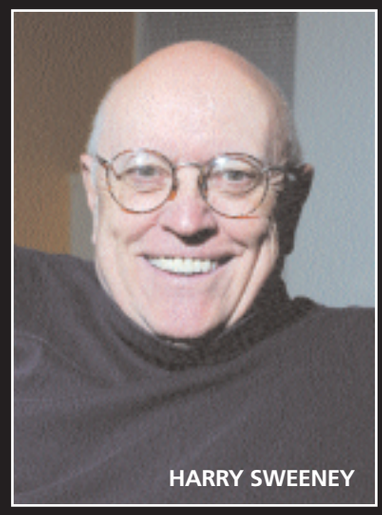
Contributed by Harry Sweeney

Back to the Future 2004


HARRY SWEENEY

Credit the Food and Drug Administration with showing up in force and spelling out its intentions clearly at Parade Magazine's Direct-to-Consumer Advertising Draft Guidance Symposium in New York City in one of the most collegial sessions I've attended in years. At the February event, Peter Pitts, FDA associate director for external affairs, set the tone for the meeting when he said the agency was expanding its charter from simply protecting consumers from potential harm to advancing America's health, an evolutionary return to the agency's origins nearly a century ago. The agency's leading social scientist, Katherine Aiken, reviewed results of the two DTC surveys conducted by the FDA with doctors and consumers as background for discussion of the three new draft guidances by Director of the Office of Medical Policy, Robert Temple, M.D., and DDMAC head, Thomas Abrams.

LESS IS MORE

The central theme of the discussions was agency recognition that "less is more," reflecting research, experience, and previously submitted comments from groups such as the Coalition for Healthcare Communications to the effect that "compliance" (with regulatory mandates) and effective "communication" are not necessarily the same thing. At various times during the symposium, FDA staffers requested that nonproprietary research be shared with the agency and reminded attendees that the newly released documents were draft guidances, inviting the formal submission of ideas and comments.

According to a FDA release, the draft guidances provide (1) alternatives to the lengthy, detailed, and technically written "brief summary" of risk information for consumer-directed print advertisements for prescription drugs, with the goal of increasing consumer understanding of the key risks of the product; (2) advice for manufacturers on the use of disease-awareness communications, which are designed to educate patients or healthcare practitioners about particular diseases or health conditions and do not promote a particular medical product, with the goal of getting more patients to discuss undertreated conditions with their doctor; and (3) advice for manufacturers on compliance with federal risk disclosure rules for consumer-directed broadcast advertising for so-called "restricted" medical devices, with the goal of assuring that consumers are getting accurate information through device advertisements. (For more information on the draft guidances, visit fda.gov/cder/guidance/5669dft.pdf; fda.gov/cder/guidance/6019dft.pdf; and fda.gov/cdrh/comp/guidance/1513.html.)

THE CREATIVE ANGLE

After the FDA presentations, creative directors from McCann HumanCare and WPP/CommonHealth's Quantum Group served up a series of "How we might fix this thing" ideas for incorporating all of the mandatory balancing and risk data into a print ad, so that the intended audience actually might get something out of it, and the ad would not run afoul of FDA requirements. While none of the worthy efforts was an out-of-the-park home run, there were quite a few singles, a couple of doubles, and a triple that seemed to sail over the head of the FDA panel.

Creating fictional drug brand names, generic names, and brief summaries let the creatives loose to experiment with a variety of layout tactics — color, subheadlines, etc. — and copy editing to make information more readable. The FDA panel reacted warily, but with obvious interest in some of the proposed solutions. One person in the audience suggested that potentially one of the biggest obstacles to such initiatives may be pharmaceutical company lawyers concerned about liability. Keep tuned on this issue.

The idea that at least one observer thought was a triple was the creation of a single, national prescription drug Website. Links would lead to consumer-friendly, prescription drug information on specific medications (branded and generic) available on a manufacturer's Website, or a computer-assisted phone-message system with a default to a live, telephone counselor. The FDA panelists didn't seem to understand the scope of what the creative directors were recommending, but the agency executives' effort certainly showed some out-of-the-box thinking.

One of the more provocative issues was a "gaming the system" example of running a reminder ad in close proximity (time or space) to a help-seeking ad. The FDA panelists were troubled by this ploy, suggesting that, in effect, such media placement amounts to the constructive creation of a branded ad that would require a brief summary.

Someone in the audience then asked how the panelists might view the use of a prominent celebrity identified with a Rx DTC product commercial in a help-seeking ad using the same graphics, colors, etc., as the brand product ad. The panelists looked bemused. It seemed obvious to me that the only reasonable conclusion would be that it was a clever (but misguided) attempt to leverage the celebrity's identification with the previously advertised drug as a trigger to slip a brand-name reminder into an otherwise immunized help-seeking ad. Mr. Pitts seemed to agree when he suggested that people should spend less time trying to see how close to the line they can get without crossing it and more time trying to effectively communicate health information.

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