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FDA Draft Guidance for Print DTCA: Less than Feared

By **John Mack**

On February 4, 2004, the FDA issued long-awaited draft guidance documents designed to improve communications to consumers and health care practitioners about health conditions and medical products. "Our new regulatory guidance," said FDA Commissioner, Mark B. McClellan, M.D., Ph.D., "provides new direction to sponsors on how to provide higher-quality health information to the public, based on recent evidence on what works and what doesn't in drug promotion."

"The number of patients who talked to their doctors about an advertised medicine has gone from 31% in 1997 to only 32% in 2001"
---Prevention Magazine

The three guidances issued were:

- Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements
- Help-Seeking' and Other Disease Awareness Communications by or on behalf of Drug and Device Firms
- Consumer-Directed Broadcast Advertising of Restricted Devices

Missing was any guidance relating to communicating risk and benefits in drug broadcast ads. This surprised some experts given all the recent negative comments about broadcast DTC ads (see article "Super Bowl DTC Debut: Was It Good for You?" in this issue).

Brief Summary: Guidance for Print Ads

The FDA sees an educational potential in DTCA and its guidance reflects this. As stated in the guidance, "the agency believes consumer-directed pro-motion of prescription drugs can convey useful health information to patients."

According to Jack E. Angel, Executive Director of the Coalition for Healthcare Communication (CHCC; see box on Pg. 11), "the primary goal of direct to consumer advertising (DCTA) is and should be to convince a consumer to discuss a medical condition with his or her doctor. To ask advertising to educate is to ask it something it is not capable of doing."

According to a Time, Inc. 2003 study, consumers rank advertising sources of information about conditions and treatments relatively low, preferring their doctors, health Internet sites, or friends and relatives (see FIGURE on Pg. 12). Advertising plays an important role, however, in the initial stages of the information process.

Less is More

CHCC contends that DTC ads are not intended to provide highly detailed information to a consumer about all of a drug product's benefits and risks. The effectiveness of all DTC advertising, both broadcast and print, can be severely undermined by requiring too much detailed information in the ads, which may actually lead consumers to "tune out" of the entire message. On this point, the FDA seems to agree.

The draft guidance "Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements" encourages manufacturers to use clearer, less cluttered formats for presenting risk information and encourages them to focus their risk disclosures on the most important and the most common risks and to do so in language easily understood by the average consumer. "FDA believes that exhaustive lists of minor risks detract from and make it difficult to comprehend and retain information on the more important risks."

In print ads, pharmaceutical companies have traditionally satisfied the brief summary re-

quirement by including the entire professional package insert on a separate page.

Prevention & *Men's Health Magazine*'s 1999 DTC Study revealed that among consumers who recall DTC ads in print, almost half (46%) don't recall the brief summary at all and of those that do, only 12% read it thoroughly.

In place of the requirement for a "brief summary," the new guidance allows the following options for providing risk information in ads:

1. **FDA-Approved Patient Labeling** – This is sometimes called a patient package insert (PPI), which is specifically designed to be consumer friendly. Some companies—e.g., Merck—already use PPIs in their print DTC ads. Generally, FDA-approved patient labeling does not address each specific risk included in the professional labeling. FDA states "We believe that omitting less serious, infrequent risks from patient labeling may actually increase the usefulness of this labeling for its audiences by making the more important risks stand out more clearly."
2. **Highlights** – A proposed new section of the professional labeling, Highlights have been under consideration by the FDA since 2000. "Ideally," says FDA, "the Highlights would be translated from language appropriate for a professional audience into language easily understood by the average consumer."

The draft guidance also allows advertisements to present key risk information in the main body of the advertisement if the data is put in bullet-point format within a "risk information window," rather than in the text.

Whichever option is used, the following risk information must be included:

- All contraindications;
- All warnings;
- Major precautions, including any that describe serious adverse drug experiences or steps to be taken to avoid such experiences; and
- The 3-5 most common non-serious adverse reactions most likely to affect the patient's quality of life or compliance with drug therapy.

How to Communicate Risk

The FDA acknowledges that it has not performed any consumer comprehension of risk studies and that there is much to learn before it develops a final risk communication guidance.

"Communication of risk information is very complicated," says Harry Sweeney, CEO of Dorland Global Health Communications, "and in the case of prescription drugs it's confounded by the amount of mandatory information required by existing law and regulations, a problem that may require a legislative or regulatory fix."

Reminder Ads and Help-seeking Ads: Keep Them Well Apart and Dissimilar!

FDA also issued a draft guidance for "Help-seeking" ads. These ads are communications disseminated to consumers or health care practitioners that discuss a particular disease or health condition, but do not mention any specific drug or device or make any representation or suggestion concerning a particular drug or device.

