Experimental Study: Examination of Corrective DTC Television Advertising

0910-New

SUPPORTING STATEMENT

Submitted by

Office of Prescription Drug Promotion
Center for Drug Evaluation and Research

Food and Drug Administration

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes the Food and Drug Administration (FDA) to conduct research relating to health information. Section 903(b)(2)(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(b)(2)(c)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act.

FDA regulations require prescription drug ads to contain accurate information about the benefits and risks of the drug advertised. When this is not the case, corrective advertising is designed to dissipate or correct erroneous beliefs resulting from a false claim.[1] Corrective advertising emerged in public debate in the United States in the 1970s as a hypothetical remedy for deceptive advertising, having first been proposed by Georgetown University law students in 1969 as a way of dispelling the effects of deceptive advertising.[2] Corrective advertising is one remedy FDA may request in response to false or misleading prescription drug promotion. In 2009, for example, Bayer HealthCare Pharmaceuticals produced and aired corrective DTC advertising for Yaz, a birth control pill, following a warning from FDA regarding misleading claims.[3] Despite these developments, researchers and policymakers currently lack empirical literature regarding the various influences of corrective DTC ads on prescription drug consumers. The current project will examine the influence of corrective messages in the realm of consumer directed prescription drug advertising.

2. Purpose and Use of the Information Collection

[1] Darke, P.R., Ashworth, L. & Ritchie, R.J.B. (2008). Damage from corrective advertising: Causes and cures. *Journal of Marketing*, *72*, 81-97; Mazis, M.B. & Adkinson, J.E. (1976). An experimental evaluation of a proposed corrective advertising remedy. *Journal of Marketing Research*, *13*, 178-183.

[2] Mazis, M. B., McNeill, D. L., & Bernhardt, K. L. (1983). Day-after recall of Listerine corrective commercials. *Journal of Public Policy & Marketing, 2*, 29–37.

[3] Singer, N. (2009, February 11). A birth control pill that promised too much. *The New York Times*, p. B1.

The present study will investigate how variations in corrective advertising may influence consumers' product beliefs. Specifically, the study will focus on the following variables of interest: (1) exposure to corrective, (2) visual similarity between the original and corrective ads, and (3) time delay between the original and corrective ads. The study findings will inform FDA of relevant consumer issues relating to corrective DTC advertising.

3. Use of Improved Information Technology and Burden Reduction

Automated information technology will be used in the collection of information for this study. The contracted research firm will collect data through Internet administration. One hundred percent (100%) of participants will self-administer the Internet survey via a computer, which will record responses and provide appropriate probes when needed. In addition to its use in data collection, automated technology will be used in data reduction and analysis.

4. Efforts to Identify Duplication and Use of Similar Information

As described in section A.1., there has been some previous research on corrective advertising. The primary focus of this past research has been on the efficacy of corrective messages in consumer package goods product categories. This study is designed to address a gap in the literature. There is scant work on the specific efficacy of televised corrective ads intended to correct misperceptions that arise from prescription drug advertising.

Given these past studies, it appears there is adequate background literature but no studies that duplicate the efforts proposed in this statement.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection.

6. Consequences of Collecting the Information Less Frequently

The proposed data collection is one-time only. There are no plans for successive data collections.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This collection of information fully complies with 5 CFR 1320.5. There are no special circumstances.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of 02/29/2012 (77 FR 12307). FDA received three public submissions. In the following section, we outline the observations and suggestions raised in the comments and provide our responses.

(Comment) One comment expressed support for the survey.

(Response) We thank this commenter for his support of our study.

(Comment) One comment expressed the concern that the internet sample would not measure individuals over 65 due to difficulties using the internet.

(Response) We have conferred with the Internet Panel provider for this study about this issue. According to GfK,[4] the 65+ Panelists are among the most reliable respondents and their representation on the panel (15.7%) is reasonably proportionate to their representation in the General Population (16.7%).

(Comment) One comment stated a "medium prevalence" condition may not represent conditions that cluster in particular demographic groups.

