0910-0847
Data to Support Social and Behavioral Research as Used by The Food and Drug Administration
Summary of Survey Conducted

The Food and Drug Administration's (FDA) Office of Prescription Drug Promotion in the Center for Drug Evaluation and Research conducted a survey to examine consumers' understanding of framing statements used to describe the level of risk in direct-to-consumer (DTC) prescription drug TV ads. It was entitled "Pilot Study Regarding Framing of Risks in DTC Prescription Drug TV Ads."

What was the problem to be investigated? Prescription drug advertising regulations (21 CFR 202.1) require that broadcast (TV or radio) advertisements present the product's major risks in either audio or audio and visual parts of the advertisement; this is often called the "major statement." There is concern that as currently implemented in DTC ads, the major statement is often too long, resulting in reduced consumer comprehension, minimization of important risk information and, potentially, therapeutic non-compliance due to fear of side effects.[1] At the same time, there is concern that DTC TV ads do not include adequate risk information or leave out important information.[2, 3] These are conflicting viewpoints. A possible resolution is to limit the risks in the major statement to those that are severe, serious and actionable, and include both a framing statement describing the level of risk and a disclosure to alert consumers that there are other product risks not included in the ad. The FDA has previously investigated the effectiveness of this "limited risks plus disclosure" strategy through empirical research.[4] This pilot project investigated the impact of framing statements describing the level of risk for prescription drug products promoted in the context of DTC television ads.

The method used to obtain the sample. Participants were recruited from a nonprobability panel of US adults that was demographically balanced, including racial and ethnic minorities, a wide range of different age groups, and individuals with relatively less educational attainment. Population-representative survey weights were applied based on GfK's probability-based KnowledgePanel™ to ensure that the results better resembled the aggregate characteristics of the target population with respect to age, gender, education and race/ethnicity so that the sample had a reasonable degree of diversity in key demographic characteristics. To qualify for the study, panel members needed to be 18 years of age or older; individuals who worked in health care, marketing, advertising, or the pharmaceutical industry or who work for the Department of Health

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1 Delbaere, M., & Smith, M. (2006). Health care knowledge and consumer learning: the case of direct-to-consumer drug advertising. *Health Mark Quarterly*, *23*(3), 9.

2 Friedman, M., & Gould, J. (2007). Consumer attitudes and behaviors associated with direct-to-consumer prescription drug marketing. *Journal of Consumer Marketing, 24*(2), 100-109.

3 Frosch, D. L., Krueger, P. M., Hornik, R. C., Cronholm, P. F., & Barg, F. K. (2007). Creating demand for prescription drugs: a content analysis of television direct-to-consumer advertising. *The Annals of Family Medicine, 5*(1), 6-13.

4 Betts, K. R., Boudewyns, V., Aikin, K. J., Squire, C., Dolina, S., Hayes, J. J., & Southwell, B. G. (2018). Serious and actionable risks, plus disclosure: Investigating an alternative approach for presenting risk information in prescription drug television advertisements. *Research in Social and Administrative Pharmacy, 14,* 951-963.

and Human Services were excluded from the study because their knowledge and experiences may not reflect those of the average consumer.

Burden imposed. A total of 8,736 panelists were invited to participate in the study and 3,047 responded. Eligible screened participants totaled 2,652, and 1,961 participants completed the 20-minute survey. The total burden for this collection was 748 hours.