Market Claims in Direct-to-Consumer (DTC) Prescription Drug Print Ads

OMB Control No. 0910- NEW
Supporting Statement Part B

B. Statistical Methods (used for collection of information employing statistical methods)

1. Respondent Universe and Sampling Methods

The eligible study population is U.S., non-institutionalized adults age 18 and older that have been diagnosed with diabetes (as measured by self-report). The sample will be balanced on age, gender, race, ethnicity and region within the US to the extent possible. The selected sample will be drawn from Ipsos's opt-in online survey panel, i-Say. The i-Say panel consists of over 800,000 members within the US. Members provide extensive individual and household demographic information, such as gender, age, race, ethnicity, education, income, health profile, and many other factors. Ipsos uses this information to target recruitment of groups of interest. Here, we will recruit panelists that report having diabetes.

Panelists identified as having been diagnosed with diabetes will be invited to participate in the survey via email. The email indicates the given compensation for completing the survey (i-Say points, which may be redeemed for cash or prizes) and provides a hyperlink to the survey. Up to two reminder e-mails will be sent after the initial invitation if no response has been received, which helps increase response rates.

Upon entering the survey, respondents are screened to confirm that they have diabetes. Individual who work in the health care, marketing, advertising, or pharmaceutical industries will be excluded via screening. Eligible respondents are then shown a consent language and asked whether they agree to participate in the study. Non-eligible respondents are thanked for their time and terminated from the survey.

We will exclude pretest study participants from the main study and follow-up study.

2. Procedures for the Collection of Information

Design Overview

The design consists of two parts; a main study and a follow-up study. We will conduct two sequential pretest waves prior to the main study and one pretest prior to the follow-up study. The purpose of the pretests are to 1) ensure the stimuli are understandable and viewable, 2) identify and address any challenges to embedding the stimuli within the online survey, and 3) ensure the study questions are appropriate and meet the study's goals.

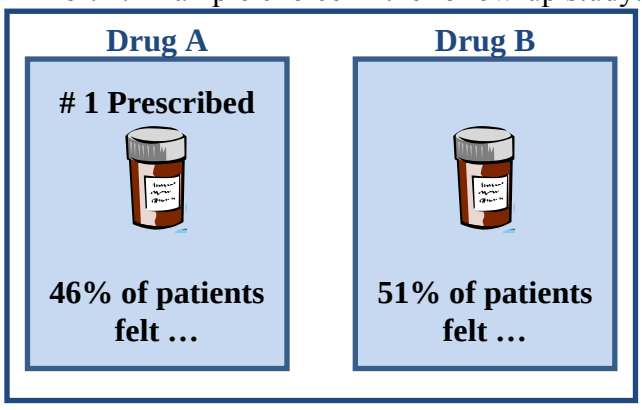
Participants in the main study will be randomly assigned to view one of nine versions of an ad, as depicted in Exhibit 1. The two variables of interest are type of market claim (#1 Prescribed, New) and type of efficacy information (High, Low, or none). Efficacy information will be operationalized in the form of realistic quantitative information (for example, "46% of patients felt their nerve pain reduced by at least half, compared to baseline").

Exhibit 1: Main Study Design

		Type of Market Claim		
		#1 Prescribed	New	None (control)
Efficacy Level Information	High	A	B	C
	Low	D	E	F
	None (control)	G	H	I

In the follow-up study, participants (n = 216) will complete a 15-minute paired choice experiment. Participants will be asked to choose between two hypothetical drugs based on print ads, one of which includes a market claim from the Main Study (#1 Prescribed or New). The ads also include different efficacy information (for example, "46% of patients felt their nerve pain reduced by at least half, compared to baseline" versus "51% of patients felt their nerve pain reduced by at least half, compared to baseline"). Exhibit 2 depicts an example choice. Participants are asked to indicate which drug they would prefer. They are given 48 such choice sets, which vary in efficacy information and the presence of the market claim.

Exhibit 2: Example choice in the follow-up study.



Procedure

Pretests: Each participant will be randomly assigned to view a print ad for a fictitious prescription drug indicated to treat diabetic neuropathy and will be asked to complete an online survey assessing their benefit/risk perceptions, intentions, and attitudes toward the

drug. Based on the pretest findings, we will revise and remove poorly performing survey items prior to full-scale testing.

Main study: Each participant will be randomly assigned to view a print ad for a fictitious prescription drug for diabetic neuropathy and will be asked to complete an online survey assessing their benefit/risk perceptions, intentions, and attitudes toward the drug.

