharmaceutical or medical device on the Internet is likely to be subject to regulations that apply to either." Thus, five FDA untitled or warning letters relating to Web sites that were issued in 2005 drew upon both broadcast and print advertising guidelines in faulting risk and efficacy information. On 2 April 2009, the FDA issued 'untitled letters' to 14 of the world’s largest pharmaceutical companies for misleading "sponsored links", in which risk information failed to appear on every Web page that stated benefits. The Pharma industry, uncertain how to handle this new medium, has lobbied for specific guidance. When the FDA did hold public hearings regarding the Internet, in November 2009, one of the five specific issues for which they sought opinions was: 'How can manufacturers, packers, or distributors fulfill regulatory requirements (e.g., fair balance, disclosure of indication and risk information, postmarketing submission requirements) in their Internet and social media promotion?' However, discussions were almost wholly focused on the issue of promotion via third-party social media tools.

Our focus here is on prescription drug company-sponsored brand sites. A handful of studies have begun to explore them. Macias and Lewis found that sites were using advertising appeals similar to those found in print ads, many with animated graphics, but with a great deal more medical and drug information. They concluded that ‘consumers have more time to read and digest the information, the medium can better organize the quantity of information required for pharmaceutical drugs, and the Web may even be able to better teach consumers the technical aspects of drugs and the conditions they treat (as discussed in future research). Therefore, the Web is better able to meet the FDA requirement of "adequate provision" by "communicating all information relevant to the product’s indication (including limitations to use) in consumer-friendly language." A follow-up study argued that a majority of direct to consumer brand sites were meeting the criteria of fair balance between benefit and risk information and adequate provision of such information, as well as several industry evaluative criteria. The value of a brand site during a product scare has also been recognized.

In stark contrast, Huh and Cude found that only one half of their sample of 60 sites provided risk information on the home page together with the benefit claims. (This has since improved, in response to FDA warning letters, with ‘safety information’ now standard on every page.) They further found that risks on 50% of the sites were couched in smaller font, and that one quarter of the sites lacked any navigational link to such information. Further doubts have now been raised by Sheehan, who points out that by the FTC’s ‘clear and conspicuous’ standards for disclosure, which require that risk be presented adjacent to benefit, only one third of the 91 sites she examined could be deemed to be in the spirit of fair balance. Sheehan further criticizes the frequent need to scroll down to risks, and more generally the multitude of formats making it so hard for the user to develop a mental schema for handling Web sites -- and comments that ‘FDA’s lack of guidelines for branded drug Web sites is clearly apparent in the range of formats and information provided at these Web sites.’ Vigilante & Wogalter additionally found that risk and benefit information are located faster, and were much preferred, when set in separate sections, at the top of the home page.

Macias and Lewis’s upbeat conclusions, mentioned above, also jar with findings about the poor usability of consumer-oriented brand name Web sites in general. An analysis published in 2007 of 500 company sites revealed that three features that might be adjudged critical to risk/benefit balance were in short supply: Just 10% used a breadcrumb trail showing the path back to the home page, 23% had a site search capacity, and just 14% offered a FAQ or Help option.

Meanwhile, Internet communication analysts have recognized that as a communications and marketing medium it is quite different from other forms of communication on several dimensions, e.g. interactivity, control, dynamic content, and depth of content. For example, online branding may have more to do with the interactive experience lived in front of the screen than with texts or icons it contains.
The conceptual structure of Web sites and the establishment of best practices have been a particular concern and a wide range of problematic communicative features have been identified. 

(a) Web sites have no obvious 'next page' or closure, nor even a clear starting point on their home page. Instead, they are 'hypermodal', i.e. constructed around an unordered series of links. One is thus constantly compelled to make navigation choices, as in a kind of maze. Average page view time has been put at 10-12 seconds. 

(b) The overall significance or thrust of a Web site is hard to judge. There is no natural place for a summary or parting message or tagline. 

(c) The individual Web page itself lends itself to modularity and discontinuity, to a reading process not based on an anticipated trajectory, and to a different logic of argumentation such as 'Web rings'. 

(d) Content is liable to change or vanish from one visit to the next, with little indication of when a page or site was last updated. 

(e) Text on a computer screen is hard to read. Indeed, there is evidence that high-literate users generally scan rather than read such text, commonly in an F-pattern, i.e. plowing the upper content bloc (typically the first two paragraphs), then a shorter bloc below it, and then scanning down the left side of the page. They read no more than 20-25% of the text on a visit to a page. 

