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OPDP Research May Lead to Changes in DTC Ad Regulation

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It’s now been more than 20 years since the FDA issued a draft guidance that provided a framework for direct-to-consumer (DTC) TV advertising. Remarkably, the framework that was established by that draft guidance in 1997, and that was finalized in a 1999 guidance, serves as the framework for DTC advertising today — despite significant changes to the health care system, to the role of patients/consumers in navigating their own health care treatments and options, and in communications more generally.

DTC ads still provide for four ways to obtain further information:

a toll-free telephone number;
referral to a print advertisement in a concurrently running print publication, or provision of enough brochures, with required product information, in various convenient outlets;
referral to a health care provider (a physician, pharmacist or veterinarian); and
an Internet Web page address.

And risk information still is provided during the ad as it was when product-specific DTC TV advertising started in 1997.

The industry is now watching the FDA to see whether changes are coming in how DTC TV ads are constructed and in how risk information is communicated. The reason for the focus has nothing to do with a new presidential administration or a (relatively) new commissioner. Rather, it has to do with the research that the FDA has been sponsoring — in some cases for several years — about how consumers receive information and about the most effective ways to communicate risks.

At all major ad promo conferences these days, presentations by the research team in the Office of Prescription Drug Promotion (OPDP) have been among the best received. The reason is that the research at some point will be used to seek to redefine how DTC TV ads should be constructed, particularly regarding communicating risks.

For example, at the recent DIA ad promo meeting in Washington, D.C., Kathryn J. Aikin, the senior social science analyst in OPDP who serves as the research team lead, announced that there would be two studies that will examine the impact of "perceptual similarity between target ads (disease awareness and product promotion) and the distance between target ads over the course of programming."

It's not clear that these two studies will change FDA policy, but combined with earlier studies that examined how risk is communicated and what consumers take away from advertising, the handwriting is on the wall: someday the information derived from the studies will be used to change the FDA's rules on DTC TV advertising.

Given the large amount of research on DTC TV ads and on risk communications, which is already concluded, what's holding up the changes? For one, there needs to be a consensus within the FDA, in the four medical centers (drugs, biologics, devices and veterinary medicine), that change is needed and appropriate. And for a fundamental change to how DTC TV ads are constructed to occur, there would need to be agreement from the Office of the Commissioner. In addition, given the impact that any changes would have on the medical products industries, plus the advertising community, a public process would probably be instituted to hear comments from the various stakeholders.

There is no hard evidence that the FDA intends to begin the process of changing its DTC TV ad guidances, and there are issues involving ad promo policies that are more pressing. However, it is, in my view, virtually inevitable that changes will occur in how DTC TV ads are constructed. The only questions are how long it will take to get there, and what changes will be made.

This is why it's important for those involved with the promotion of medical products, and especially with how they are promoted directly to consumers, to pay attention to the research that the FDA — specifically the unit within OPDP headed by Dr. Aiken — has been conducting. From this research will emerge the direction and the justification for how DTC TV ads will be constructed in the future.

Editor's Note: Wayne L. Pines is the editor-in-chief of Thompson Information Services' FDA Advertising and Promotion Manual. He is president of healthcare at APCO Worldwide and a former FDA associate commissioner.

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