These communications are not subject to the disclosure requirements of the Federal Food, Drug, and Cosmetics Act and FDA regulations. So why the guidance?

The guidance is aimed at circumstances in which help-seeking ads are combined with "Reminder Ads." A reminder ad mentions the brand name but no indication. An example would be those Viagra ads where everyone notices something different about a happy guy after visiting the doctor, but can't quite pin down what it is ("You got a raise?"). These ads also do not require any disclosure information.

In particular, the FDA is concerned about "book ending" help-seeking and reminder ads; i.e., when a help-seeking ad is presented in combination with a reminder ad. Some drug firms have broadcast such ads, which are perceptually similar to one another, separated only by a brief period containing unrelated matter. FDA says it will treat such combinations as labeling or advertising.

Also of concern is the mis-use of celebrities in ads. Would using Bob Dole—who is strongly identified with Viagra—in a help-seeking ad convert the ad into a "product" ad that would require the disclosure information?

The agency is encouraging the development of new approaches to presenting risk information and FDA staffers took the opportunity at *Parade Magazine*'s Direct-to-Consumer Advertising Draft Guidance Symposium 2004 held in in New York on February 10, 2004, to underscore its desire for ideas and research data on risk communication from the regulated industries and the advertising community.

Continues on next page… ☞

As Sweeney quipped: “Solving the problem of how to effectively communicate prescription drug risk information may become the Full Employment Act for social science researchers everywhere.”

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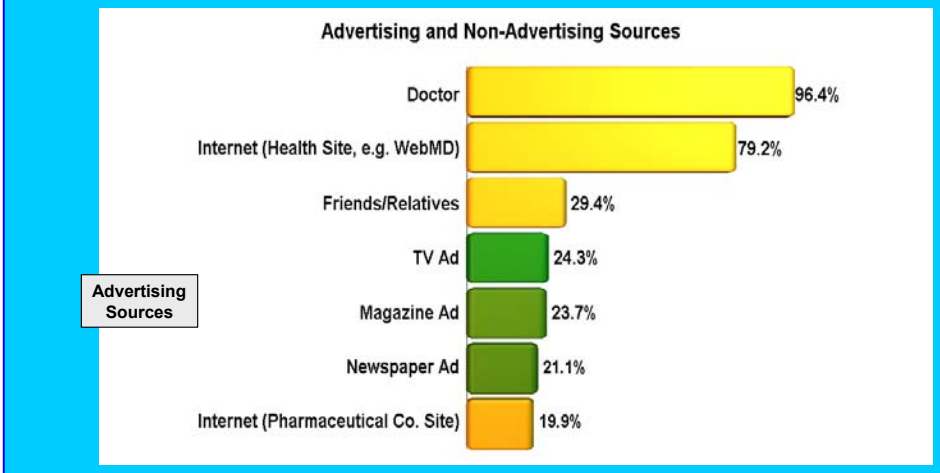
Sources of Information for Conditions/ Treatments — Net All Stages



Note: Summary of major sources
Source: CNW Marketing Research, Inc.

Coalition for Healthcare Communication

The Coalition for Healthcare Communication (www.cohealthcom.org) is a non-profit organization representing eleven major organizations engaged in medical communications including advertising, publishing, continuing medical education, and the dissemination of information on healthcare products and services.

The members are: American Association of Advertising Agencies , American Advertising Federation, American Business Media, American Medical Publishers Association, Association of Medical Publications, Association of National Advertisers, Healthcare Businesswomen’s Association, Healthcare Marketing and Communications Council, Medical Marketing Association, Midwest Healthcare Marketing Association, Public Relations Society of America.

Resource List

The following resources were consulted in the preparation of this article or cited within this article.

- "New FDA Draft Guidances Aim to Improve Health Information"; FDA Press Release, February 4, 2004. http://www.fda.gov/bbs/topics/NEWS/2004/NEW01016.html (accessed 4 Feb 2004). This document contains links to the following guidance documents: "Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements," " 'Help-Seeking' and Other Disease Awareness Communications by or on behalf of Drug and Device Firms," and "Consumer-Directed Broadcast Advertising of Restricted Devices."
- Edwin Slaughter, "Consumer Reaction to DTC Advertising of Prescription Medicines 1997-2002: A Six-Year Tracking Study From Prevention and Men's Health Magazines", Rodale, Inc. Presentation made at FDA Direct-To-Consumer Promotion Public Meeting on September 22 and 23, 2003. http://www.fda.gov/cder/ddmac/P1Slaughter/tsld001.htm (accessed 5 Feb 2004).

Experts Consulted and/or Cited In Articles

The following experts were mentioned or consulted in the preparation of this article.

- **Jack E. Angel**, Executive Director, Coalition for Healthcare Communication, 203-661-3314, jeangel44@aol.com
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