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FDA Draft Guidance on Risk Communication

Reading the Tea Leaves

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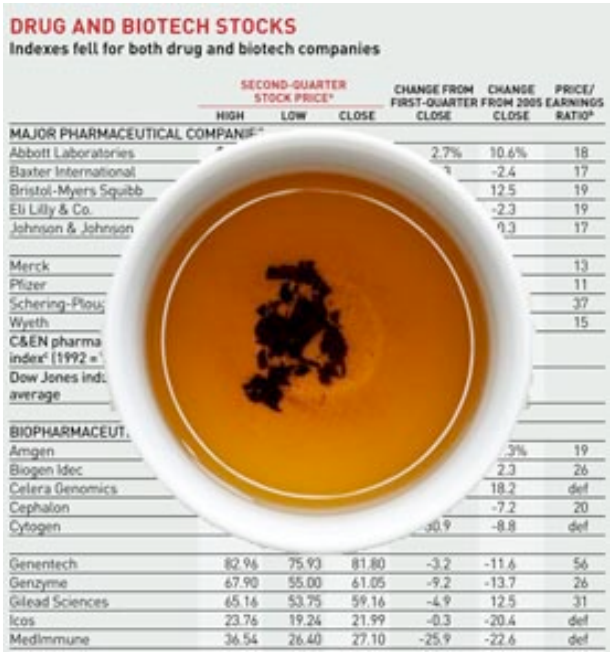

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The FDA likes to boast that it is a science-based organization that depends upon data to make decisions having far reaching effects on the multi-billion dollar drug industry. Lately, however, it has been receiving criticism from some quarters that its regulatory actions with regard to promotion via the Internet are not based on facts about how consumers interact with such promotions.

Most recently, for example, DDMAC was criticized for not understanding the Internet when it issued the infamous 14 letters citing paid search engine advertising for violating regulations regarding fair balance; ie, presentation of major risks in drug promotion pieces. In fact, the FDA may have understood how marketers pay for search better than some consultants and other digital media experts (see "Missing FDA Letters Found. More Questions"; http://tinyurl.com/n43t6d).

Arnold Friede, currently Counsel to the law firm McDermott Will & Emery LLP, however, is convinced that the FDA does not understand the uniqueness of the Internet and its distinct technical capabilities. He is attempting to correct that by organizing an ad hoc industry coalition to respond to the FDA's 14 enforcement letters (see "The 14 Letters. Who at the FDA Knew What and When?"; http://bit.ly/XTfVy).

Meanwhile, on May 27, 2009, FDA published in the Federal Register draft "Guidance for Industry, Presenting Risk Information in Prescription Drug and Medical Device Promotion." A review of the major "thinking" found in the draft guidance is provided on page 4.

The Draft Guidance is open for comment for 90 days after publication in the Federal Register, which provides an opportunity for the drug industry to develop and then submit a response to the 14 letters citing paid search ads. Such a response could provide alternative "thinking" for regulation of risk disclosures in sponsored links and other internet communications that acknowledges the "uniqueness of the medium and its distinct technical capabilities."

In the absence of such specific guidance from the FDA regarding promotion of drugs via the Internet, pharma marketers must "read the tea leaves" in existing guidance in order to apply FDA's "thinking" to Internet ads such as display ads and paid search engine advertising. This article reviews the draft guidance on presenting risk information with a special focus on how it may apply to the Internet.

Hopefully, this discussion can help pharma marketers raise the issue of FDA regulation of internet ads in comments submitted in response to the draft guidance.

FDA Neglects the Internet in Its Studies

The draft guidance has been criticized by many health communications experts who believe the FDA is basing its recommendations on nothing but its own opinions. "Apparently those who are guiding DDMAC policy are woefully unfamiliar with the Internet and how it is used by patients," said Mark Senak in his Eye On FDA Blog.

