

Hearing, Aging, and Direct-to-Consumer Television Advertisements

0910-NEW

SUPPORTING STATEMENT

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 FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the 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.

Older adults use a disproportionate number of prescription drugs (1) and watch more television than other age groups. (2) Age-related changes in hearing are common (3-5) and, depending on their severity, influence the understanding of speech. DTC television advertisements (ads) contain large amounts of complex information about prescription drug treatments that may be particularly relevant to a population that is experiencing some level of hearing loss. Moreover, much of the information in these ads is conveyed by voiceover, meaning that the audio channel is the only way to receive the information. Although people with serious hearing loss may compensate by using closed captioning (which may or may not be available for ads) or hearing aids, some individuals experience the effects of hearing loss without realizing that it is the cause and others choose not to use external compensatory aids (6). For these reasons, FDA is proposing research to investigate how people at various ages and levels of hearing ability comprehend DTC ads.

Sponsors of DTC ads cannot control the hearing abilities of their audiences. Nonetheless, researchers have identified several aspects of DTC ads within their control that influence the understanding of speech in individuals who experience aging-related hearing loss. First, frequency thresholds differ as people age—that is, older adults are not able to hear higher frequencies as well (7, 8). Second, DTC television ads contain a risk statement of the most serious and most common side effects, called “the major statement.” FDA regulations require that the major statement must be included in at least the audio portion of the ad (9). The risks of a medical product often include highly technical medical terms that should be transformed into consumer-friendly language to convey the risks appropriately. This is easier in some cases than in others. In addition, there are techniques to help reduce the complexity of the major statement, such as maintaining active voice, reducing instances where words need clarification from other

later words in the broadcast, and using shorter sentences. Third, television ad spots are typically bought in increments of 15 seconds, leading to a preponderance of 30- and 60-second ads, and some 75-second ads when risk information is especially dense. In order to fit the required information into this time frame, the audio presentation speed may be adjusted to be faster or slower. Research has shown that fast speech is more difficult to understand than slower speech, even for healthy young adults (10).

Thus, we propose to examine the effects of three aspects of DTC ads (voice frequency, complexity of major statement, speed of major statement) on the comprehension of the ads among four different age groups of individuals. Because hearing losses begin to occur as people age, we will examine a group of middle-aged adults (40-50 years), young-old adults (60-74 years), and old-old adults (75+ years), and a group of young adults (18-25 years) as a control. The use of young adults as a control group is common in studies of age changes in memory, cognition, and hearing (11-14). Our primary outcomes will be verbatim and gist memory, and confidence in memory judgments, but we will also seek to apply findings from previous studies showing age changes in hearing ability (15, 16) to the particular situation of DTC ad viewing. It is important to note that despite hearing and cognitive losses, older adults generally use linguistic context well. That is, they are as good as or even better than younger adults at using context to determine what they are hearing. They are also skilled at using the intonation of words, which words are stressed, where pauses occur, and how words are lengthened before pauses, all components of something called the prosody of language (17). Thus, even though older adults generally perform worse than younger adults with rapid speech, older adult recall of sentences is still relatively high, at 80%, presumably because older adults use linguistic context. Moreover, to approximate real DTC ads, participants will view an ad that has a typical amount of superimposed text, some of which may repeat the information in the audio. Our task thus involves viewing realistic DTC ads, which provide more context than lists of unrelated words or sentences, as often found in laboratory experiments. Thus, it is an open question whether hearing loss will impede the comprehension of DTC ads or whether the ability to make use of context will counteract these decrements across the lifespan.

General Research Questions

1. How do hearing and cognitive declines in older adults affect comprehension of DTC television ads, and the major statement in particular?
2. How do the frequency, speed, and complexity of the major statement influence the comprehension of the major statement and DTC ads as a whole?
3. How do hearing and cognitive declines interact with the frequency, speed, and complexity of the major statement to affect the comprehension of DTC ads?

2. Purpose and Use of the Information Collection

The purpose of this project is to investigate factors in television DTC ads that may help or hinder the communication of risk information. Although older adults are by no means a monolith, they often have normal age-related hearing loss, use more prescription drugs than other members of the population, and watch a disproportionate amount of television. Given this relevant population, and the fact that everyone in the population will enter this category at some point, it is important to assess how risks can be best communicated under varying levels of ability and conditions. Part of FDA's public health mission is to ensure the safe use of prescription drugs; therefore it is important to communicate the risks and benefits of prescription drugs to consumers as clearly and usefully as possible. Taking into account widespread characteristics of the viewing population is part of this mission.

3. Use of Improved Information Technology and Burden Reduction

Automated information technology will be used in the collection of information for this study. After the audiometric assessment, one hundred percent (100%) of participants will self-administer the 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. Burden will be reduced by recording data on a one-time basis for each participant, and by keeping the written parts of surveys to less than 30 minutes in both the pretests and main study.