(Response) Recruitment to KnowledgePanel® is based upon a random selection of residential addresses. Every residential address in the United States has an equal probability of

[4] Formerly Knowledge Networks.

selection within each recruitment cohort (cohort sizes may vary from recruitment wave to wave and the residential housing stock changes over time which results in differing probability of selection between recruitment waves). Thus, mailings have a proportional likelihood of reaching any specific demographic group. Finally, as the weights are calculated based upon Current Population Survey benchmarks, final adjustment of survey respondents to the US population can be easily made. The panel recruits in English and Spanish with all mailings being bilingual.

We plan to use asthma and weight loss as our two medical conditions. While the particulars of an individual corrective campaign may vary, the type of violation (for example, overstatement of efficacy, minimization of risk) can occur in any drug class. Therefore, we believe that the cognitive processes involved in understanding a claim and subsequently correcting problematic claims applies across multiple medical conditions. Those with debilitating conditions might be less likely to respond to the recruitment and survey invitations but it is likely that they would be less likely to respond to other modes of survey data collection as well.

Finally, we note that this is a randomized control trial design: we are not attempting to make population estimates from these results.

(Comment) One comment asked if the participants would be a random and representative selection of the target audience.

(Response) We are planning to recruit panel members who self-report having been diagnosed with asthma (Phase 1) or self-identify as having a weight problem with a BMI of 25 or above (Phase 2). These are the relevant target audiences for the medical conditions being advertised. As described above, the panel of active profiled adults are weighted to be representative of the US population on age, gender, race, Hispanic ethnicity, language

proficiency, region, metro status, education, household income, home ownership, and Internet access using post-stratification adjustments to offset nonresponse or noncoverage bias.

(Comment) One comment stated that even if participants are randomly selected, the final study sample may be self-selected due to dropout over time.

(Response) We agree that dropout is a concern common to all longitudinal research. We plan to employ the following techniques to improve retention of respondents over time:

1. It is very important to notify respondents at the time of their invitation that this is a longitudinal survey and that we intend to contact them multiple times during the duration of the survey. This in an important part of the informed consent procedure. We will therefore explicitly ask respondents if we can contact them in the future. This will allow us to contact them even if they leave the panel.

2. Periodic contact also provides a vehicle to retain engagement with respondents and can be conducted via email. KnowledgePanel® members are accustomed to receiving periodic communication about surveys that they previously participated in and respond well to periodic contact.

3. When later survey waves are fielded, respondents will be reminded that they participated in the earlier survey wave, that we appreciated their agreeing to participate in subsequent survey waves and that this survey is a follow-on to the prior survey wave. The date of the prior survey field wave will be included.

4. Finally, even if a respondent has left the panel, respondents have given explicit permission, as was noted in item 1 above, to contact them regarding this survey. Thus we do not anticipate an unusual loss of participation on subsequent survey waves. In past multi-wave surveys, it was not unusual for 75% to 85% of

respondents to the first wave of a study to respond to a subsequent survey wave more than one year later.

(Comment) One comment questioned whether the study would be adequately powered to ensure meaningful results.

(Response) We have powered our study to detect small to medium effect sizes. We have provided a power analysis for both the main study phases and pretests (see Table 7).

(Comment) One comment suggested that rather than similarity and time delay, the proposed study should include an evaluation of both 1) a truly informative, non-distracting, clear and conspicuous corrective ad and 2) an unclear and inconspicuous corrective ad.

(Response) We appreciate the suggestion to include clarity as an independent variable. Because we cannot study every variable of potential interest in a single study, we offer the following explanation for our choice of similarity and time delay. FDA has previously provided guidance on ways in which separate ads may be implemented in such a way as to be perceived as linked to one another:

> Psychology and marketing research suggests that the greater the perceptual similarity between disease awareness communications and reminder or product claim promotions (i.e., similarities in terms of their themes, such as story lines, or other presentation elements, such as colors, logos, tag lines, graphics, etc.), and the closer they are presented physically or in time to one another, the more likely it is that the separate messages contained in the two pieces will be remembered together in memory as one entity. Perceptual similarity is an important factor because research indicates that pieces are most likely to be linked together in memory when they have prominent cues in common, such as distinctive visual elements, a common narrator or background music, or a common story line.[5]

The recommendations in this guidance were based on the social science literature which suggests these properties influence people's associations. We selected similarity and time delay as our

[5] From Guidance for Industry: "Help-Seeking" and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms. Available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070068.pdf. Last accessed May 16, 2012.

independent variables of interest in this study in order to provide information on the effectiveness of FDA guidance on this issue.