Meanwhile, at recent Drug Information Association conferences, representatives from the FDA reviewed its ongoing research programs focused on communicating benefits and risks in print and TV DTC ads including:

- Visual Distraction During Risk in DTC Television Ads
- Presentation of Efficacy Information in DTC Print Ads
- Toll-free Number for Reporting Side Effects in DTC Television Ads
- Impact of Incentives in DTC Print Ads
- Presentation of Quantitative Information in DTC Print and Television Ads
- How to Improve the Presentation of Brief Summary Information in DTC Print Advertisements (see box, pg XX)

None of these, however, involves DTC advertsing via the Internet. This is a very strange omission since the Internet is where patients most often go first to find information on health (see, for example, "The Empowered Patient: What It Means for Pharma Marketers"; PMN Reprint #84-02; http://bit.ly/9brOD). And more often than not, consumers are likely to get misinformation on the Internet, especially from shysters and snake-oil salesmen as well as dubious sources of prescription drugs. FDA-regulated drug information provided by pharmaceutical companies can counterbalance this misinformation.

"Pharmaceutical marketing dollars can provide a useful source of medical information to the consumer," said Steven Niles, MedAdNews, "Excessive constraints around the way the information is presented may protect the FDA from criticism, but isn't necessarily improving consumer decisions about medication."

Lack of FDA guidance for the drug industry regarding the Internet may be one reason why the drug industry spends so little of its marketing budget on Internet promotion compared to other top advertisers in the US (see Figure 1, pg 3).

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Omission of Risk Information
According to the FDA, "omission or minimization of risk information is the most frequent violation of [FDA] regulations cited in advertising and promotion enforcement letters sent to sponsors."

One of the studies of DTC advertising done by the FDA and cited in the draft guidance suggested that 60 percent of patients believe ads directed at them do not provide enough information about risks. Also, 60 percent of physicians believe that patients have little or no understanding from these ads about what the possible risks and negative effects of the products are, while 72 percent of physicians believe that patients have little or no understanding from these ads about who should not use the product.

The FDA issued the draft guidance to "aid sponsors" [ie, drug and device companies] in effectively communicating risk information in their promotion to both healthcare professionals and consumers. The draft guidance describes how FDA reviews prescription drug and medical device promotional pieces to determine whether they adequately present risk information. The guidance addresses promotions aimed at both lay consumer and healthcare professional audiences.

The Reasonable Consumer Standard
FDA says it employs "trained professionals … with expertise in areas including communication, drug information, medicine and law" who evaluate claims in promotional pieces from the perspective of a "reasonable consumer."

The agency believes that the reasonable consumer standard is "the appropriate standard to use" and is similar to the FTC standard:

"[W]e examine the practice from the perspective of a consumer acting reasonably in the circumstances. If the representation or practice affects or is directed primarily to a particular group, the Commission examines reasonableness from the perspective of that group."

