United States Food and Drug Administration

Empirical Study of Promotional Implications of Proprietary Prescription Drug Names

OMB Control No. 0910-NEW

SUPPORTING STATEMENT

Part B.   Statistical Methods

1. Respondent Universe and Sampling Methods

The main study sample will include 448 primary care providers (PCPs) and 448 members of the general population.

The HCP sample will include physicians, nurse practitioners, and physician assistants. Lightspeed Health will recruit study participants from its panel of more than 5.5 million consumers and more than 2 million healthcare providers (HCPs) and send invitations to the online survey (see Appendix B for recruitment language). The first study will use a general population convenience sample of participants who are 18 years of age or older. We will exclude individuals who have worked in the health care, marketing, advertising, and pharmaceutical industries and those who work for the Department of Health and Human Services. Participants from the pretest (Promotional Implications of Proprietary Prescription Drug Names: Pretest (OMB Control No. 0910-0695)) will also be excluded from participating in the main study. Screeners for both the consumers and HCPs can be found in Appendix C.

We will require that HCPs engage in patient care at least 50% of the time. Participants for our study will be randomly selected using the study's profile criteria, taking account of predicted response rates by target demographic to avoid over-contacting panelists and to ensure that we do not introduce a bias in the responses. The study participants will not be probability-based samples of consumers, but we will aim to recruit a mix of participants in terms of race/ethnicity, gender, and other characteristics. No weighting of the data will be required because the objective of the studies is to estimate the causal effects of experimental manipulations rather than to estimate descriptive statistics for these populations.[1]

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[1] Solon, G., Haider, S. J., & Wooldridge, J. (2015). What are we weighting for? *The Journal of Human Resources*, *50*(2), 301–316. http://dx.doi.org/10.3368/jhr.50.2.301

We can expect response rates similar to those found in the pretest, as eligibility criteria and other parameters for the sample are the same. In the pretest, for the provider sample, 65% of those who began the screener and a full 100% who were eligible and consented completed the study. For the consumer sample, 64% of those who began the screener and 92% of those who were eligible and consented completed the study.

Invited panelists will review an online informed consent form, and panelists who agree to participate will begin the survey. We will begin the data collection with a soft launch (10% of completes) to ensure that randomization is working as intended and check for any other potential errors in programming, etc. Lightspeed Health will ensure quality of the data with validation checks. Lightspeed Health maintains the quality of its panel by rigorously validating HCPs against known HCP databases, which include license numbers and work emails. During the course of the survey, Lightspeed can conduct IP checks to weed out duplicates in the consumer sample and require a PIN for redeeming honoraria. They also conduct data quality and consistency checks and remove poor performers. In addition, they have made mobile compatibility standard on all surveys. All questions are compatible with any device's screen size and orientation.

2. Procedures for the Collection of Information

Part A of the supporting statement described the rationale for conducting the study.

We will use a within-subjects design for the main study to increase efficiency and keep the sample size small. Participants will view drug product names for two medical indications in random order (one list for high cholesterol and one list for gastroesophageal reflux disease, or GERD).

The main study will include a total of 14 drug names, 7 for each of two medical conditions (one extreme name, one neutral name, and five target names). The list of drug names to be used in the study can be found in Appendix D. At the beginning of the survey, we will assess ability to recognize the items with a recognition task, which asks participants to check the names that they saw on a list (several foils will be included). We will then conduct a manipulation check to determine whether embedded indication information in the target names is obvious to participants. Participants will then answer questions about all fourteen names independently. Once all names have been shown, participants will complete a few additional ranking questions. The specific items can be found in the questionnaire (Appendix A).

The survey will not exceed 20 minutes. Survey items will include benefit perception items and attitude and behavioral intention items.

Hypotheses

Based on a preliminary scan of the literature, we have identified the following potential hypotheses and research questions. These hypotheses and research questions will be revisited after the completion of the literature review task, as we expect the literature to identify additional rationale and potential variables of interest:

Hypothesis 1: Benefit perceptions will be higher for proposed names than neutral names, but lower for proposed names than extreme names.

Research Question 1: Will risk perceptions be lower for proposed names than for neutral names and/or higher for proposed names than extreme names?

Rationale:

It is possible that proposed names may overstate the benefits or underplay risks compared to neutral names. (Extreme names will be developed to intentionally overstate benefits and underplay risks compared to neutral names, such that we have something with which to compare the proposed names). Some research has found an inverse relationship between perceptions of risks and benefits.[2]

Hypothesis 2: Participants will be better able to recall proposed names than neutral names, but less able to recall proposed names than extreme names.

Rationale:

- Brand names that suggest desirable attributes of a product have been found to produce higher recall than neutral brand names.[3]
- Congruence or consistency between a drug name and a suggested positive effect may aid memory and thus increase recall.[4]

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[2]   Alhakami, A. S., & Slovic, P. (1994). A psychological study of the inverse relationship between perceived risk and perceived benefit. *Risk Analysis*, 14(6), 1085-1096; Finucane, M. L., Alhakami, A., Slovic, P., & Johnson, S. M. (2000). The affect heuristic in judgments of risks and benefits. *Journal of Behavioral Decision Making, 13*(1), 1–17. doi:10.1002/(Sici)1099-0771(200001/03)13:1<1::Aid-Bdm333>3.0.Co;2-S

[3]   Keller, K. L., Heckler, S. E., & Houston, M. J. (1998). The effects of brand name suggestiveness on advertising recall. *Journal of Marketing, 62*(1), 48–57. doi:10.2307/1251802

[4]   Craik, F. I., & Tulving, E. (1975). Depth of processing and the retention of words in episodic memory. *Journal of Experimental Psychology: General*, 104(3), 268-294.

