Drug Ads on TV and Radio May Need to Be More Explicit About Risks to Consumers

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The lobbying group, Pharmaceutical and Research Manufacturers of America (PhRMA), has questioned the accuracy of that study and, consequently, the implication that current TV and radio ads are underplaying product risks.

The FDA considers four tests to determine whether a major statement is presented clearly and conspicuously and in a neutral manner:

- Is the information presented in language that is easily understood by consumers?
- Is audio information understandable in terms of the volume, articulation, and pacing used?
- Is the textual information placed appropriately and presented against a contrasting background for a sufficient period of time and in a size and style of font that allows the information to be read easily?
- Does the ad include distracting statements, text, images, or sounds (or a combination thereof) that could detract from the communication of the major statement?

Pharmaceutical companies, pharmacy groups, and consumer advocates are besieging the FDA from all sides as the agency decides how to implement a three-year-old congressional dictate that requires drug companies to upgrade explanations of medication risks in television and radio advertisements.

Current FDA advertising rules already require companies to give equal weight to assertions of effectiveness and disclosures of risk in those ads. Disclosures of risk mention contraindications and potential side effects in the “major statement.” The FDA implementation of the new law raises the specter of wholesale changes to the current generation of pharmaceutical ads on television and radio.

An FDA study of a random sample of drug ads appearing on TV and radio in 2008, a year after the FDAAA was passed, concluded that fully one-third of major statements were not presented in a “clear, conspicuous, and neutral manner.”

The FDA of 2007 forces companies to be more explicit about the risks by mandating that the major statement be produced in a “clear, conspicuous, and neutral manner.”

The FDA is considering going further; unlike the matter of the terms “clear” and “conspicuous,” there is no regulatory history around the phrase “in a neutral manner.” The FDA takes on that definition as a component of criterion No. 4 within the concept of “distraction.” The intent is that the major statement not be obscured by other elements in the ad occurring at the same time that the major statement is presented.

Although PhRMA is protesting very little over the specifics in the proposed rule, individual companies oppose some aspects of the four tests. Michele Sharp, PharmD, Senior Director of Global Regulatory Affairs for Lilly, says that the requirement in criterion number one for quantitative descriptors such as “more than half” might lessen the consumer’s comprehension of risk, particularly in populations with lower health literacy or in numeracy-challenged groups of people. She adds that this could also be true in communicating information about a product’s benefits.

She explains: “Rather than a general requirement to use more quantitative descriptors, Lilly would support a more case-specific approach that is applied on an ad-by-ad basis and that could be objectively tested with the target audience to assess whether the risk information is comprehended and understood.”

Lilly and other companies would do that testing, of course. Some pharmacy groups favor pre-approval of major statements too—but by the FDA, not the drug company. However, Justine Coffey, JD, LLM, Director of Federal Regulatory Affairs at the American Society of Health-System Pharmacists (ASHP), says that the FDA should do the pre-approval of the most common risk statements.

She states: “In addition to wording, the other elements (e.g., font size, color, placement) should be pilot-tested with consumers. [The] FDA should conduct research to provide an evidence-based assessment of the standards to ensure they result in consumer-directed ads that effectively communicate necessary risk information in a clear, conspicuous, and neutral way.”

Unlike the matter of the terms “clear” and “conspicuous,” there is no regulatory history around the phrase “in a neutral manner.” The FDA takes on that definition as a component of criterion No. 4 within the concept of “distraction.” The intent is that the major statement not be obscured by other elements in the ad occurring at the same time that the major statement is presented. Thus, graphics, music, and other elements cannot be used to distract viewers or listeners, particularly if those other elements are being used simultaneously to present information on the benefits of a drug, thereby drowning out or minimizing the risks.

The FDA is considering going further; it may take a “dual-modality” approach by requiring the major statement to be provided both in audio and video. For example, there might be type running continued on page 529
across the screen as an actor reads the major statement. Pharmaceutical companies are none too excited about that prospect. Sandra Kerr, RPh, Senior Director at Merck’s Office of Medical/Legal, says that studies conducted by her company show that a dual-modality approach does not improve the public’s recall or understanding of important risk information in direct-to-consumer ads. The ASHP, however, supports a dual-modality standard because of the different learning styles in the adult population.

It’s not clear when the FDA will issue a final rule. Whenever it does, rest assured, given the dueling comments, someone (and maybe everyone) will feel that his or her ox has been gored.