Follow-up study: Each participant will be asked to view a series of pairs of print ads for a product that treats diabetic neuropathy. One ad will contain a market claim. Both ads will contain quantitative efficacy information that varies along a continuum of effectiveness in a series of 48 trials. In each comparison, participants will be asked to choose one of the two drugs.

Participants

Eligible consumer participants for the pretests (N = 612), main study (N = 495), and follow-up study (N = 216) will be adults who speak English and self-identify as having been diagnosed with diabetes. We will exclude individuals who work in the health care, marketing, advertising, or pharmaceutical industries. We will also exclude pretest study participants from the main and follow-up studies.

Analysis Plan

Main Study: We will conduct ANOVAs (for continuous variables) and chi-squares and logistic regressions (for categorical variables) to examine the impact of market claim and quantitative efficacy information. Before conducting analyses, we will assess whether the inclusion of covariates is justified. If they are, we will conduct the analyses both with and without covariates (e.g., sex, age, race/ethnicity, education, numeracy) included in the model. If the one-way ANOVA is significant, we will implement a series of two-way comparisons (e.g., #1 Prescribed vs. control, #1 Prescribed + high efficacy quantitative info vs. control, #1 Prescribed vs. #1 Prescribed + high efficacy quantitative info) to test for significant differences among the experimental arms.

Follow-up Study: Logistic regression will be applied to the binary choices (i.e., drug choice) made by participants on each trial. The regression will indicate the probability of choosing one of the drugs as a function of the difference in efficacy, for each participant. From the regression equation, we can determine the "equal point" between the two drugs; in other words, the difference in efficacy at which the participant is equally likely to choose either drug. The null hypothesis is that the "equal point" is when there is no difference in efficacy. Alternatively, if market claims influence participants' decision making, the equal point will not be zero. For instance, if participants prefer a drug that is associated with a claim, participants will choose the drug without a claim only if it has a 5% greater efficacy than "#1 Prescribed" drug. In this way, we can quantify the advantage of a claim in units of efficacy.

Power

The main study will include 495 consumer participants. We conducted a power analysis for a 3x3 analysis of covariance (ANCOVA) using G-Power.[1] The analysis assumed four degrees of freedom in the denominator, a power level of 0.90, an α-level of 0.05 and allowed two covariates. Using a small to medium effect size of 0.18, the required sample size is 495 (481, adjusted upward to allow an equal number of respondents per experimental condition).

The follow-up study will include 216 participants to obtain 90% power to observed a small effect size (.1) at $\alpha = 0.0.5$. The critical analysis is the comparison of the efficacy difference at which the two drugs are equally likely to be chosen. An estimate is calculated for each participant, and the estimates are compared to the null hypothesis of zero in a one-sample 2-tailed t-test.

3. Methods to Maximize Response Rates and Deal with Non-response

This experimental study will use existing research panels to draw a sample. The consumer panels comprise of 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 (clearly written and with appealing graphics);
- Administer the survey over the Internet, allowing respondents to answer questions at a time and location of their choosing;
- Field the survey for 2 to 4 weeks to allow participants reasonable time to access and complete the survey;
- Provide up to 2 e-mail reminders throughout the course of the field period;
- Provide a Member Services contact person for respondents to contact via email if they have questions or technical difficulty as they complete the survey.

There are several approaches to address the potential for nonresponse bias analysis in this study, such as comparing response rates by subgroups, comparing respondents and nonrespondents on frame variables, and conducting a nonresponse follow-up study.[2] For the proposed project, we will compare responders and nonresponders on demographic variables.

4. Test of Procedures or Methods to be Undertaken

[1] Faul, F. (2010). G*Power Version 3.1.3.
[2] Office of Management and Budget, *Standards and Guidelines for Statistical Surveys*, September, 2006. https://www.whitehouse.gov/sites/default/files/omb/inforeg/statpolicy/standards_stat_surveys.pdf. Retrieved March 21, 2016.

The stimuli and draft questionnaire were tested in cognitive interviews. The cognitive testing examined the stimuli and draft measures to refine the stimuli, improve question wording, and narrow the pool of questions. Additionally, we will conduct pretesting to test and further refine the measurements to be used in the main study.

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

The contractor, Ipsos, will collect and analyze the data on behalf of FDA as a task order under Contract HHSF223201400503G. Aysha Keisler, Ph.D., 202-420-2021, is the Ipsos 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, coordinated by Kathryn J. Aikin, Ph.D., 301-795-0569, and Kevin R. Betts, Ph.D., 240-402-5090.