October 19, 2012

In The FDA Crosshairs: Composite Scores In Drug Ads

Law360, New York (October 19, 2012, 12:30 PM ET) -- On Aug. 23, 2012, the U.S. Food and Drug Administrationpublished a notice announcing proposed research titled "Communicating Composite Scores in Direct-to-Consumer (DTC) Advertising," designed to study and collect information regarding how consumers understand and interpret composite endpoint scores in DTC advertising.

By way of background, the efficacy of a pharmaceutical company's drug is often measured by multiple endpoints, that is, multiple individual symptoms, which may be combined to form an overall score also known as a "composite score." A pharmaceutical company may market a drug for the relief of a particular symptom when the drug has a significantly better composite score than the placebo.

According to the FDA, however, a better composite score for a particular symptom does not necessarily translate into a better endpoint score for that particular symptom. In addition, unlike scientists and medical professionals, the public may not understand composite scores.

Finally, the FDA advised of its belief that most DTC drug advertisements do not explain that the pharmaceutical company used composite scores to demonstrate efficacy. For example, a September 2011 focus group study cited by the FDA showed that few participants were aware of composite scores or were able to interpret efficacy information without difficulty.

Given that backdrop, the FDA now wants to evaluate how consumers interpret DTC prescription drug advertisements including benefit information based on composite scores and how those scores may best be communicated to laypeople.

Specifically, the FDA's research will explore: whether consumers are aware of how efficacy is measured for specific drugs; how well consumers comprehend the concept of composite scores; whether exposure to DTC advertisements with composite endpoint benefit information influences consumers' perceptions of a drug's efficacy and risk; and whether certain methods of presenting composite endpoint benefit information in DTC advertisements will improve consumer comprehension and informed decision making.

The FDA will undertake two studies as part of its research. The first study will use a web-based survey to explore consumers' awareness of how efficacy is measured and their understanding of composite scores in a drug advertisement.

The second will use a web-based panel in a randomized, controlled study to examine whether DTC advertisements (in this case, a nasal allergy drug) with composite endpoint information influences consumers' perceptions of a drug's efficacy and risk and how DTC advertisements can best communicate composite endpoint benefit information to maximize consumer comprehension and decision making.

The FDA is conducting the research pursuant to the authority set forth in section 1701(a)(4) of the Public Health Service Act, 42 U.S.C. § 300u(a)(4), and section 903(b)(2)(c) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 393(b)(2)(c).

The FDA is required to allow 60 days for public comment in response to the notice. Accordingly, the notice requests written or electronic comments by Oct. 22, 2012. A copy of the notice in the Federal Register is available here.

This is the most recent study proposed by the FDA to evaluate DTC advertising with respect to prescription pharmaceuticals. Earlier this year, the FDA advised that it would be moving forward with a study proposed to research the effects of promotional officers in DTC prescription pharmaceutical print advertising.

The results from these various studies will inevitably impact DTC advertising and how various things are presented in that advertising, including how composite scores are used. Pharmaceutical companies will need to be aware of this research, and any results, as it may ultimately impact any requirements set forth by the FDA with respect to DTC advertising.

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