Animation in Direct-to-Consumer Advertising

OMB Control No. 0910-NEW

SUPPORTING STATEMENT

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

1. Respondent Universe and Sampling Methods

The survey sample will be drawn from Research Now's database. Research Now's opt-in online survey panel is demographically balanced, including racial and ethnic minorities, a wide range of different age groups, and individuals with relatively less educational attainment. They recruit panel members through a combination of e-mail, online marketing, and by invitation, with over 300 diverse online and offline affiliate partners and targeted website advertising. By using multiple recruitment methods, Research Now is able to recruit a diverse set of representative consumers and decision makers to participate in their panels. Panel inclusion is by invitation only, and Research Now invites only pre-validated individuals with known characteristics to participate in the consumer panels.

Using Research Now's database, we will recruit 1,800 individuals for the pretest and main study combined. (See **Appendix B** for the Screening Instrument). **Table 1** shows the current sample design and sample sizes.

Table 1. Sample Design and Sample Sizes

Category	Number of Participants
Pretest	300
Main study	1,500

The sample will be drawn from panel members who report a diagnosis of chronic dry eye or psoriasis. Although Research Now's database is always growing and changing, the current demographic distribution of the panel is presented in **Table 2**.

Table 2. Demographic Distribution of Sufferers of Chronic Dry Eye and Psoriasis in Research Now's Respondent Database

	Percent	
Demographic Characteristic	**Chronic Dry Eye**	**Psoriasis**

	Percent	
Demographic Characteristic	**Chronic Dry Eye**	**Psoriasis**
Gender		
Female	71%	61%
Male	29%	39%
Age		
18–24	2%	4%
25–34	19%	20%
35–44	19%	20%
45-54	21%	20%
55-64	22%	20%
65 or over	16%	15%
Education		
High school graduate or less	8%	9%
Some college	24%	26%
College or technical school graduate	41%	40%
Graduate school	27%	25%
Total	**100%**	**100%**

2. Procedures for the Collection of Information

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

General Research Questions

1. How does consumer processing of a DTC prescription drug ad differ depending on whether the ad is live-action, rotoscoped, or animated?
2. Does consumer processing differ depending on whether the sufferer, the disease, or the benefit is the focus of the animation?

Design Overview

To test these research questions, we will conduct two experiments. Both experiments will be examined in two different medical conditions: chronic dry eye, and psoriasis. The mock drugs we will create for these conditions mimic currently available medications and were chosen for their variance in serious side effects, i.e., medications for psoriasis have very long, serious lists of risks and side effects, whereas chronic dry eye medications have relatively few risks and side effects.

The first experiment will examine whether animation itself influences consumer processing, defined as consumer recall of risks and benefits, perceptions of risks and benefits, and attitudes and emotional responses to the ad, the brand, the product, and the character (Table 3. We will examine two different types of animation in addition to a control ad which will be shot with live actors: an "in-between" animation technique, rotoscoping, in which live scenes are drawn to look animated, and full animation with nonhuman characters. The live action and rotoscoped ad will be identical except for the rotoscope treatment. The animated ad will follow the theme and message as closely as possible within the limitations of animation itself. The benefits and risks of the product will be identical, although the ad's storyline may vary somewhat to account for a nonhuman protagonist.

Table 3. Experiment 1: Animation design.

Type of Animation			
Medical Condition	Non-human sufferer	Rotoscoped human sufferer	Human sufferer
Chronic Dry Eye	•	•	•
Psoriasis	•	•	•

The second experiment will examine whether the object of the animation influences consumer processing of the ad (Table 4), defined as consumer recall of risks and benefits, perceptions of risks and benefits, and attitudes and emotional responses to the ad, the brand, the product, and the character. The animation will focus on the animated character who will personify either the sufferer of the medical condition, the disease itself, or the benefit from the drug. In this study, all ads will contain the same kind of full animation and the general theme will be as similar as possible, accounting for the variations in focus of character. The experiments will be conducted concurrently, and the same participants in the nonhuman sufferer groups will be part of both.

Table 4. Experiment 2: Personification design.

Non-human Personification			
Medical Condition	Sufferer	Disease	Benefit
Chronic Dry Eye	•	•	•
Psoriasis	•	•	•

In both cases, a professional firm will create all ads such that they are indistinguishable from currently running DTC ads.

Pretesting will take place before the main study to evaluate the procedures and measures used in the main study. We will recruit adults who have experienced chronic dry eye or psoriasis. We will exclude individuals who work in healthcare or marketing settings because their knowledge and experiences may not reflect those of the average consumer. A priori power analyses revealed that we need 300 participants for the pretest to obtain 80% power to detect a moderately small effect size. Each experiment will include 30 participants per condition for a total of 180 participants each, but 60 of those in the nonhuman sufferer conditions will overlap between the two experiments. We will need 1,500 unique participants for the main study to obtain 90% power to detect a moderately small effect size. There will be 150 participants per condition for a total of 900 participants in each experiment, with 300 participants in the overlapping nonhuman sufferer conditions.