4. Efforts to Identify Duplication and Use of Similar Information

Although the literature revealed a rich background on which to base the current research, we found no studies that have examined the issues we propose to study.

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

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 accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of June 25, 2015 (80 FR 36545). Two comments were received. We will address the issues raised in each comment subsequently, beginning with those of AbbVie.

Comment: The Agency should place research results in the context that older adults are diverse and increasingly involved in new technologies.

Response: We agree that older adults are not homogenous. Regarding our focus on television ads, the fact that older people are increasingly able to look at advertisements online does not eliminate the fact that many continue to be exposed to television advertising and that advertising is not always presented with closed-captioning. We will ensure that we frame our research results in the proper context.

Comment: A bias may exist in asking survey participants to self-declare “a hearing loss” as hearing loss can be viewed as a negative consequence/indicator of aging. Thus, those in older age groups may underestimate their true hearing loss as well as the need for some type of hearing aid or assistance.

Response: We will not rely solely on self-reported hearing loss. We have arranged for trained audiologists to conduct in-person audiological assessments with validated approaches as well.

Comment: As the Agency plans to test multiple variables and age groups, it is important to test these variables independently; testing only in combination with other variables or aggregating across age groups or variables may mask true drivers. Individual cells with a sample size of 33 are too small to compare to other individual cells. A *minimum* of 50 is necessary to understand individual variables within and across age groups.

Response: We are aware of no statistical or research standard that specifies that groups must contain 50 individuals. We conducted power analyses (see Part B) to determine that 33 individuals per cell is adequate and statistically defensible for our study goals.

Comment: The Introduction and Debriefing state that the study ‘involves information about a drug that is not yet available for sale.’ However, survey questions 8, 10, 18, 30 refer to respondents having access to the drug with verbiage such as “even if you have never taken the drug,” “ask the doctor to prescribe Drug X,” and “have you seen any

advertising for Drug X before today.” Yet none of these could happen if Drug X is not yet available for sale.

Response: We acknowledge that we are posing hypothetical possibilities in some questions that respondents should not have previously experienced. We have changed the introduction to reference “advertising for a new product” rather than “information about a drug that is not yet available for sale.” However, using language such as “even if you have never taken the drug” will assure respondents that their answers are welcome even if they do not have direct experience with the drug. The question about asking the doctor to prescribe the drug measures behavioral intentions, not actual behavior related to the drug. The question asking whether they have seen an ad for the drug will allow us to capture false reporting tendencies.

Comment: Question 13 refers to ‘claims’. We suspect ‘claim’ is not as readily understood by consumers as is the more general term ‘information’ used in Question 17. Also, there are only minor differences in the wording of two recognition choices for Questions 13a vs. 13b; was this intended?

Response: Thank you for your close review of the questionnaire. The two ad versions (simple and complex) are designed to include the same information but stated differently. Thus, these two questions (then 13a and 13b; now 14a and 14b) should be similar in nature and only two of the subitems are stated differently (#2 and #4). Participants will see either question 14a OR 14b depending on their experimental condition.

The next responses address issues raised by Eli Lilly and Company.

Comment: What are the objectives of the pretest? The proposed sample size for the pretest ($n = 640$) appears excessive to test the procedural flow and survey procedures.

Response: The pretest will be used to assess whether the instrument as a whole as well as individual sections work equally well across respondent groups (e.g., age). In addition, the pretest will include manipulation checks as a main function of the task. The sample size for the pretest (640 participants equally split across the four age groups) was determined based on an assumption of a need for 80% power with an alpha of 0.10 to detect a small effect size. With eight experimental conditions across four age groups, the calculation resulted in a need for 20 individuals per cell, or 640 total participants.

Comment: The age groups selected are logical, but why are people aged 51-59 excluded and why are 18-25 year olds selected as the control? “Although 18-25 year olds as a control group might be common in studies of age changes in memory and hearing, this

age group does not seem as relevant for pharmaceutical advertisements about cholesterol lowering drugs.” Also, the age group of 60-75 should be capped at 74 to make sure the groups are mutually exclusive.

Response: We agree that there is a likely slow progression of age-related hearing loss across the lifespan and if our focus was on this progression, we would want to include 50-59 year olds. The approach we are taking will ensure that we can see contrasts between younger and older people. We also have a middle-aged group to see whether any contrast between the youngest and oldest groups appears to be relatively linear or is curvilinear. Including the 50-59 year age group would not add substantial information to this design, although we do acknowledge that we will not be able to address when decline occurs if it appears to drop dramatically from our middle-aged group to our young-older age group.

We are including participants between 18-25 years as a baseline for our measurement of hearing ability, as that is an integral part of this research. The entire sample will be drawn from the general population, and although there may be distinct differences in potential interest in the advertised drug, we feel the addition of this younger group is worth measurement. We have included a question to assess whether participants have been diagnosed with high cholesterol and can use that as a proxy for interest, regardless of age. Thank you for pointing out the need to cap the young-old age group at 74 rather than 75 to ensure the groups are mutually exclusive.