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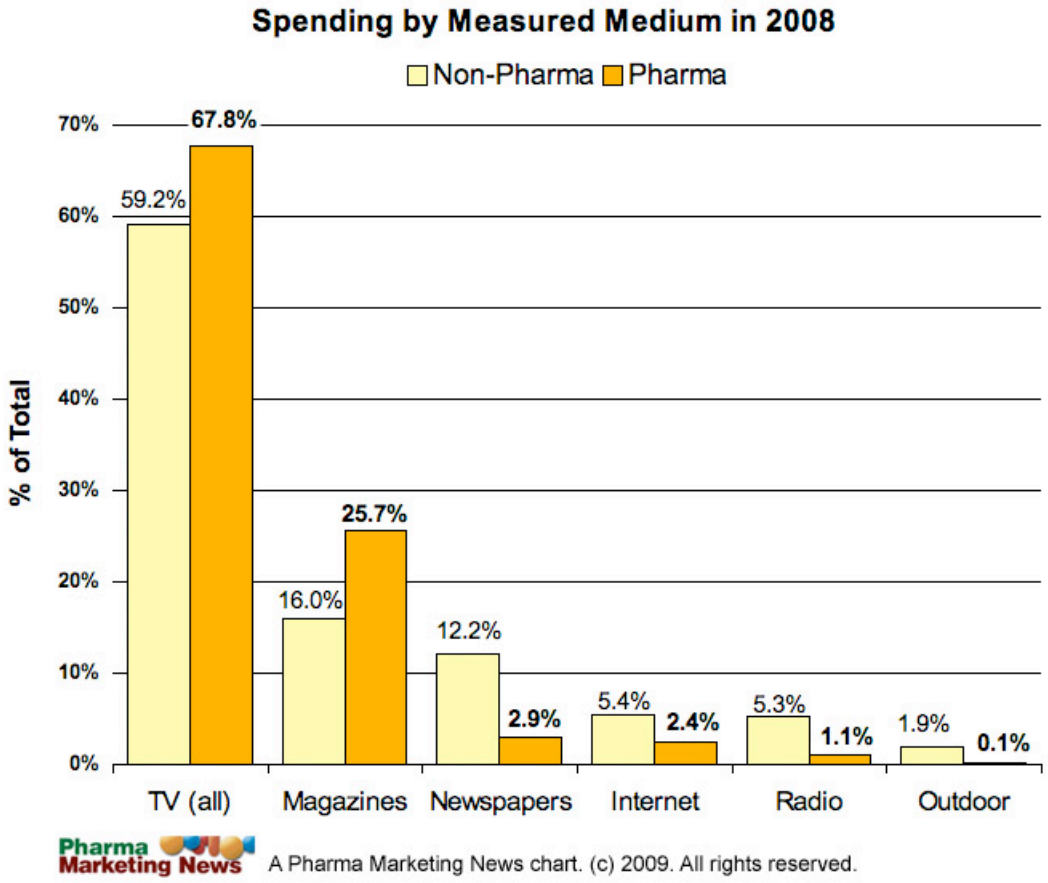

Figure 1: Marketing mix of the 14 pharmaceutical companies in the AdAge's 2009 list of Top 100 National Advertisers (based on 2008 ad spending data). Compares the average of the 14 pharma companies with the average of non-pharma companies on the list (see http://tinyurl.com/kv8qzv).

FDA Draft Guidance on Risk Communication – A Summary

By Ellen Hoenig Carlson

Originally published in Notes from the Back of the Book Blog (http://blog.advancemarketworx.com)

General Considerations:

1. Consistent use of language appropriate for the target audience Ie. If benefit claims are presented in consumer friendly language then risk language should also be in similar consumer friendly language and not medical lingo.
2. Use of Signals (e.g. headlines in a print ad) should be consistent across benefit and risk information; content of signals are important too. FDA is looking for specific and clear signals vs those that are vague or abstract.
3. Framing Risk Information with the same terms or with the same degree of specificity as benefit information.
4. Hierarchy of Risk Information--the most important risk information, including relevant warnings and contraindications, should be placed or stated first...

Considerations of Content

1. Quantity: As the amount of benefit information conveyed increases, the amount of risk information conveyed should similarly increase. The amount of information presented is one component that, together with choice of words, color, graphics, voiceover, and other aspects of the piece, can affect cognitive load, the mental effort required to understand the various components of information in the piece. This suggests comparable treatment of the risk and benefit information in each piece.
2. Materiality and Comprehensiveness: Material facts are those that would influence reasonable consumers (or healthcare professionals) about a product-such as: The relevant properties of a product, appropriateness for themselves or their patients, willingness to accept the risks or burdens associated with using or prescribing a product.