(f) One consequence of such F-pattern scanning is that on link labels the first two or three words are commonly all that gets noticed, often adding to navigational problems. 

(g) Printing out the site is no easy solution but a long and tedious operation. 

(h) Site search engines, the best alternative resort, are often problematic, owing to the issue of hyphens, plurals and the like, as well as varying forms of prioritization. 

Consistency in Web design has been identified as one of the most critical principles of Web page usability. In the words of Jakob Nielsen, 'The more users' expectations prove right, the more they will feel in control of the system and the more they will like it.' When an Internet user is on a high-involvement information search, these expectations are heightened.

All of this is particularly hard on seniors, the less literate, and on others who find reading a challenge. Seniors had a 53% success rate at four fact-based Web tasks compared with 78% for a control group aged 21-55, took overall 70% longer, and voiced strong preference for the high-usability sites.

Eyesight, memory and precision of movement pose further problems. The less literate (defined as below 9th grade reading level) were estimated in 2005 as comprising 30% of Web users, projected to rise to 40% by 2010. They are thought to view Web sites quite differently: rather than scan to identify key information, they read word for word, scrolling disorient them, as do busy Web pages and graphics; spelling search terms is a problem. In a Pfizer-funded study, a less-literate group had a 46% success rate (vs. 68% for a higher-literacy group) at seven fact-based Web tasks at a major Pharma product site, designed by a respected agency; but this rose to a 82% success rate when the site was simplified, e.g. by placing chief information at the top and listing main choices in a linear menu.

Legibility problems are not confined to seniors. Tiny fonts were nominated as by far the worst design mistake of 2005 by readers of the Jakob Nielsen newsletter, followed by link navigation issues.

This is not to suggest that there is a health-seeking Babel, or that cyberquackery and cyberchondria reign supreme, as the medical journals sometimes imply. For one thing, search engines are structuring certain online information in ways which evoke the 'traditional' media, giving the spotlight to governmental, biomedical and charitable interests, and now also to a lot of quality content from Wikipedia, although much searching does require sifting through piles of poor-quality sites. Users have shown some skill at identifying quality sites. As the digital media penetrate every corner of society, qualitative studies reveal that weaker groups have been acquiring some basic techniques and comfort level in their online 'health habitus'. However, all is clearly not well. A research review published in 2004 reported that people seldom went beyond the first page of a search, had limited search and evaluation skills, and often paid no attention to credibility cues.

Two further problems, by no means inherent to the Web but endemic to commercial Web sites, are 'stickiness' -- the use of multiple strategies to detain a visitor -- and 'patchworking', the general tendency of designers to patch together materials from quite disparate sources to make up a page. Thus, for example, a Learn About Allergies page mixed a voice-over style ('If you’re looking...you’ve come to the right place!') with statistics and long paragraphs. Or, arriving at an FAQ page, one may have the distinct feeling that the "answers" were written by some pundit and the questions added as an afterthought.
With all these communicative handicaps, the consumer is ill-equipped to deal with what we are going to suggest is the most striking characteristic of brand drug sites: the fuzzy mix of promotion and information.

It is remarkable that no attempt has been made by the FDA or Industry to draw up specific guidance for brand Web sites, which today perform a function parallel to and in many ways superior to the other media used in direct-to-consumer advertising, both print and broadcast -- especially in terms of their capacity and ease of access.

FDA guidance for direct-to-consumer drug promotion in broadcasting and print ('promotion' and 'advertising' are used interchangeably by the FDA, although some would distinguish the two) has had a lot to say about the definition of 'false and misleading' and the doctrine of 'fair balance' between information about effectiveness and information about risk. Essentially, balancing information has to appear in the primary text of the promotional material, in consumer-friendly language. As practice has evolved, the FDA has revisited the issue, primarily in the ongoing but diffuse form of warning letters, e.g. faulting 'minimization of risk' where efficacy claims were 'presented using large, bolded headers and with significant amount of white space around them' while risk information was 'presented in the bottom half of the ad in difficult to read font and typography' (gist of warning letter for Prograf, 8/31/06); so too, occasionally, have the courts. Meanwhile, clinicians and researchers have voiced persistent alarm, mitigated only by evidence that advertising promotes greater health awareness.