Hypothesis 3: Attitudes toward proposed names will be more positive than those toward neutral names, but less positive than those toward extreme names.

Hypothesis 4: Intentions to use or prescribe drugs with proposed names will be higher than those for neutral names, but lower than those for extreme names.

Rationale:

Brand names that suggest desirable attributes of a product or use sound symbolism to imply a benefit may result in more positive attitudes toward the product and/or higher intentions to use the product.[5]

Power

The two studies will run concurrently. Within each participant sample, we will analyze data related to the two indications separately. Essentially, we'll have a model for Indication 1, and separate, replication model for Indication 2. We have set statistical power for the main study to test as many as five proposed names against both the neutral control name and the extreme control name, using a 7 x 7 Latin square design. With a Bonferroni correction for ten pairwise comparisons, we've assumed a family-wise alpha level of 0.005 and power set to 0.90. The proposed samples will be sufficient to detect small main effects of proposed proprietary names ($f \geq 0.06$). Follow-up dependent-samples t tests will be sensitive enough to detect small within-subjects pairwise differences between each of the five proposed names relative to the neutral control and extreme control names ($dz \geq 0.21$).

Analyses

Within each participant sample, we will analyze data related to the two indications separately. Essentially, we will have a model for Indication 1 and a separate, replication model for Indication 2. We have set statistical power for the main study to test as many as five proposed names against both the neutral control name and the extreme control name, using a within-subjects design. With a Bonferroni correction for 10 pairwise comparisons, we have assumed a family-wise alpha level of 0.005 and power set to 0.90 for all tests.

Nonparametric tests and repeated measures ANOVAs will be conducted.

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[5] Klink, R. R. (2001). Creating meaningful new brand names: A study of semantics and sound symbolism. *Journal of Marketing Theory and Practice, 9*(2), 27–34.

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

    The study will be administered via Internet. To help ensure that the participation rate is as high as possible, FDA and the contractor will:

    -   Design a protocol that minimizes burden (short in length, clearly written, and with appealing graphics);

    -   Use incentive rates that meet industry standards. In addition to offsetting respondent burden, using market-rate incentives tends to increase response rates, reduce sampling bias, and reduce nonresponse bias.

    Participants will be convenience samples, rather than probability-based samples of U.S. adults or U.S. HCPs. Rather, the strength of the experimental design used in this study lies in its internal validity, on which meaningful estimates of differences across manipulated conditions can be produced and generalized. This is a counterpoint to observational survey methodologies where estimating population parameters is the primary focus of statistical analysis. The recruitment procedures in this study are not intended to fit the criteria for survey sampling, where each unit in the sampling frame has an equal probability of being selected to participate. In an observational survey study, response rates are often used as a proxy measure for survey quality, with lower response rates indicating poorer quality. Nonresponse bias analysis is also commonly used to determine the potential for nonresponse sampling error in survey estimates. However, concerns about sampling error do not generally apply to experimental designs, where the parameters of interest are under the control of the researcher—rather than being pre-established characteristics of the participants—and each participant has an equal probability of being assigned to any of the experimental conditions.

    Generally, there are several approaches to conducting a nonresponse bias analysis, such as comparing response rates by subgroups, comparing respondents and nonrespondents on frame variables, and conducting a nonresponse follow-up study. For the proposed project, we will examine nonresponse for its descriptive value by comparing our full sample with population estimates for age, race, and gender.

4. Test of Procedures or Methods to be Undertaken

    Before beginning drug name development, we conducted a literature review and an environmental scan to inform the process of drug name development. To get a better sense of which strategies are used most frequently by drug companies in naming drugs, we also

conducted an environmental scan. A team of Multimedia and Creative Services staffers who have experience with branding and drug name development worked to create an initial set of names, and a linguistics expert reviewed them. These names were assessed in a pretest with approximately 120 consumers and 120 healthcare providers (Promotional Implications of Proprietary Prescription Drug Names: Pretest (OMB Control No.

0910-0695)).

Findings from the pretest survey were consistent and unequivocal. Participants discerned differences between the most promising extreme and neutral names for both indications on all four outcome measures and across both populations. Evidence from these tests support using "ACIDARID" as the extreme name for GERD drugs in the main study and "INPARINA" as the corresponding neutral name for that indication. Findings from the pretest also suggest that consumers and HCPs perceived "CHOLESTANORM" to be a drug indicated for the management of high cholesterol, while "GORMALIN-XR" was relatively neutral with regard to that indication. We are confident proceeding with these four names for the main study.

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

The contractor, RTI, will collect and analyze the data on behalf of FDA as a task order under Contract HHSF223201510002B. Bridget Kelly, Ph.D., M.P.H., 202-728-2098, is the 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 Amie C. O'Donoghue, Ph.D., 301-796-0574, and Kevin R. Betts, Ph.D., 240-402-5090.