Considerations of Format

To process information, a person must first pay attention to it. As a general matter, risk and benefit information should be comparably noticeable or conspicuous and able to be read with similar ease (e.g., comparably legible and understanding)

Print Promotion--layout and formatting factors:

1. Overall location of risk information should generally appear in the same parts of the piece as the benefits.

2. In addition to appearing with or near benefit information, risk information should appear as an integral part of the piece, just as benefit information does. (This is often called "peppering" by regulatory advisers and largely where J&J's Ultram ER got into trouble and received a recent warning letter for their video)

3. Font size and style that affect the prominence and readability of information

4. Contrast between text and background should not highlight the benefits more than the risks.

5. Use of White Space should be similar for risks vs benefits.

Non-Print Promotion

As with print, FDA considers factors such as location, proximity, type size and style, and contrast when evaluating videos or broadcast ads. But the FDA also evaluates other formatting factors such as audio components, motion within the visual component, the juxtaposition of visual and audio components, and duration of exposure.

1. Textual Elements: FDA provides many recommendations when using SUPERS to insure they are legible, understandable and in close proximity with the claim. In addition, if qualifying information is complex and requires more than one line of text, FDA recommends using other means to convey this information.

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FDA Draft Guidance on Risk Communication – A Summary

(continued from pg 4)

2. In addition to distracting visuals during the audio presentation of risks, the use of even inherently compelling, vivid visuals which may be deemed too inconsistent in tone or imagery that they distract the audience from listening to or processing the risks.

3. Audio Considerations such as speech quality, pacing, volume and background music need to be comparable during both benefit and risk presentations.

The FDA's view of the reasonable consumer takes into account consumers preconceived ideas about the amount of scrutiny drug print and TV ads undergo. "Many [consumers] believe FDA exercises tight regulatory control over the content of these ads and to some extent, believe that all ads have been pre-reviewed prior to airing. As a result, consumers are likely to expect that the most relevant risks have been included in the ad."

Arnold Friede, Counsel to the law firm McDermott Will & Emery LLP, who was a guest on Pharma Marketing Talk (see "Towards a Rational FDA Policy Addressing the Internet and Social Media"; http://bit.ly/X4Be), blasted FDA's right to define "reasonable man" (consumer or physician) without external input.

"It is true that FDA in the Draft Guidance officially adopts the 'reasonable man' standard for interpreting advertising and promotional claims," said Friede in a personal communication. "That is nice and long overdue. And the agency also says that in interpreting advertising it attends to the First Amendment. Likewise nice and long overdue."

"At the same time, of course, FDA continues to aggrandize entirely to itself the right and the ability to decide what the 'reasonable man', whether physician or consumer, understands in the context of any given promotional piece.

"By contrast, the FTC's Deception Policy Statement, from which FDA explicitly borrows the 'reasonable man' standard, acknowledges that except when the claim is explicit on its face, the Commission will usually consider consumer survey evidence in determining what meaning to ascribe to the advertising.

"FDA's apparent unwillingness to consider anything but its own views in determining what the 'reasonable man' thinks suggests that adoption of that standard may amount to nothing more than elevation of form over substance. And it belies the agency's professed attention to the First Amendment."

Friede is in favor of crafting a response to the Draft Guidance that hinges on the concept of "reasonable man" in order to contest the "reasonableness" of claims made in FDA's search ad enforcement letters.

The Case of Adwords

As mentioned above, FDA's risk communication draft guidance focuses almost exclusively on print and broadcast promotional ads. As far as the FDA is concerned, "[u]nless otherwise specified in this draft guidance, the principles set forth below apply to all promotional pieces, regardless of the medium used, or the target audience."

The draft guidance mentions the Internet only once by way of example, as in:

"Example 13: If a Web site for a product approved to treat high blood pressure presents information about a product's benefits in postmenopausal women, any risks specific to postmenopausal women are particularly material."