However, in practice, scant attention has been paid by the FDA to some equally crucial aspects of 'fair balance' and 'false and misleading': the part played by the reader/listener, and the nature of the genre and the medium. As practice has evolved, the FDA has revisited the issue, primarily in the ongoing but diffuse form of warning letters, e.g. faulting 'minimization of risk' where efficacy claims were 'presented using large, bolded headers and with significant amount of white space around them' while risk information was 'presented in the bottom half of the ad in difficult to read font and typography' (gist of warning letter for Prograf, 8/31/06); so too, occasionally, have the courts. Meanwhile, clinicians and researchers have voiced persistent alarm, mitigated only by evidence that advertising promotes greater health awareness.

To appreciate these issues requires some knowledge of discourse analysis, an approach that asks how the various elements in a text combine to send a message or a mixed message -- and the central role of context. What, for example, if the quantity of risk and efficacy information is the same but the latter is more accessible or more appealing than the former? Or what if a media company employs ‘postmodern’ text which tests the limits of what is literal or appropriate? But most important, for the present topic, is this: What if health information is merged with product hype? And, more fundamentally, what is the nature of an Internet site, how do users relate to it, and how is the information there processed?

**Objective**

In this paper we wish to use insights from linguistics and discourse analysis to suggest that prescription drug brand Web sites give the outward appearance of being a place to go for straightforward information about a specific brand -- but that, in reality, they present a confused mix of brand information, health information and hype and hence, effectively, an imbalance between benefit and risk content. In so doing, they breach the letter and spirit of the regulations governing direct-to-consumer advertising. Taken together with the discourse properties of these sites and the many communicative problems shown to be posed by Web sites in general, in particular for the elderly and less literate, they necessitate a rethinking of the verbal-visual design of these drug sites -- and new guidance. At stake is not just the quality of health information at brand drug sites but also their credibility.

**Method**

Recent years have seen great advances in the understanding of the variables of communication and its context -- in particular, how language reflects and affects its social context and how composite texts (such as newspapers and advertisements) are organized.

How and by what means a communication is interpreted is a matter of extraordinary complexity, variability and often even ambivalence. Interpretation depends, inter alia, on text, content, situation and communicative goals.

Text is known to correlate with independent variables in the situation and the sender’s goals. One influential model has tentatively proposed the following major situational variables: content of message, setting, participants, tone, mode (e.g. oral, written), norms of interaction (e.g. conversational etiquette), norms of interpretation, genre (e.g. poetry, prose, myth, report), and the actions and interactions taking place. Some of these variables, such as setting and
genre, are in turn dependent to some degree on what is being said.

Three major communicative goals may be identified: presentation (describing, requesting and so on), orientation (expressing an attitude to the message, the addressees and so on), and organization of the message.[^82]

Such study of texts, spoken or written, thus involves going beyond the study of linguistic structures (so-called 'core linguistics') to embrace broader features of communication. In this paper, we wish to draw on two broad communications approaches, discourse analysis,[^83,84] and ethnography of language,[^85] as well as on linguistic observation per se.

Discourse analysis examines the holistic interplay between text and context. For instance, the sentence 'Don't let seasonal allergies cloud your day' will not convey the same message or be equally appropriate in the context of a commercial voice-over, a magazine feature or header, a casual conversation, or a formal warning. The surrounding text and image can affect interpretation; so too can the participants' knowledge and the assumptions they bring to bear, their social and personal relationship and even their mood. What all these factors are and how they interact in, say, a magazine or a lecture is still far from fully understood. One focus has been 'multimodal' communication,[^86] combining such modes as oral and written text, still and moving image. Web page technology routinely offers a combination of all four modes.

A pertinent accessory to discourse analysis is pragmatics, which theorizes how meanings are arrived at in practice and pays special attention to inferencing and connotations. Thus, the sentence 'You may be ready to switch to <medication>' can be a lot more than a descriptive statement. As used in a promotional context, it may amount to an encouragement, in much the same way as can 'you may wish to [...] in consultative and advisory contexts. Indeed, the phrase 'ready to do x' sometimes strongly suggests that x is desirable.

Ethnography of language asks what different types of text are seeking to do and are perceived as doing -- and how this is reflected in language, format etc. What are termed 'advertisements' and 'technical information' in our culture are two recognizable types of text or genre.[^87] Other genres are press reports, recommendations, interrogations, and love letters. At the same time, a culture also classifies activities by the situation, institution, social group and so on (as against the form of the text); examples of 'activity types' are the job interview, the committee meeting, advertising, lecturing -- and this extends to 'virtual situations' such as the provision/doing of written interviews, the provision/reading of information leaflets and so on. The discourse of parents and children, the elderly, the legal system and medical encounters has attracted considerable attention. Specific activity types often go together with genres and styles: there is a typical lecture style and a typical promotionalese. In a consult, a patient is typically asked 'How have you been' and responds with details of his or her health (rather than replying, 'And how are you?')

