

United States Food and Drug Administration

Study of Oncology Indications in Direct-to-Consumer Television Advertising

OMB Control No. 0910- NEW

SUPPORTING STATEMENT

Part 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 FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(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.

OPDP's mission is to protect the public health by helping to ensure that prescription drug promotional material is truthful, balanced, and accurately communicated, so that patients and healthcare providers can make informed decisions about treatment options. OPDP's research program provides scientific evidence to help ensure that our policies related to prescription drug promotion will have the greatest benefit to public health. Toward that end, we have consistently conducted research to evaluate the aspects of prescription drug promotion that we believe are most central to our mission, focusing in particular on three main topic areas: advertising features, including content and format; target populations; and research quality. Through the evaluation of advertising features we assess how elements such as graphics, format, and disease and product characteristics impact the communication and understanding of prescription drug risks and benefits; focusing on target populations allows us to evaluate how understanding of prescription drug risks and benefits may vary as a function of audience; and our focus on research quality aims at maximizing the quality of research data through analytical methodology development and investigation of sampling and response issues. This study falls under the topic of advertising features (content and format).

Oncology products are increasingly being promoted to consumers via DTC television advertising. Oncology indications are often complicated and supported by different clinical endpoints such as overall survival, overall response rate, and progression-free survival (Ref. 1) that are referenced in the DTC TV ads. The first objective of this project is to determine whether disclosing information about the nature of the endpoints that support the indications for oncology products helps consumers understand the drug's efficacy. This objective complements OPDP's research examining disclosing information about FDA's accelerated approval pathway to consumers (May 8, 2019, 84 FR 20148) and OPDP's research on disclosing oncology information to healthcare professionals (OMB control number 0910-0864--Disclosures of Descriptive Presentations in

Professional Oncology Prescription Drug Promotion). Although these studies all contribute to our knowledge of the communication of cancer treatment information, the current study specifically examines particular endpoints that are well-known to the professional oncology community and are now used in DTC advertising.

Because of the length of some indications, sponsors sometimes convey some of the indication in superimposed text rather than in the audio in the TV ads. The second objective is to test whether consumers adequately comprehend indication statements when portions of the indication are presented only in the superimposed text of television ads while other information is conveyed in the audio. This objective extends OPDP's previous research on the use of dual-modality *risk* presentations (presenting the information in two modes at the same time; OMB control numbers 0910-0634--Experimental Evaluation of the Impact of Distraction, 0910-0652--Experimental Study: Toll-Free Number for Consumer Reporting of Drug Product Side Effects in Direct-to-Consumer Television Advertisements for Prescription Drugs, and 0910-0772--Eye Tracking Study of Direct-to-Consumer Prescription Drug Advertisement Viewing) to the context of *indication* statements. This previous research supports the use of dual modality to increase consumers' understanding of risk information (January 27, 2012, 77 FR 4273) (Refs. 2 and 3).

2. Purpose and Use of the Information Collection

Cognitive interviews and pretesting will be used to refine the study materials and procedures. Study 1 will examine DTC television ads with different oncology endpoints and disclosures designed to better-describe these endpoints to consumers. Study 2 will examine various ways of presenting complicated oncology indications to consumers in DTC television ads. Part of FDA's public health mission is to ensure the safe use of prescription drugs; therefore, it is important to communicate the benefits and risks of prescription drugs to consumers as clearly and usefully as possible.

3. Use of Improved Information Technology and Burden Reduction

Automated information technology will be used in the collection of information for this study. One hundred percent (100%) of participants in the pretests and main studies will self-administer the survey via the Internet, 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. Burden will be reduced by recording data on a one-time basis for each participant, and by keeping surveys to less than 20 minutes.

4. Efforts to Identify Duplication and Use of Similar Information

We conducted a literature search to identify duplication and use of similar information. The available literature yields little information on this topic.

5. Impact on Small Businesses or Other Small Entities

There will be no impact on small businesses or other small entities. The collection of information involves individuals, not small businesses.

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

There are no special circumstances for this collection of information.

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

In the Federal Register of June 21, 2019 (84 FR 29213), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received four submissions that were PRA-related. Within those submissions, FDA received multiple comments, which the Agency has addressed below.

(Comment) One comment voiced support for the current study and recommended future research to examine how DTC advertising addresses value-based care.

(Response) We thank the commenter for their support for this study and will consider their recommendations for future research.

(Comment) Two comments suggested limiting study recruitment to patients already diagnosed with and/or treated for cancer and their caregivers and family members. The comments suggested that patients who have already been diagnosed and/or treated are likely to have a higher level of disease comprehension than the general population and that this would make the results more reflective of the population seeking cancer treatment information.

(Response) We chose a general population sample for the first study on this topic because of concerns about being able to recruit a sufficient number of participants if we selected a cancer-specific sample. However, we agree that in the future, a small, carefully-designed replication study with cancer patients and their caretakers and family members would be valuable. Prior to this study, we conducted both general-population focus groups and cancer-survivor focus groups. We will use the information gleaned from these focus groups to consider the ways in which these groups do and do not differ when discussing the limitations of the study's general-population sample. We will also ask participants if

they have been diagnosed with cancer and whether they are a caregiver for someone with cancer.

