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Focus Groups About Drug Products as Used by The Food and Drug Administration
Summary of Survey Conducted

FDA's Office of Prescription Drug Promotion in the Center for Drug Evaluation and Research conducted a series of focus groups to learn more about how consumers understand oncology indications and endpoints. It was entitled "Focus Groups on Oncology Indications."

What was the problem to be investigated? Oncology products are increasingly being promoted to consumers via direct-to-consumer (DTC) television advertising. Oncology indications are often complicated, with different endpoints such as overall survival, overall response rate, and progression-free survival. These focus groups were the first step in a research project that will help determine how to communicate oncology indications and endpoints in DTC television ads.

The method used to conduct the focus groups. We conducted eight focus groups (two in each of four locations across the United States). We recruited a general population sample for half of the focus groups, and cancer patients who had completed treatment for the other half of the focus groups. Participants completed a consent form, and then the focus group moderator guided the focus group sessions. The focus groups explored participants' understanding of common oncology clinical trial endpoints (e.g., overall survival). Half of the groups focused on this exclusively, while half also discussed advertising claims and a disclosure related to these endpoints.

Burden imposed. We conducted the one-hour focus groups with 72 participants, for a total of 72 burden hours. Along with the screener, the total burden for this collection of information was estimated to take 112 hours.