However, we frequently nuance and even mask our behavior by borrowing stylistic features from one activity into another. For example, the physician will often preface the consult with a 'How are you' that belongs to the realm of socializing.

Discourse analysis and ethnography of language focus on the text, the framing texts, and the context. While they can offer important pointers to how a text will be interpreted and even contested and to cognitive questions of how a text was intended, they make no predictions. Rather, they can complement empirical research, suggesting hypotheses and theoretical explanations. They are also important tools for social criticism and social policy making.

Both approaches favor a qualitative methodology, largely based on analyst interpretation, owing to the complexities of messages and contexts, although quantitative studies are also sometimes feasible.

Our data are drawn from an ongoing qualitative and quantitative discourse analysis that we are carrying out on the brand drug sites for the 100 top-selling prescription drugs of 2007-2009 and in part from our unpublished analyses for the years 2001-2006. The list of drugs is available by a Google search for 'Pharmacy Times top 200'. Our goal is to illustrate what this kind of qualitative analysis can offer, as well as to provide some analysis and conclusions.

Results and Discussion
Let us consider some common features identified by our analysis, with special regard for how promotion and education act and interact.

1. **Metadiscourse (texts about texts)**
   Metadiscourse (texts about texts) helps create a frame that sets up user expectations and even interpretations.

   a. **Names for genres in lay language**
      In popular parlance, brand Web sites appear to be classed simply as 'Web sites'; our experience suggests that they are not called by any 'genre label' commonly used for non-Internet texts such as 'advertisements', 'commercials',

[^82]: 82
[^83]: 83
[^84]: 84
[^85]: 85
[^86]: 86
[^87]: 87
'articles', 'newsletters', nor anything else that might help one identify them as promotional or informational. We found some support for these impressions when we examined the link titles and two-line page descriptions listed in search results for the 'official' sites of the 100 top-selling prescription drugs of 2009. The only terms that we could find there were the generic 'site' or 'official site'. Industry does not appear to use or promote any other nomenclature.

b. Link titles and page descriptions: promise and reality

We now turn to the Web sites themselves -- and to how they are individually 'packaged'. To a discourse analyst, jackets of books, titles of papers or poems, and -- in this case -- the link titles and page descriptions listed in search results are of considerable significance. Users and analysts tend to see them as encapsulating something defining about the work (although in reality aesthetic and other factors may play a part), which in turn may serve to frame the work for the user. Web site descriptions are likely to influence decisions about whether to enter a site.

For each search result, Google, Yahoo and Bing return a link with a short 'title', created by the site designer; this title also appears as the page header at the home page. Beneath this link is a one or two line 'page description' for the home page, automatically generated from the page to be most relevant to the user's query -- and beneath that, the Web site URL.

First, compare three drug site descriptions provided by a Google search in June 2010. (The ellipses are in the text.)

- **Aranesp® (darbepoetin alfa)** Manufacturer provides indications, side effects, contraindications and mechanisms of action of this treatment for anemia associated with chronic renal...

- **PLAVIX® (clopidogrel bisulfate): Help prevent Clot formation for ...** PLAVIX, proven to help protect against future heart attack or stroke. Click for safety and Full Prescribing Information Including Boxed Warning.

- **VALTREX and Genital Herpes Information -- Valtrex.com** Genital herpes information from VALTREX, the once-daily herpes medication that may be right for you.

The Aranesp description sounded strictly informative, but the descriptions for Plavix and Valtrex contained a promotional element ('proved to', 'once-daily... may be right for you'). A promotional element also figured in the Plavix 'title' ('Help prevent...').

The data lent themselves to a quantitative analysis of the Google links and page descriptions for the 'official' sites of the 100 top-selling prescription drugs of 2009 in terms of theme and goal. This yielded three categories: (1) condition and product information, (2) product information, or (3) product information and promotion. Promotion was defined as involving comparisons such as 'the only...', 'a different kind of type 2 diabetes medication', appeals such as efficacy ('powerful night and day relief', 'with the power of 3 HIV meds in one pill daily') and ease of use ('easy-to-use'), and general encouragement to learn about the product ('Find out what you can do to manage high blood pressure').