(Comment) One comment suggested that the duration of the study ads be consistent with the duration of real-life ads.

(Response) The duration of the study ads will be consistent with the duration of real-life ads.

(Comment) One comment suggested adding screening questions to assess whether participants watch television, whether they watch ads, and how they are most likely to view DTC television ads.

(Response) We added questions about television viewing to the end of the questionnaire.

(Comment) One comment agreed with the hypothesis that consumers who view an ad with material information in both audio and text will have greater retention of that information. However, they do not believe there is enough time in a television ad to include the full indication in the audio, and they do not believe it is necessary because they believe the primary objective of ads is to raise product awareness so that consumers can seek additional information about the drug from health care providers or adequate provision sources.

(Response) The duration of the ads used in this study will be consistent with those currently airing on television and that duration will be sufficient to include all material information (Ref. 4) in the audio and text. While consumers may be able to find this information through other sources, the intent of this study is to determine what effect, if any, the material information has when delivered as an integrated part of the DTC advertisement.

(Comment) One comment notes that the Study 1 results would not be generalizable to an ad for a drug that has overall survival data but advertises with claims about overall response rate or progression-free survival.

(Response) We agree that our results would not generalize to this situation.

(Comment) One comment suggested wording changes for the claims in Study 1, including deleting “decrease the number of detectable cancer cells in the body” from the multiple myeloma overall response rate, describing progression-free survival as “delayed disease progression or live longer without cancer getting worse,” and using the disclosure statement “clinical trials are still ongoing to determine if there is an overall survival benefit with Drug X.”

(Response) We thank the commenter for these suggestions and will consider them, along with the feedback from our focus group participants, when we finalize the language for the main study.

(Comment) One comment suggested changes to the Study 1 questionnaire, including rewording Q2 to make it clearer, adding a “don’t know” response to Q4, removing Q5 because it is speculative, and rewording Q7 from “any side effects it may have” to “side effects described in the ad.”

(Response) We revised Q2 to ask what the drug can do for people, added a “don’t know” response to Q4, and edited Q7 as suggested. Q5 will only be asked of participants who already report that the drug will help people live longer; its purpose is to gauge their perception of how much longer people will live. We plan to keep this item, but we will cognitively test and pretest it to determine whether it should be revised or deleted.

(Comment) One comment suggested changes to the Study 2 questionnaire, including changing Q2 to ask about what disease the drug treats rather than who it is for, so it is less similar to Q4, adding Q10 from the Study 1 questionnaire to measure behavioral intentions, and revising Q7-Q12 because they are too detailed and require the respondent to recall a lot of information from the ad.

(Response) We agree that Questions 2 and 4 are similar; they are both designed to elicit responses related to the material information, not just the disease the drug is indicated to treat. However, Question 4 will only be asked of participants who respond “no” to Question 3. We believe this will provide context for those participants, but we will ask whether this series of questions is too repetitive or confusing in cognitive interviews, and we will review participants’ responses in a pretest. We will add Q10a and Q10b to the Study 2 questionnaire. Questions 7 through 12 are designed to measure participants’ retention and understanding of the material information. We will cognitively test and pretest the items to determine whether they should be revised or deleted.

External Reviewers

In addition to public comment, OPDP sent materials and received comments from two individuals for external peer review in 2019. These individuals are:

1. Gregory Abel, MD. Senior Physician; Director, Older Adult Hematologic Malignancy Program, Dana-Farber Cancer Institute; Associate Professor of Medicine, Harvard Medical School

2. Stacy Gray, MD. Physician; Associate Clinical Professor, Division of Clinical Cancer Genomics, Department of Population Sciences, City of Hope; Associate Clinical Professor, Department of Medical Oncology and Therapeutics Research, City of Hope

9. Explanation of Any Payment or Gift to Respondents

Cognitive interviews participants will receive \$75 for their one-hour in-person interviews. For completing the pretests and main studies, participants will receive approximately \$1.50 in points. Internet panelists are compensated for taking part in surveys using a structured incentive scheme that reflects the length of the survey and the nature of the sample.

Following OMB's "Guidance on Agency and Statistical Information Collections," we offer the following justification for our use of these incentives.

Data quality: Because providing a market-rate incentive should increase response rates, it should also significantly improve validity and reliability to an extent beyond that possible through other means. Previous research suggests that providing incentives may help reduce sampling bias by increasing rates among individuals who are typically less likely to participate in research (such as those with lower education (Ref. 4)). Furthermore, there is some evidence that using incentives can reduce nonresponse bias in some situations by bringing in a more representative set of respondents (Refs. 5-6). This may be particularly effective in reducing nonresponse bias due to topic saliency (Ref. 7).

Past experience: The Internet vendor for this study has conducted hundreds of health-related surveys in the past year. The Internet vendor offers incentives to its panel members for completing surveys, with the amount of incentive for consumer surveys determined by the length of the survey. Their experience indicates that the requested amount is reasonable for a 20-minute survey.