(Comment) Two comments expressed concern that the time delay conditions were not realistic, stating that a time delay of six months to a year might be more realistic.

(Response) We agree that a six-month exposure delay more closely approximates real-world exposure to original and corrective messaging. In response to concerns about the realism of our approach, we have changed the study design in two ways (see Table 6). First, participants will view the stimuli embedded in a "clutter reel" of other ads three times over a three week period to approximate multiple exposures in a real-world context. Second, we have added a six-month delay condition.

(Comment) One comment critiqued the references included in the 60-day Federal Register notice, stating "…the references offered in the instant [sic] notice seemed less concerned with presenting corrective advertising in a manner most likely to inform the consumer about the safety and efficacy of a given product and more concerned with determining whether the corrective ad might be bad for sales. Furthermore, the only example of application of a judicial remedy to enforce corrective advertising cited by one of these references distorted the clear intent of the opinion cited."

(Response) Some of the research on corrective advertising, as the commentator notes, has assessed potential damage to an advertiser's reputation. Darke and colleagues (2008) note the possibility of reputational damage, for example. Other papers cited in the 60-day notice, though, do not focus primarily on reputational damage. Mazis' work, both in the 1970s and 1980s and then again more recently (e.g., Mazis, 2001),[6] as we have seen a resurgence of corrective advertising, has been concerned with the efficacy of corrective messages. Mazis and

[6] Mazis, M. B. (2001). FTC v. Novartis: The return of corrective advertising? *Journal of Public Policy & Marketing, 20*, 114–122.

colleagues (1983), for example, focused attention on the extent to which viewers actually noticed and remembered the corrective message inserted into Listerine ads. Moreover, our study was designed to address a gap in the literature – there is scant work on the specific efficacy of televised corrective ads intended to correct claims made regarding prescription drugs – rather than to simply extend and replicate past literature. The primary focus of our study is correction of misperceptions that arise from prescription drug advertising. The dependent variables we describe in the 60-day notice do not include advertiser reputation but rather are comprised of constructs such as belief in advertised claims that overstate efficacy or minimize risk, perceived risk of the advertised drug, and perceived efficacy of the advertised drug.

External Reviewers

In addition to public comment, FDA sent materials to three individuals for external peer review, receiving comments from two. These individuals were:

Gita Johar, Senior Vice Dean, Columbia Business School

Andrea Tangari, Assistant Professor of Marketing, Wayne State University

9. Explanation of Any Payment or Gift to Respondents

Internet panel participants receive points for completing a survey. Because of the multiple sessions required of participants, Phase 1 participants will receive up to 20,000 points (approximate monetary equivalence of $20). Phase 2 participants will receive up to 40,000 points (approximate monetary equivalence of $40), depending on the number of pre-exposure sessions a person completes. Members are allowed to use their points to exchange for vouchers and gifts from a partner network. Internet panel participants are enrolled into a points program that is analogous to a 'frequent flyer' card: respondents are credited with sweepstakes entries or bonus points in proportion to their regular participation in surveys. (For the households provided Internet appliances and an Internet connection, their incentive includes the hardware and Internet

service in addition to the sweepstakes entries and bonus points). Traditionally, panelists earn sweepstakes entries on some surveys (including surveys more than 15 minutes in length) and bonus points for surveys that are longer or require special tasks by the panel member. Panelists may elect to redeem their points for checks (5,000 points = $5) or raffle entries as they accrue them.

10. Assurance of Confidentiality Provided to Respondents

No personally identifiable information will be sent to FDA. All information that can identify individual respondents will be maintained by the independent contractor in a form that is separate from the data provided to FDA. The information will be kept in a secured fashion that will not permit unauthorized access. The privacy of the information submitted is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by Part 20 of the agency's regulations (21 CFR part 20). These methods will all be approved by FDA's Institutional Review Board (Research Involving Human Subjects Committee, RIHSC) prior to collecting any information.