The results (n=92) were:

1. condition and product information 10%
2. product information 54%
3. product information and promotion 36%

Meanwhile, running beneath each page description, the URL <brand name>.com indicated that the sites were brand-oriented but users were entitled not to infer from this that they were promotional or at least not exclusively so. Thus, only a minority of the Web sites signaled that they were promotional. The majority give the appearance of being a place to go for straightforward information about a specific brand.

In reality, we found that page descriptions and link titles were frequently misleading in this respect. Here are two examples: A page at singulair.com entitled What Exactly Is Asthma? displayed a prominent For more information with two links, one to Parent Of An Asthma Sufferer and the other to I am Asthma Sufferer -- but both were promoting the product. Similarly, clicking on the Google search link to Valtrex.com, which promised a page of genital herpes information, brought us to a page promoting Valtrex.

To combine promotional and consumer education per se is not peculiar to drug promotion. Discourse analysis of advertising and consumer education has established that each likes to borrow 'tricks' out of the other's book, in part because the two share some overlapping goals. Advertising, indeed, is commonly attached to or embedded in other texts, tending to draw on their authority. The best ads have been likened to 'bandits, raiding the accompanying discourse but with the sense not to stay too long.' Ultimately, advertising is as inventive as literature. Ethical criticism of the more hybrid sorts of advertising has highlighted such genres as newspaper consumer supplements, with their mix of objective and flattering tones and their ads and links suggestive of endorsements. Advertising campaigns for non-medical products such as detergents have long cultivated 'scientific' discourse, and the same strategy is being used with quasi-medical products such as functional foods.
However, the name and frame of the text will commonly make it possible to categorize it as either promotional with some informational content (which many will interpret with due caution) or as informational with some promotional content. Examples of the former are product brochures and infomercials. An interesting example of the latter are newspapers: Some newspapers have overwhelmingly advertising content, but their title (e.g. Daily Tribune), the type of news they carry, and popular reference to them as 'newspapers' will probably signal that the editorial and news content is to treated as non-promotional.

Where, then, a user comes to a Web site for information and finds it mixed with promotion, the lack of a clear mental schema may increase confusion. A socialized skepticism for ads will often further reinforce this.

2. Organization of menu and page content
Less egregious but particularly widespread was the practice of jumbling health and product links within the same menu. Thus, on the home page of purplepill.com, a vertical bar menu listed six items, the first and last of them product links and the intervening four health links; meanwhile, in a horizontal row of anchor links, the left two were strongly promotional while the rightmost was a health link. Our data for the same 100 top-selling drugs sites found that only 18% of sites kept condition ailment information distinct from brand information or promotion.

The discourse analyst will wish to assess such mingling against general mingling of advisory and promotional discourse in American culture, in specific genres and specific realms. Supermarket consumer newsletters, for instance, may be able to tolerate a specific amount or type of advertising.

In general, muddled navigation and organization of content was found to be common. Thus, arriving at a page, we often found that the material was a word-for-word copy of another page, or, maybe worse, just slightly different. The following was typical: A page entitled Consumer Information offered two links, ostensibly, to a disease-specific and a product-specific page. However, we found not one but three product pages, for there was a third link, bewilderingly entitled Product Information -- and a fourth link, entitled Your Guide to xxx Tablets. The third and fourth pages, in fact, were almost carbon copies, but just different enough to suggest that two editors created them without conferring with one another.

It is hardly surprising if Internet users have been found to drift about, not paying attention to names of links or precise wording of texts, often not finding what they want or knowing how to get back to where they started. There are usability and credibility issues here, quite apart from any ethical or regulatory considerations. When the consumer comes looking for information and finds repeatedly -- as our data indicate -- that home pages are strongly promotional, there is evidence that it compromises the credibility of informational content elsewhere on the site. Two factors are at work here: (a) Information seekers usually skip 'in-your-face' advertising using banners, animations and the like,95 (b) Internet users in general give less credence to pages that are muddled in form or function.96, 97

3. The dominance of promotional imagery
Promotional imagery has come to dominate drug ads for TV and print ads -- despite regulators' frequent caveats about distraction effects -- and now similarly for brand drug sites. Most sites in a study of 113 of the top 200 drugs of 2004 used female models bubbling with health.98 If the home page prominently displays a image that is promotional (i.e. suggestive of well-being, quirky, highlighting a free trial, providing a video testimonial, or the like), it is probable that the user will categorize the home page and possibly the entire site as an advertisement -- particularly in the absence of any framing that suggests otherwise.

Analyzing home pages at the 'official' sites of the 100 top-selling prescription drugs of 2009, we found that 68% displayed a prominent promotional image. For most companies, then, but by no means all, the official Web site was an extension of their advertising campaign.