Reduced survey costs: Recruiting with market-rate incentives is cost-effective. Lower participation rates will likely impact the project timeline because participant recruitment will take longer and, therefore, data collection will be slower and more costly.

10. Assurance of Confidentiality Provided to Respondents

No personally identifiable information will be sent to the FDA. The contractor, RTI, will maintain all information that can identify individual respondents in a form separate from the data provided to the FDA. The information will be kept in a secured fashion that will not permit unauthorized access. Confidentiality of the information submitted is protected from disclosure under the Freedom of Information Act 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 be approved by the FDA's Institutional Review Board before collecting any information.

All respondents will be assured that the information will be used only for research purposes and will be kept secure to the extent allowable by law, as detailed in the consent forms (Appendices A and B). The study instructions will include information explaining this, and respondents will be assured that their answers to screener and survey questions will not be shared with anyone outside the research team and their names will not be reported with responses provided. Respondents will be told that the information obtained from all the surveys will be reported in aggregate in a summary document so that details of individual questionnaires cannot be linked to a specific respondent.

All electronic data will be maintained in accordance with the Department of Health and Human Services' (DHHS's) ADP Systems Security Policy, as described in the DHHS ADP Systems Manual, Part 6, Chapters 6-30 and 6-35. Also, all data will be maintained in accordance with the FDA Privacy Act System of Records #09-10-0009 (Special

Studies and Surveys on FDA Regulated Products). All study files will be stored on password-protected computers at both FDA and RTI and destroyed within 3 years of the study's end date.

Additionally, for the pretests and main studies, the Internet panel includes a privacy policy that is easily accessible from any page on the site. A summary of 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.

11. Justification for Sensitive Questions

This data collection will not include sensitive questions. The complete list of questions is available in Appendices C and D.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Cognitive Interview screener	30	1	30	0.08 (5 minutes)	2.4
Cognitive Interviews	18	1	18	1 (60 minutes)	18
Pretests 1 and 2 screener	200	1	200	0.08 (5 minutes)	16
Pretests 1 and 2	120	1	120	0.33 (20 minutes)	39.6
Study 1 screener	1,167	1	1,167	0.08 (5 minutes)	93.36
Study 1	700	1	700	0.33 (20 minutes)	231
Study 2 screener	867	1	867	0.08 (5 minutes)	69.36
Study 2	520	1	520	0.33 (20 minutes)	171.6
Total					641.32

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

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

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

The total estimated cost to the Federal Government for the collection of data is \$652,824 (\$130.565 per year for 5 years). This includes the costs paid to the contractors to program the study, draw the sample, collect the data, and create a database of the results. The contract 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 data, and to draft a report (\$73,000 over 5 years).

15. Explanation for Program 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 Part B 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 2. – Project Time Schedule

Task	Estimated Number of Weeks after OMB Approval
Cognitive interviews conducted	8 weeks
Pretest data collected	30 weeks
Main study data collected	60 weeks

Data collection will begin after the Census response period ends on August 30, 2020.

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.

References

1. Kim, J., J. Gao, L. Amiri-Kordestani, et al., "Patient-Friendly Language to Facilitate Treatment Choice for Patients with Cancer." *The Oncologist*, 10.1634/theoncologist.2018-0761, 2019. Available from: <http://theoncologist.alphamedpress.org/content/early/2019/05/16/theoncologist.2018-0761.short?rss=1>
2. Aikin, K.J., A.C. O'Donoghue, C.M. Squire, et al., "An Empirical Examination of the FDAAA-Mandated Toll-Free Statement for Consumer Reporting of Side Effects in Direct-to-Consumer Television Advertisements." *Journal of Public Policy & Marketing*, 35(1):108-123, 2016.
3. Sullivan, H.W., V. Boudewyns, A.C. O'Donoghue, et al., "Attention to and Distraction from Risk Information in Prescription Drug Advertising: An Eye-Tracking Study." *Journal of Public Policy & Marketing*, 36(2):236-245, 2017.
4. Gyll, M., R. Spoth, R., and C. Redmond, "The Effects of Incentives and Research Requirements on Participation Rates for a Community-Based Preventive Intervention Research Study." *Journal of Primary Prevention*, vol. 24(1), pp. 25-41, 2003.
5. Castiglioni, L., and K. Pforr, "The effect of Incentives in Reducing Non-Response Bias in a Multi-Actor Survey." Presented at The 2nd Annual European Survey Research Association Conference, Prague, Czech Republic, June, 2007.
6. Singer, E., "Nonresponse Bias in Household Surveys." *Public Opinion Quarterly*, vol. 70(5), pp. 637-645, 2006.
7. Groves, R., M. Couper, S. Presser, E. Singer, R. Tourangeau, G. Acosta, and L. Nelson, "Experiments in Producing Nonresponse Bias." *Public Opinion Quarterly*, vol. 70(5), pp. 720-736, 2006.