

OPINIONS

The New DTC Guidelines

In January, for the first time since 1998, the FDA announced changes to the regulations that govern the content and format of the product disclaimer or brief summary that must accompany print advertising of DTC products. The FDA revealed three new draft guidelines for the \$2.6 billion DTC industry, which would have pharma companies revamp and reduce the brief summaries in print ads and encourage more disease awareness spots on TV.

PharmaVOICE asked what your suggestions would be to the FDA on how these guidances can advance public health and at the same time observe smart business tactics.



Less is not more

I think less is more but I don't know if industry, from a liability perspective, can pick and choose unless there is clear guidance from the FDA about what is "most important" in terms of risks.

Robin Shapiro
PRESIDENT
HEALTH ADVOCACY STRATEGIES, LLC

Less is still not more

While as a copywriter I'm all for less copy, in printed materials, boxing or bulleting fair balance will eat up more space than is currently being done. As far as language, consumers need to be more informed about their medication, not fed some third-grade pabulum that will likely undersell the risks inherent in taking a specific medication. As a consumer, and not a copywriter, I am extremely suspicious of efforts to say less about a drug. The pharmaceutical lobby in Washington, D.C., is powerful enough, and I suspect they are behind this proposal to some degree.

Rob McMichael
ASSOCIATE CREATIVE DIRECTOR, COPY
STRATEGIC MEDICAL COMMUNICATIONS,
A DIVISION OF HEALTHSTAR ADVERTISING INC.

E-mail and Web are more cost-effective

The FDA recommendations for more visually clear bullet formats and breakout boxes would certainly improve consumer awareness of risks, but the FDA's call for "unbranded" messages — help-seeking or disease-awareness ads on "mass media" (TV/radio) — would be extremely challenging because of time constraints and targetability. Other mediums, such as opt-in e-mail marketing and Web portals provide more cost-effective "venues" for achieving this "fair content balance" and can be used to more effectively target those consumers who are potential candi-

dates or compliant-challenged users of their products.

In order for a 30-second or 60-second television or radio spot to be effective, it must drive home brand-name recognition and effective call-to-action messaging that supports actionable decision-making. A 30- or 60-second spot is simply not enough time to focus the consumer on a fair balance of help-seeking and branded messaging, whereas e-mail messaging and Web portals are not necessarily "time-dependent" venues and have relatively limitless abilities for building relationships with consumers through a fair balance of help-seeking and branded messaging.

Andy Weissberg
EXECUTIVE VP
CPRi COMMUNICATIONS

FDA efforts can help legitimize DTC

Nonbranded, disease-state awareness advertising is an excellent method of increasing the quality of care in the United States while providing the pharmaceutical industry with an effective platform to build on a consumer's need for effective products. The FDA's interest in revamping brief summaries has the potential to truly legitimize DTC advertising in the eyes of consumers, healthcare professionals, and regulatory bodies. Current brief summaries, whether consumer- or professional-directed, serve very little purpose because the data are "cherry-picked" and focusing only on side-effects and contraindications and the language is complicated and lengthy. Revamped summaries with simple, consumer-friendly bullet points that include not only adverse side-effects and contraindications, but clinical indications in clear consumer terms would be a win-win for consumers, regulators, and the pharmaceutical industry. This type of revamped brief summary would allow consumers to make truly informed decisions with regard to their healthcare. It is imperative that pharmaceutical marketers work with the FDA to devise a new

format for brief summaries that is of benefit to all stakeholders.

Andy Galler
CHIEF SCIENTIFIC OFFICER
ALPHAMEDICA INC.

FDA needs to be realistic

For the first time, the FDA is approaching the issue from a cooperative rather than industry-combative perspective, which is a huge leap over its past attempts to regulate DTC communications. While there is clearly a commercial incentive for the industry, there also is a favorable public-health benefit to educating consumers/patients. The medical knowledge and desired involvement in their own healthcare between today's patient generation and that of our parents' generation is enormous.

While patients are more educated, my first suggestion would be for the FDA to be realistic in the level of understanding that the average consumer possesses. Clearly medically complex terminology is not in the realm of the average consumer/patient. The ideas that have been thus proposed to unclutter and to simplify the language to be more consumer-friendly is a good place to start.

The second suggestion is to place trust in the system of the licensed healthcare practitioner (M.D., NP, PA, etc.) acting as the learned intermediary that already exists as a safety valve. The system requiring an Rx for access to prescription medications is for the most part a sound and effective way to ensure that patients receive the appropriate therapeutic options (or not) for any conditions from which they may (or may not) be suffering. Having an educated patient going into a consultation with a healthcare practitioner, even if that requires steering the patients in a different direction, is better than patients who cannot understand their situation. An appropriately informed patient is more likely to be a compliant patient, therefore leading to better patient outcomes.

My third suggestion, especially given the impending departure of Dr. McClellan, is for the

new FDA leadership to not lose the unprecedented positive dialog established between the agency and industry attributable to Dr. McClellan's tenure. When respective forces work coop-

eratively, greater things can be achieved than those same forces working in opposition. If the agency and industry cooperate, patients will undoubtedly benefit.

Mark S. Perlotto
EXECUTIVE VP, GENERAL MANAGER
ADAIR-GREENE
HEALTHCARE COMMUNICATIONS

More portable technology

My cellphone is my lifeline

Not long ago, traveling outside the office meant dragging along multiple pieces of equipment, from a cellphone to a laptop to a PDA. Each had its specific use, and at the time, my Mac platform was not in sync with all of the capabilities of my PDA.

My cellphone is still my lifeline, although its expanded use as a recording device allows me to store creative ideas that come to me, whether watching my son's soccer game or on the way to a client meeting. And my laptop, of course, is essential for presentations and for working on the go, although the Blackberry may soon replace the communication capabilities of the laptop when I'm out of the office and traveling.

It's the iPod, however, that has changed the world for me. I use it for almost everything. Its powerful hard drive is great for far more than simply listening to and downloading music. It

also gives me the ability to transfer files between locations and among colleagues, so I can load and transport large graphic files while I am at a photo studio, for example, without having to wait and burn a CD. The iPod's calendar, when synced with my laptop, lets me categorize activities, so I can see personal vs. business events at a glance. Finally, it has complete address book capabilities, so I'm never at a loss for contacts.

Jeff Lipman
EXECUTIVE VP, CREATIVE DIRECTOR
INTEGRITY HEALTHCARE COMMUNICATIONS

WiFi aids communication

As head of a young, fast-growing healthcare agency, I need to be able to communicate with our clients — and with our staff — 24 hours a day. For me, wireless access has been a real boon.

Wireless access — a low-cost technology that

allows every computer and portable device to be connected to the Internet at all times, without a wire, at minimal cost — lets me get on the Internet almost anywhere I go. I can search and research information, access and send e-mail, plan out strategies, and look at creative anywhere.

Even inside our offices, we use WiFi to communicate not only quickly and easily but also cost effectively, since we don't have the expense of a wired office. Brainstorming sessions, for example, can happen anywhere, we all bring our laptops and we're ready to roll.

At Concentric, we embrace state-of-the-art technology to help us do a better job of servicing our clients and staying in contact while keeping costs down.

Ken Begasse Jr.
PARTNER AND DIRECTOR OF CLIENT SERVICES
CONCENTRIC HEALTHCARE ADVERTISING