At several sites, the home page was dominated by the promotional image, with Safety Information tucked away 'beneath the fold'. At one home page, a tiny 'Individual results may vary' was almost lost against a large promotional image.

This raises several issues. First, do information seekers resist promotional images uniformly, as they have been shown to do with online banner ads and the like, or is there a tolerance for the soft-sell imagery so commonly used -- such as the inviting track through the meadow under the slogan 'A medicine to help you move forward' at abilify.com? Second, given the proven difficulties with scanning a Web page, how easily do information seekers skirt this promotional matter? Third, to what extent do designers even separate informational content from promotional areas? At that same abilify.com home page, we found that all the menus for informational content were located within the promotional image and in the same style and color -- a clear if subtle attempt to inject brand promotion into help seeking. Even
more subtle, and widespread, is the use of a brand design (using color, font and images without borders) for the entire home page or even an entire site, as we found at purplepill.com, akin perhaps to a brand theme tune running through an ad. Paradoxically, FDA Draft Guidance (2009) warned that 'problems can arise when parts of a print promotional piece appear so unrelated that the risks do not look to be part of the piece' (e.g. 'Risk information is placed in a thin column along the side of an ad in a different font and color scheme.'). However, the Guidance fails to address what may be a much more frequent phenomenon of print information (risks or benefits) embedded in promotional hype.

A further issue of concern is the popularity of 'postmodern' promotional imagery, using ironies, paradoxes, puns and ambivalences. As imagery is usually interpreted through text, there is a risk that postmodern text can subvert trust in informational content, particularly where this is embedded in a brand design. Whatever may be known about the interactions between promotional and informational content in print, the nature of communication and usability on the Web may produce quite different interactions.

4. Who is the 'sender'?
At 75% of the 100 top-selling sites we examined, a page with ostensibly objective but anonymous expert advice was flanked by a prominent product pitch (such as a free offer, a testimonial or a 'how <medication> may help', the latter very often part of a site template. Thus, a piece beginning 'Your doctor can help you reach your cholesterol and heart-health goals' was set alongside a prominent 'Get money-saving offers and save on LIPITOR'.

Discourse analysis is concerned with who is (and who appears to be) doing the talking, to whom, and on behalf of whom -- or, to use the technical term, what is the "footing" of the text? A distinction may have to be made between the animator (the end 'speaker'), the scriptwriter, and the 'principal' (the responsible party). Who then is, or is represented as, the voice of these drug sites? Behind the nameless copywriters and media agencies, users are allowed to hear the company (via its discrete logo and its brand) -- but who else? The medical profession? The FDA? Satisfied customers? Is the brand itself projected as a person, e.g. by deployment of anthropomorphic images? In the cases we examined, the company seemed to portray itself as animator and principle for the entire site, including the health information. In the absence of named authors or institutions to vouch for the health information, how users assess the voice behind this information may depend in part on the overall footing of the page and on background knowledge about such web sites and the Pharma Industry.

Similarly, is the implied addressee a patient thinking of seeing, or already seeing, a doctor about the condition? (Recall the ubiquitous 'Ask your doctor about...') patients' families? Or a broader public that needs educating? In actual fact, the implied addressee for a TV ad -- a broad class of viewer, exposed to this ad as passive spectators -- may be rather different from the implied reader of a product site, who presumably went looking for the site in the first place.

Consumers have told researchers that they care intensely who is behind pharmaceutical and medical help sites -- fearing who lurks on the Web. And of commercial sites in general, the 2002 Princeton Survey of Web users found that only 29% of lay users said they trusted them. A small observation study found that those same participants who claimed to check sources, disclaimers and the like did no such thing, while few participants even recalled Websites they had used. One wonders how many health information seekers are, in fact, thinking that all these 'official' drug sites have been passed by the FDA. Precisely this was found to be the belief about TV drug ads. In any event, one study of brand drug Web sites reports that indication of professional authority, such as authorship and academic sources, was relatively scarce -- in sharp contrast with the vague 'research shows, experts suggest' language that food supplement sites are freely allowed to deploy.

5. Relationship to the receiver and the content
Besides its content, a text often expresses the sender's relationship to the receiver and the text. In this respect, promotional style differs sharply in tone from informational or educational style. Two common features of 'promotionales' are the use of 'invitational' imperative verbs and a relationship-building 'you, yours', as in this message at one home page: 'Get ready to learn more here on our Allegra Web site and discover the allergy relief you've been looking for.' A study of probiotic yogurt sites has highlighted a similar use of the imperative and the pronoun 'you' as relationship builders.

