United States Food and Drug Administration

Study of Multiple Indications in Direct-to-Consumer Television Advertisements

OMB Control No. 0910-NEW

SUPPORTING STATEMENT

Part B.   Statistical Methods

1. Respondent Universe and Sampling Methods

For all phases of this research, we will recruit adult volunteers 18 years of age or older with certain medical conditions. For additional screening materials, see the "Participants" section below.

The samples for the pretests and main studies will be drawn from Dynata's consumer database. Dynata's opt-in online survey panel is demographically balanced, including racial and ethnic minorities, a wide range of different age groups, and individuals with relatively less educational attainment. Dynata recruits panel members through a combination of e-mail, online marketing, and by invitation, with over 300 diverse online and offline affiliate partners and targeted website advertising. Panel inclusion is by invitation only, and Dynata invites only pre-validated individuals with known characteristics to participate in the consumer panels. Panel members will be invited to participate by receiving an e-mail invitation (Appendix D) and, if interested, can click on a hyperlink within the e-mail and gain access to the study. The sample is not intended to be representative of the population.

2. Procedures for the Collection of Information

Design Overview

We propose to test three types of fictional DTC television ads – one that promotes a single indication, one that promotes an indication plus a similar indication, and one that promotes an indication plus a dissimilar indication – in two different medical conditions (Table 1).

Procedure

We plan to conduct two pretests (one for each main study) and two main studies not longer than 20 minutes, administered via internet panel. Participants will be randomly assigned to view one study ad and then complete a questionnaire (Appendix C) that assesses recall and comprehension of the drug's benefits and risks, benefit and risk perceptions, attitudes, and behavioral intentions. We will also measure covariates such as demographics and health literacy.

Table 1: Study Design -- 1 x 3 factorial experiment repeated in two medical conditions.

	Indication 1	Indication 1 plus a similar indication	Indication 1 plus a dissimilar indication
Study 1: Diabetic peripheral neuropathy (DPN)	DPN	DPN + fibromyalgia	DPN + general anxiety disorder
Study 2: Rheumatoid arthritis (RA)	RA	RA + psoriatic arthritis	RA + leukemia

Participants

For all phases of this research, we will recruit adult volunteers 18 years of age or older from an Internet panel. For Pretest 1 and Study 1, we will recruit participants who self-report being diagnosed with diabetes (N = 60 in Pretest 1 and N = 402 in Study 1). For Pretest 2 and Study 2, we will recruit participants who self-report being diagnosed with rheumatoid arthritis (N = 60 in Pretest 2 and N = 402 in Study 2). We will exclude individuals who work for the Department of Health and Human Services or work in the healthcare, marketing, or pharmaceutical industries. We will also exclude pretest participants from the main studies, and participants will not be able to participate in both Studies 1 and 2. See Appendix B for the study screener.

Hypotheses

We hypothesis that participants will be more likely to correctly recall and understand the first indication when it is presented alone, compared with when it is presented with a second (similar or dissimilar) indication. We will explore whether similarity of the indications affects participants' likelihood to recall and understand the indications. We will also explore the effects of the indication presentation on benefit and risk perceptions, attitudes toward the drug and the indication information, and intentions to look for more information and ask a doctor about the drug.

Analysis Plan

We will conduct ANOVAs (for continuous variables) and logistic regressions (for dichotomous variables) with interaction terms and planned comparisons to test the hypotheses outline above.

Power

We conducted power analyses for each main study, taking into consideration the study's purpose, expected outcome measures, and potential key analyses. Both studies have been powered to detect a small effect size (no smaller than Cohen's $f = .15$), with a power of .90 and an alpha of .05. Given the achieved effect sizes of previous FDA studies that manipulated aspects of the drug in direct-to-consumer television ads, we propose an effect size of $f = .18$, resulting in a total sample size of 402 for each study (with approximately 134 participants per experimental group). If a significant main effect is found, we will also be able to conduct three planned contrasts using a Bonferroni-adjusted threshold of .0167 with enough sensitivity to detect small to moderate effects ($f = .20$). This sample size is also consistent with Cohen's (1988) definition of small effect size (e.g., f between .10 and .24).

Cohen, J. (1988). Statistical power analysis for the behavioral sciences (2nd ed.). Hillsdale, NJ: Erlbaum.

3. <u>Methods to Maximize Response Rates and Deal with Non-response</u>

    The pretests and main studies will use an existing research panel to draw a sample. The panel comprises individuals who have signed up to participate in online studies. To help ensure that the participation rate is as high as possible, FDA will:

    - Design an experimental protocol that minimizes burden (short in length, clearly written, and with appealing graphics);
    - Administer the pretests and main studies over the Internet, allowing respondents to answer questions at a time and location of their choosing.

4. <u>Test of Procedures or Methods to be Undertaken</u>

    We will conduct nine hour-long qualitative interviews to cognitively test the study stimuli and materials. For each main study, we will conduct a pretest to test the experimental manipulations and pilot the main study procedures. Finally, we will run each main study as described elsewhere in this document.

5. <u>Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data</u>

    The contractor, RTI International, will collect the data on behalf of FDA as a task order under Contract HHSF223201510002B. Mihaela Johnson, 919-990-8365, is the contractor's Project Director for this project. Data analysis will be overseen by the Research Team, Office of Prescription Drug Promotion (OPDP), Office of Medical Policy, CDER, FDA, and coordinated by Helen W. Sullivan, Ph.D., MPH, 301-796-4188, and Kathryn Aikin, Ph.D., 301-796-1200.