FDA's Goldilocks Syndrome: Too Much, Too Little, or Just Enough Risk Disclosure in Direct-to-Consumer Prescription Drug Advertising?

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On February 18, 2014, the Food and Drug Administration (FDA) issued a *Federal Register* notice soliciting comments on research entitled, "Disclosure Regarding Additional Risks in Direct-to-Consumer (DTC) Prescription Drug Television (TV) Advertisements (Ads)."[1] The comments and FDA's study are intended to evaluate the effect of limiting risks provided in DTC prescription TV ads to only those "serious and actionable." In addition, the review would include whether any such limitation should inform consumers that there are other product risks not disclosed in the ad. FDA is requesting comments by April 21, 2014, to this "limited risks plus disclosure" strategy, to use the agency's phrase. The following is a summary of the information request:

- We will not discuss here the "major statement" provisions of DTC TV ads, as we believe most in the regulated industry understand the basic concept. However, there has been some criticism that the major statements are too long, whereby consumers might not truly understand the risks or lose interest and, essentially, tune out the message. Therefore, FDA is concerned that a TV ad may have little or no effect in describing the product risks, as consumers might ignore the important risk messaging. The counter concern is that the messaging omits important risk information or is not provided sufficiently.
- FDA is proposing to limit the risk information described in the major statement to those that are serious and actionable, although these terms are not defined by the agency. The ad, however, would inform consumers that there are additional product risks not included in the ad, such as, "This is not a full list of risk and side effects, talk to your Doctor and read the patient labeling for [DRUG NAME] before starting it."
- The agency, notably the Office of Prescription Drug Promotion, will take the lead in evaluating the "limited risks plus disclosure" approach. It will conduct inferential statistical tests and make its recommendations based on empirical research.
- Without going into too much detail here on FDA's proposed study methodology, here is an overview:
    - Participants will include consumers, at least 18 years of age, who self-identify as having been diagnosed with one of three possible medical conditions.
        - Individuals who work in the healthcare or marketing settings will be excluded.
    - Recruitment and administration of the study will take place over the Internet and should take approximately 30 minutes.
    - The participants will be randomly assigned to view one of four possible proposed TV ads:
        - one will represent an ad, such as one that might be aired today, which includes the full major statement;
        - a second version of the ad will include a full major statement and the disclosure about additional risks;
        - a third version will include an abbreviated statement of risks, without the disclosure about additional risks; and
        - the fourth version will include an abbreviated statement of risks, and a disclosure statement about additional risks.

1 79 Fed. Reg. 9,217 (Feb. 18, 2014), available at: https://www.federalregister.gov/articles/2014/02/18/2014-03390/agency-information-collection-activities-proposed-collection-comment-request-disclosure-regarding.

- Participants will respond to questions about information presented in the ad to evaluate, in part, perception and understanding of the product risks and benefits, disclosure about additional risks, perceptions of product quality, intent to seek more product information, and perceptions about the product claims and sponsor.

AGG Observations

- There is no deadline by which FDA must make a final decision. Depending on the number of comments submitted in response to the *Federal Register* notice, we would not expect the agency to issue further guidance for at least six months after the April 21, 2014 comment deadline expires. Six months is an aggressive expectation because, not only must the FDA consider comments submitted, but it must complete and publish its research.
- The definition of "serious" and "actionable" must be explained and developed.
- It is too early to know what the FDA will find or decide. The agency might leave the status quo, pick one or two of the four models described for more discussion, or recommend one singular approach.

We will continue to monitor this issue and keep clients updated.

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