In fact, expression of relationship involves several variables. For example, a linguist will consider:
Social distance: intimate, formal, distant?
Social power: forceful, diffident?
Degree of seriousness: sober, light, factually loose, ironic?

Degree of seriousness involves a relationship to the text as well as to the receiver, in particular a variable of factuality:
How factual is the sender about the message, or how factual does he/she wish to appear?

Regarding seriousness and factuality, direct-to-consumer drug advertising raises a difficult issue: How accurate must all the content be? The mission of the FDA’s Division of Drug Marketing, Advertising and Communication unequivocally requires prescription drug information to be ‘truthful, balanced, and accurately communicated’, but nonetheless a culture of promotional hype -- often suggesting (but never asserting) that the drug cures you and makes you happy or that the drug is better than its competitors or that you would be socially desirable for taking it -- has been allowed in broadcast and print advertising (although it has sometimes stirred the FDA to express concern). In the explicit statements about the medication, everything may be truthful and accurate, but in the implicit claims about the outcome of the treatment or the desirability of the medication, all is not true or subject to validation.

To take three instances of suggestive claims in our data: Remicade used an effectiveness and happiness message that it ‘has been used to treat more than one million people worldwide across all uses’, accompanied by a cool, smiling male in dark glasses. A verbal social desirability appeal was the ‘Angela was born to be wild’ campaign on Lantus.com, depicting a biker under the slogan ’Her power’. Or again, the message ’You may be ready to add or switch to <medication>’ is subtly suggesting that this medication is better and that one just needs to wait for the circumstances to be right. Consumers have been assumed by regulators to be capable of shrugging off the hype they hear in this ‘caveat auditor’ zone. However, from the outset there has been a different regulatory convention for labeling and print promotion: Any promotional labeling has to be accompanied by a detailed and technical patient leaflet while print ads require the equivalent on an adjoining page -- all of this with zero hype.

6. Degree of coherence or dissonance in style and format: Copywriters’ attempts to inject a sober and informative element amid the promotion sometimes produced stylistic dissonances. Consider this, from an ‘All About’ page: ’Learn how once-a-day Allegra works to manage your seasonal allergy symptoms and how it works best when taken as directed by your physician.’ What sounds normal as a sign-off to a commercial voice-over sounds quite bizarre here as written text in an educative context. In the same way, the attempt to pack disparate content and formatting into a single page creates a sharper dissonance on a Web page than in print, owing to the cognitive problems of Web page processing referred to earlier. The presence of large blocks of safety information on the same screen as an attractive image is a case in point.

Coherence in language and formatting has more than just cognitive value. Not only can it serve, in our case, to distinguish education from promotion but it can also have a symbolic value, by signaling to consumers that the material was coherently thought out and that they can trust that education. This may be acutely felt where readers are unwilling to take such coherence for granted.

Conclusion

With its mix of written, oral and visual modalities, its maze of navigational choices, its atomized viewing giving little sense of the whole, and its many other cognitive peculiarities, Internet analysts have consistently warned that the Web poses severe difficulties for all users, the elderly and less literate in particular. A large proportion of users have no clear gestalt or iterative schema to tell them what to make of a web site, nor even an opportunity for interacting with other users and coming to a shared meaning.

Amid this communicative tangle, brand drug sites appear to pose a particular communicative problem. Whereas print and broadcast ads are clearly seen as ‘advertising’, function as such, and are regulated as such, brand drug sites have been designed to function simultaneously as advertising and as a repository of technical and consumer information. Both companies and regulators have welcomed the opportunity to provide the kind of product information that the Law requires but which cannot possibly be packed into a 30 second spot. However, our communicative analysis of these sites has identified a hybrid of advertising and information which existing regulations were not designed to address -- and which is not meeting consumers' needs for adequate and balanced information. This confirms the assessment regarding the findings of the Prevention Magazine 2010 Direct-to-Consumer Advertising Survey with respect to online drug advertising, voiced by Cary Silvers, Director of Consumer Insights for the publisher: "Consumers are more responsive to the ‘fair balance’ in traditional media due to its familiarity and the recognizable formula. In magazine and TV ads, risk has appeared in a very consistent manner, mainly the black and white page and the voice-over. New and evolving online formats have not delivered the same level of recognition thus far." 113

In this paper I have illustrated two methods of communicative analysis -- discourse analysis, the study of texts and their interaction with image and context, and ethnography of language, the study of language as action -- which we have been employing to analyze brand prescription
drug sites, with particular reference to the 'official' sites of the 100 top-selling prescription drugs of 2009.

