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FDA pushes "consumer-friendly" presentation of quantitative data in DTC promotions

Agency also announces three studies that aim to promote drug information transparency

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On Tuesday, the Food and Drug Administration (FDA or the agency) published a draft guidance document, "Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer Promotional Labeling and Advertisements," which offers recommendations on how companies can best present quantitative efficacy and risk information in direct-to-consumer (DTC) promotional materials. Also on Tuesday, FDA issued three notices of agency information collection activities, highlighting its focus on promoting drug information transparency between the pharmaceutical industry and the consumer.

The draft guidance provides a number of illustrative examples and specific recommendations for DTC promotional labeling and advertising. FDA cited research showing the use of quantitative information, rather than qualitative terms (e.g., "most," "rare," or "common"), may allow consumers to form more accurate and precise perceptions of the information presented. Thus, FDA suggested companies should

- ensure consistency in presentation, for example in numeric formats (e.g., absolute frequencies versus percentages) and in expression of quantitative versus qualitative descriptions of risk or efficacy information;
- use consistent denominators that are easy for consumers to understand (e.g., 31 out of 100 compared to 50 out of 100, rather than 1/3 compared to 1/2);
- express probabilities as whole numbers to the extent possible, and when impossible, use decimals as opposed to rounding up or down;
- select appropriate visual depictions of data (e.g., bar charts for comparisons, line charts for time series) and label them clearly;
- include quantitative information for the relevant control group as well as the treatment group; and

- in presenting information on probability of efficacy or risk, highlight absolute frequencies, which are better understood by consumers rather than depictions of relative frequencies, which may require additional context.
    - For example, when presenting information stating that in clinical trials most patients experienced a response after 12 weeks of treatment with Drug X, the firm can add numerical values to help consumers understand the presentation by stating, "In a clinical trial, 78 out of 100 patients experienced a response after 12 weeks of treatment with Drug X."

Of the three studies that FDA announced Tuesday, perhaps most relevant to the draft guidance is the agency's announcement seeking public comment on a study titled "Experimental Study of an Accelerated Approval Disclosure." The research is intended to examine how information about a product's accelerated approval (which carries with it less certainty about effectiveness because it is based on surrogate endpoints and typically requires confirmatory studies after approval) might best be conveyed to consumers in DTC advertising.

FDA announced a study titled "Disease Awareness and Prescription Drug Promotion on Television," focusing on how the similarity, temporal positioning, and frequency of exposure to disease awareness communications and prescription drug television promotion may affect consumer perception and understanding of the benefits and risks of a prescription drug product.

The agency also announced a study titled "Physician Interpretation of Information About Prescription Drugs in Scientific Publications vs. Promotional Pieces." that will investigate how physician perception of prescription drug information is influenced by: (1) variations in information context (e.g., the presence of graphical elements and the information delivery vehicle, such as medical journal abstract or sales aid), (2) methodologic rigor of the underlying clinical study, and (3) whether or not physicians reviewing the information are under time pressure to make a decision quickly.

The draft guidance and three FDA notices were published in the Federal Register today, and the comment period for each ends December 16. If you have any questions or want to discuss submitting a comment, please contact any of the authors listed below or the Hogan Lovells lawyer with whom you regularly work.

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