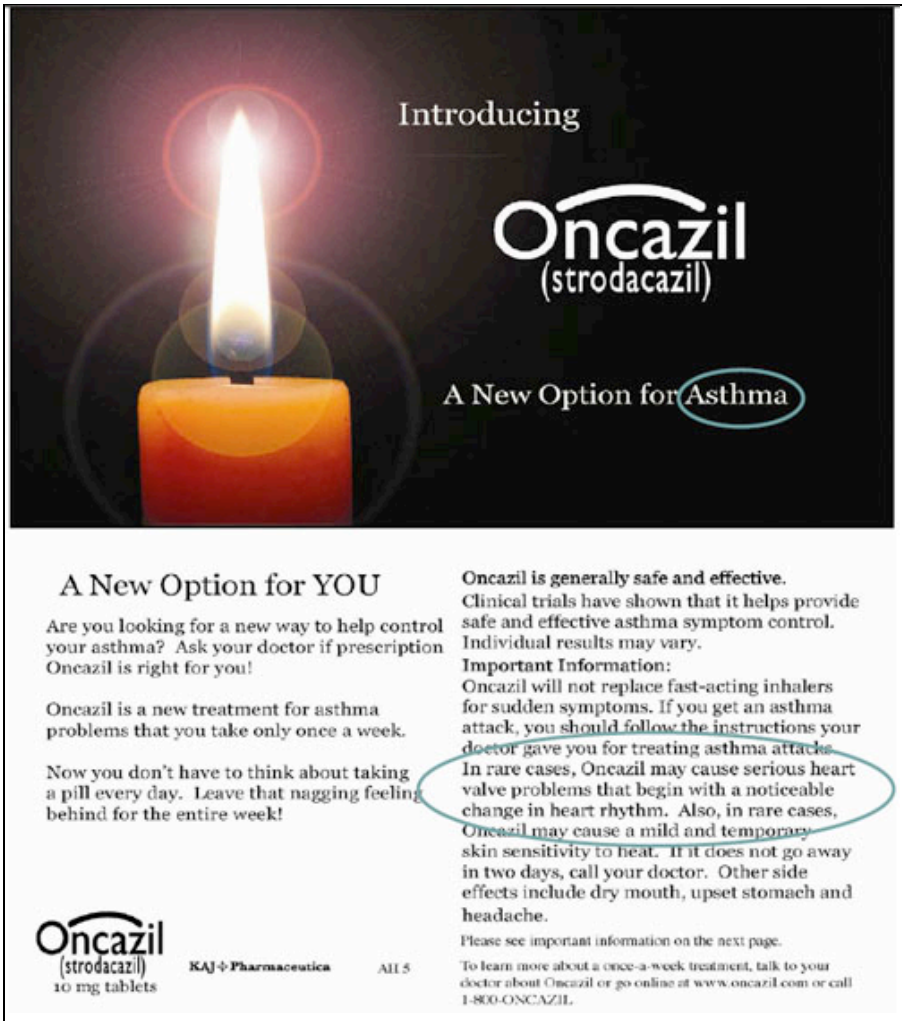
To illustrate how non-specific this is with regard to the Internet, all you have to do is substitute "Print ad" for "Web site." Perhaps this is FDA's way of saying that the same rules apply to the Internet as to print ads. This is true only in so far as a Web page or display ad on the Internet is just another static piece of text/graphic.

"FDA is applying the same rules to all promotional communications regardless of the medium," says Friede. "This is a serious problem in the context, particularly, of new media, which has different technological capabilities and limitations."

FDA's thinking has not kept pace with the Internet, which has evolved to be much more interactive and user-generated. It seems that we'll have to wait for Obama-era appointees to work their way down the hierarchy at FDA before we see the FDA evolve more quickly. For now, this draft guidance, which was in the works for at least a year, will have to do.

Friede argues that when the "reasonable consumer standard" is properly applied in the case of Adwords, the result is that "people understand that if they have an interest in learning the information, they simply click on the link [in the Adword]. There's a more than

Continues, pg 7...



FDA Study: How to Improve the Presentation of Brief Summary Information in DTC Print Advertisements

(See http://bit.ly/o3Xxk and Federal Register, DOCID:fr25ap06-80] for study details.)