Comment: We advise caution in reporting results for individual cells (e.g., 40-50 year old respondents who see an ad with a male voice, simple statement, low speed) due to the low sample size ($n = 33$). We recommend excluding results for a sample that has fewer than 50 respondents.

Response: We are aware of no statistical or research standard that specifies that groups must contain 50 individuals. We conducted power analyses to determine that 33 individuals per cell is adequate and statistically defensible for our study goals.

Comment: Because the Summary Brief of the project does not adequately provide details regarding the individual ads to be tested, we seek clarification on whether multiple ads will be tested and the variability of ad content. With greater variability of the ads tested, there is potential for a new source of bias to be introduced into the study.

Response: We agree that extraneous variability should be kept to a minimum. For this study, the same base ad will be manipulated such that all else remains constant except for the gender of the voiceover announcer, the complexity of the risk information, and the speed at which it is stated. The visuals will be as similar as possible except for minimal

differences in length of time on screen to account for the different lengths of the voiceover. The same male and female voice actors will record all variations of the ad.

External Reviewers

In addition to public comment, OPDP solicited peer-review comments from academic researchers in fields relevant to the communication of DTC prescription drug information. We received responses and incorporated the thoughts of the following individuals:

Dr. Susan Blalock, University of North Carolina at Chapel Hill, School of Pharmacy

Dr. Robert McKeever, University of South Carolina, School of Journalism and Mass Communications

9. Explanation of Any Payment or Gift to Respondents

Participants who complete the in-person hearing evaluation and who participate in the survey (pre-test and main study) or survey and interview (cognitive interview) will receive a monetary incentive. Providing a monetary incentive is consistent with industry standards and expectations, and is based on the amount of time the participant spends in the study, and what is required of them. Monetary incentives are used to ensure compliance with scheduling and protocol, and to ensure adequate recruitment rates.

We estimate participation in the pre-test and main studies in Raleigh, NC will take 45 minutes, including time for the hearing evaluation and survey completion. Recruitment facilities have confirmed that \$50 is the appropriate standard incentive for consumers participating in studies lasting 30 to 45 minutes.

We expect participation in the cognitive interviews in the Washington, DC area to last 60 minutes. According to recruitment facilities, \$75 is the appropriate standard incentive for consumers participating in studies lasting 60-90 minutes. This is consistent with other research conducted by RTI, including recent and current studies with FDA, where \$75 has been used as the incentive for a 60 minute study (OMB Control Number 0910-0695, OMB Control Number. 0910-0707, OMB Control No. 0910-0743, OMB Control Number 0910-0497).

These amounts have been carefully considered for their appropriateness to ensure the ability to attract a reasonable cross-section of participants, including reasonable diversity in age, income, and education.

10. Assurance of Confidentiality Provided to Respondents

All participants will be provided with an assurance of privacy to the extent allowable by law. See Appendix A for the consent form.

No personally identifiable information will be sent to FDA. All information that can identify individual participants will be maintained by the independent contractor in a form that is separate from the data provided to FDA. For all data, alpha numeric codes will be used instead of names as identifiers. These identification codes (rather than names) are used on any documents or files that contain study data or participant responses.

The information will be kept in a secured fashion that will not permit unauthorized access. Throughout the project, any hard-copy files will be stored in a locked file cabinet in the Project Manager's office, and electronic files will be stored on the contractor's password-protected server, which allows only project team members access to the files. 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 have been approved by FDA's Institutional Review Board (Research Involving Human Subjects Committee, RIHSC). These methods are currently under review by RTI's Institutional Review Board. We will wait for approval prior to collecting any information.

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. 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).

11. Justification for Sensitive Questions

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

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

For both the pretests and main study, the questionnaire is expected to last no more than 30 minutes. This will be a one-time (rather than annual) collection of information. FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden					
Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response ¹	Total Hours
Cognitive Interview screener	96	1	96	0.08 (5 minutes)	8
Cognitive Interviews	9	1	9	1 (60 minutes)	9
Pretest screener	1,280	1	1,280	0.08 (5 minutes)	102
Pretest	640	1	640	0.75 (45 minutes)	480
Main Study Screener	2,112	1	2,112	0.08 (5 minutes)	169
Main Study	1,056	1	1,056	0.75 (45 minutes)	792
Total	5,193	1	5,193	--	1,560

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 \$994,588 (\$248,647 per year for four years). This includes the costs paid to the contractors to manipulate the stimuli, program the study, draw the sample, collect the data, and create and analyze 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 resultant data, and to draft a report (\$96,000; 8 hours per week for four 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 section 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 completed	3 weeks
Pretest completed	11 weeks
Main study data collected	41 weeks
Final methods report completed	44 weeks
Final results report completed	48 weeks
Manuscript submitted for internal review	56 weeks
Manuscript submitted for peer-review journal publication	64 weeks

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.