These methods have recognized that in our culture, advertising and consumer information (or advice) count as distinct types of activity and that each has its own range of linguistic styles, genres, factuality and so on -- amounting to two distinct types of discourse. This distinction involves a lot more than the words themselves. Discourse types arise out of a complex of factors, such as verbal-visual interaction, style, situation, and speakers' own perceptions and expectations. In the case of advertising and consumer information there can be considerable overlap, with each borrowing the other's 'tricks' and advertising seeking to morph and masquerade. Nonetheless, a reader or viewer will generally have adequate clues for categorizing the whole as 'essentially' advertising or information, and for evaluating it all accordingly.

This, however, does not appear to hold true for brand drug sites, in view of the qualitative and quantitative findings that we have described for six types of discourse feature. Summing up these findings and some of their possible implications:

1. In lay nomenclature and search result listings, the sites are classed neither as promotional or informational. In the listings, a majority of the link titles and page descriptions signaled that the site or page contained product information rather than promotion, but the reality was frequently otherwise.
2. A large majority of the sites jumbled health and product links within the same menu. More generally, muddled navigation options and organization of content was widespread.
3. Most of the sites prominently displayed promotional imagery, which may create a suggestion that the site is promotional and that informational content embedded in it is less than objective. Another common feature of textual-visual interaction was brand templating of entire pages.
4. Expert content was delivered without a source and flanked by a prominent product pitch at most of the sites. Embedding in a brand template was common. Thus, the company seemed to portray itself as the voice behind the entire site, including the health information.
5. Sites sometimes sought to create a relationship with the addressee, using a promotional grammatical style. They also frequently played loosely with the facts of the product's benefits, by way of suggestive promotional hype.
6. The mingling or juxtaposition of educative and promotional style or format sometimes produced a dissonance, which may impede trust in the message.

Companies have used their legal leeway to mix information and promotion at many levels: At the level of image and text, at the organizational level of links and pages, in style, in tone (hype and sobriety), and in an ambivalence of authorship and addressee.

The FDA has insisted that the Web, being written matter, should be subject to all the constraints of magazines and labeling. However, it is by now clear that the hype of drug promotion has migrated to the Web; and there, far from being fenced off as with labeling or print ads, it mingles in an unstable and unpredictable manner with serious content such as risk and safety information. Combining with the intrinsic cognitive difficulties of the Web, this kind of discourse may be jeopardizing the effectiveness of risk information and undermining the credibility of the whole. There may, in principle, be nothing wrong with housing advertising and consumer information under one roof, but to allow them to co-mingle is ethically questionable, even if risk information per se is presented in a balanced way. Indeed, it raises the issue of accuracy of health information in a new and sharper form, and may warrant reassessing accuracy and hype in drug advertising in general. Given the often uncharted waters of the Internet, with customized and intimate conduits for social promotion evolving all the time, it appears desirable that educative or informational drug content be kept free of trivializing, intimate or factually loose language, while urgent investigation is conducted into how users are interpreting and responding to the Web and to other digital media.

A common-sense divide between promotion and information is assumed by FDA, Industry and the consumer, and should be possible to maintain.
Recommendations

- Regulators and Industry should urgently devise Internet-specific guidance for brand drug Web sites.
- Informational content should be kept distinct from promotional content, with particular attention to inappropriate style, pervasive images, and misleading links or titles.
- Safety information or a prominent link to it should be easily visible without scrolling, for the sake of the low-literate.
- Among other shortcomings to be remedied: poor site organization and navigation, such as duplicate and overlapping pages; poor site mapping; lack of indication of expert authority.
- Any new guidance should draw upon linguistics and discourse analysis for their holistic insights into the workings of Web sites.

End Notes

15. See fn. 6.
17 http://searchengineland.com/google-adds-new-health-search-feature-for-medications-44757
Accessed July 2, 2010

18 McEvoy G. American Society of Health-System Pharmacists (personal communication).


24 http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM055773
Accessed July 1, 2010

Accessed July 1, 2010


Accessed on August 20, 2010


Food and Drug Administration Center for Drug Evaluation and Research (CDER) Guidance for Industry: Consumer-Directed Broadcast Advertisements. (August 9, 1999), Federal Register, 64 (152), 43197^3198 (Docket 97D-0302).


Accessed June 26, 2010