In this content study, FDA investigated the role of context in providing useful risk information to consumers. It has been theorized that long lists of minor risks may detract from the understanding of more serious risks. Nonetheless, if the risk information is presented with proper supporting context, people may find the information facilitates rather than distracts from the understanding of the risk information.

The purpose of study was to answer the following questions:

- How do people use the brief summary in its current form?
- Does risk information on the promotion page affect use of brief summary?

The study involved recruiting 1,800 people at shopping malls. Participants examined different mock ads for a fictitious product called Oncazil. In one ad, Oncazil is presented as a treatment for asthma, in another it was a treatment for high cholesterol, and in the third it treated excess weight. In some ads, both the full page and brief summary warned of a serious side effect. "In rare cases, Oncazil may cause serious heart valve problems that begin with a noticeable change in heart rhythm," the copy read. Others contained no such warning.

Specific Questions

- Does risk info or medical condition affect:
  - time spent reading the ad
  - comprehension
  - selection of topics
  - intent to ask doctor for info
- What brief summary topics are most useful?

Preliminary Conclusions

- **Adding a serious risk did not impede searching for further information (did not decrease time, comprehension, number of topics selected, or intent to ask doctor)**
- **In general, results were consistent across medical conditions**

A credible case to make that the linked information—the information on the landing page—should be considered a component of the advertising and not distinct from it," said Friede in a recent Pharma Marketing Talk podcast interview (http://bit.ly/X4Be).

This is akin, says Friede, to print ads where the complete prescribing information appears on the back side of the ad.

The FDA, however, seems focused on the main part of the advertising piece and NOT what's on the back of a print ad and, by extension, not what's on the landing page of a Web ad.

"For a piece to be accurate and non-misleading," FDA says, "risk information should be included in the *main part* [my emphasis] of a piece. If the omission of risk information in any part of a piece makes that part of the piece false or misleading, the problem cannot be corrected simply by including the risk information in a separate part of the piece. To be comparably prominent to benefit information, risk information should generally appear in the same parts of the piece as the benefits."

FDA says that the risk generally information should be included on the promotional page and presented in a manner comparable with the benefit information. If you consider an Adword to be similar to a print ad in a magazine, then you might interpret the FDA guidance to mean that Adwords must also contain risk information that is comparable to the benefit information in the Adword.

Now, you may not like that the FDA views an Adword as the "main piece" of a promotion, but there it is. Arguments about "reasonable man standard" are not likely to change DDMAC's mind on this.

The draft guidance also states:

"Complete separation of benefit and risk information (e.g., presenting several pages of benefits before any risks) is one example of a lack of appropriate prominence."

and

"As a general matter, risk and benefit information should be comparably noticeable or conspicuous in promotional pieces, and audiences should be able to read both risk and benefit information with similar ease [my emphasis]."

Although FDA is talking about print ads here, it is easy to read the tea leaves and extend the thinking to Internet display ads and paid search engine ads.

No matter how you define a "reasonable man," having to click a link in an Adword to get fair balance is not as easy as reading the benefits right there in front of you. Be honest, how often do you just read the first part of a news story in a newspaper without bothering to flip through to the page where it is continued (the so-called "jump" page)?

Perhaps 95% of people (ie, "reasonable consumers") who view Adwords do NOT click on them (if you have some secret sauce for increasing the click-through rates on Adwords, please let me know). Nevertheless, the ad has some value—building brand awareness as marketers say.

Internet Studies Needed

Interpreting what the FDA thinks about Internet ads based on its guidance for print and TV ads has its limits.

Of course, both Friede and I our basing what our "reasonable" consumer is apt to do or not to do online on our own pre-conceived notions rather than any scientific data, of which the FDA is so fond. Which brings us to this final thought: Perhaps the FDA should undertake a few studies focused on communicating benefits and risks in online DTC ads in addition to the studies it is doing for print and TV ads. That at least will give it some "creds" the next time it issues "notice of violation" letters regarding drug promotion on the Internet.

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