All respondents will be provided with an assurance of privacy to the extent allowable by law. The Internet Panel includes a Panel Privacy Policy that is easily accessible from any page on the site. A link to the Privacy Policy will be included on all survey invitations. The Panel complies with established industry guidelines and states that members' personally identifiable information will never be rented, sold, or revealed to third parties except in cases where required by law. These standards and codes of conduct comply with those set forth by American Marketing Association, the Council of American Survey Research Organizations, and others. In addition, a consent form will be displayed before participants begin the survey (Appendix 4). The consent form states that participation is voluntary.[7]

[7] This satisfies section D.b.4.1 and D.b.4.2 of the OMB Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002.

All electronic data will be maintained in a manner consistent with the Department of Health and Human Services' ADP Systems Security Policy as described in the DHHS ADP Systems Manual, Part 6, chapters 6-30 and 6-35.[8] All data will also be maintained in consistency with the FDA Privacy Act System of Records #09-10-0009 (Special Studies and Surveys on FDA Regulated Products).[9]

11. Justification for Sensitive Questions

This data collection will not include sensitive questions. The complete list of questions is available in Appendix 2.

12. Estimates of Annualized Burden Hours and Costs

The total annual estimated burden imposed by this collection of information is 5,496 hours for this one-time collection (Table 1).

12 a. Annualized Hour Burden Estimate

Table 1. Estimated Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Respondents	Hours per Response[2]	Total Hours
Sample availability (pretests and main survey)	24,635	--	--	--	--
Screener completes (60%)	14,891	1	14,891	0.0333	496
Eligible (85%)	12,658	--	--	--	--
Pretest (stimuli) completes (65%)	1,450	1	1,450	0.333	483
Pretest (questionnaire) completes (65%)	200	1	200	0.5	100

[8] This satisfies section D.b.4.3 of the OMB Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002.
[9] This satisfies section D.b.4.4 of the OMB Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002.

Phase 1 completes (65%)	1,000	1	1,000	.416	417
Phase 2 completes (45%)	4,000	1	4,000	1	4,000
Pretest / Study completes	6,650	--	--	--	
TOTAL	**--**	**--**	**--**	**--**	**5,496**

These estimates are based on FDA's and the contractor's experience with previous consumer studies.

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General public	5,496	$18.90[a]	$103,874
Total			$103,874

[a]Based on the 2011 median weekly income of $756 for both sexes, as reported by the Department of Labor, http://www.bls.gov/news.release/pdf/wkyeng.pdf.

13. Estimates of Other Total Annual Costs to Respondents and Record Keepers

There are no costs to respondents. There are no record keepers.

14. Annualized Cost to the Federal Government

The total estimated cost to the Federal Government for the collection of data is $1,158,859 ($386,286 per year for three years). This includes the costs paid to the contractors to create stimuli, program the study, draw the sample, collect the data, and create a database of the results. The task order was awarded as a result of competition. Specific cost information other than the award amount is proprietary to the contractor and is not public information. The cost also includes FDA staff time to design and manage the study, to analyze the resultant data, and to draft a report ($120,000; 15 hours per week for 3 years).

15. Explanation for Programs Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Conventional statistical techniques for experimental data, such as descriptive statistics, analysis of variance, and regression models, will be used to analyze the data. See Section B below for detailed information on the design, hypotheses, and analysis plan. The Agency anticipates disseminating the results of the study after the final analyses of the data are completed, reviewed, and cleared. The exact timing and nature of any such dissemination has not been determined, but may include presentations at trade and academic conferences, publications, articles, and Internet posting.

Table 4. Project Timetable

Task	Estimated Completion Date
External Peer Review	August, 2012
RIHSC Review	December, 2012
30-day FR notice publication	December, 2012
OMB Review of PRA package	January, 2013
Pretesting	April-June, 2013
Data Collection	September, 2013-June, 2014
Receipt of Data and Methods Report from Contractor	July, 2014
Data Analysis	August-September, 2014
Draft Executive Summary and Manuscript	October, 2014
Internal Review of Draft Executive Summary and Manuscript	November, 2014
Revisions	December, 2014
Final Clearance	February, 2015

17. Reason(s) Display of OMB Expiration Date is Inappropriate

No exemption is requested.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.