In both experiments, participants who have been diagnosed with either chronic dry eye or psoriasis will be recruited via opt-in Internet panel to watch one ad for a prescription drug that treats their medical condition. In experiment 1, participants will be randomly assigned to view either a live-action, rotoscoped, or fully animated ad. All themes in experiment 1 will focus on the main character as the sufferer of the condition. In experiment 2, participants will be randomly assigned to a personification condition: sufferer, disease, or benefit. All ads in experiment 2 will be fully animated. Participants will watch the ad once and then answer an online survey with questions addressing recall of risks and benefits, perceptions of risks and benefits, and attitudes and emotional responses to the ad, the brand, the product, and the character. The questionnaire is available upon request. Participation is estimated to take approximately 25 minutes.

Specific Research Questions and Hypotheses

We will focus on answering the following research questions in Experiment 1:

Research Question 1A. Does animation in DTC television advertisements influence the processing of prescription drug information?

Research Question 1B. Does the impact of animation on processing of prescription drug information in DTC television advertisements vary by medical condition?

Additionally, we will test hypotheses related to several of our dependent variables. Although we incorporate two medical conditions into the study design, we view analyses involving the medical-condition factor as essentially exploratory. Characteristics of the medication profiles and

ads will not be controlled *across* medical conditions. As a result, significant effects by medical condition — especially interaction effects — would be open to multiple interpretations. With this in mind, our theoretical rationale for Experiment 1 focuses on advertising effects by different types of animation.

Experiment 1 hypotheses stem from theory and previously observed relationships between animation, attitudes, and information processing. Animated characters are often used to grab attention, increase ad memorability, and enhance persuasion to ultimately drive behavior[1]. However, there is reason to expect that different types of animation techniques will elicit different reactions from an audience. Following Clayton and Leshner[2], we expect that an ad featuring a rotoscoped human character will activate an avoidance response, leading participants to develop an unfavorable attitude toward the character and give less attention to the ad. The mechanism underlying these effects draws from Uncanny Valley Theory[3], which argues that characters that closely resemble human beings, but are eerily unnatural in movement or appearance, evoke discord in the viewer and a sense of revulsion. In turn, the unpleasant emotional response evoked by the rotoscoped character is expected to activate the aversive motivational system[4], leading to withdrawal from the ad, lower attention, and reduced memory of message content[5]. An animated nonhuman character, on the other hand, is not likely to evoke the eerie feelings expected of a rotoscoped human character.

Lastly, research on the affect heuristic provides a basis for Experiment 1 hypotheses concerning the influence of participant attitudes on perceptions of risk and benefit. Here, affect refers to "the specific quality of goodness or badness (a) experienced as a feeling state (with or without consciousness) and (b) demarcating a positive or negative quality of a stimulus"[6]. Notably, by this definition, *affect* is conceptually indistinct from *attitude*, or "a psychological tendency

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[1] Bell JA. Creativity, TV commercial popularity, and advertising expenditures. International J Adv. 1992;11(2):165–172; Diao F, Sundar, SS. Orienting response and memory for Web advertisements: Exploring effects of pop-up window and animation. Communication Res. 2004;31:537–567; Fox J, Lang A, Chung Y, Lee S, Schwartz N, Potter D. Picture this: Effects of graphics on the processing of television news. J Broadcasting Electronic Media. 2004;48:646–674; Garettson JA, Neidrich RW. Spokes-characters: Creating character trust and positive brand attitudes. J Adv. 2004;33(2):25-36; Heiser RS, Sierra JJ, Torres IM. Creativity via cartoon spokespeople in print ads. J Adv. 2008; 37(4):75-84; Leiner M, Handal G, Williams D. Patient communication: a multidisciplinary approach using animated cartoons. Health Educ Res. 2004;19(5):591-595; Luo JT, McGoldrick P, Beatty S, Keeling K A. (2006). On-screen characters: their design and influence on consumer trust. J Services Market. 2006;20(2):112-124.

[2] Clayton RB, Leshner G. (2015). The uncanny valley: The effects of rotoscope animation on motivational processing of depression drug messages. J Broadcasting Electronic Media. 2015;59(1):57-75.

[3] Mori M. (1970/2012). The uncanny valley (K. F. MacDorman & Norri Kageki, Trans.). IEEE Robotics and Automation. 1970/2012;19:98–100. doi:10.1109/MRA.2012.2192811.

[4] Cacioppo J T, Gardner WL, Berntson GG. The affect system has parallel and integrative processing components: Form follows function. J Personality Soc Psychol. 1999;76:839-855.

[5] Lang A. The limited capacity model of mediated message processing. J Communication. 2000;50:46–70.

[6] Slovic P, Peters E, Finucane ML, MacGregor DG. (2005). Affect, risk, and decision making. Health Psychol. 2005;24:S35–S40, p S35.

expressed by evaluating a particular entity with some degree of favor or disfavor"[7]. The affect heuristic refers to a mental short-cut whereby judgments about an object (e.g., perceived risk and benefit) are based on a readily available affective impression of it, rather than retrieval and integration of information about the object's relevant attributes and features. In short, lacking sufficient motivation or ability, people who feel favorably about a stimulus will make judgments and decisions aligned with that positive affect (e.g., greater perceived benefits, fewer risks); people who feel unfavorably about it will make judgments and decisions aligned with that negative affect (e.g., lower benefits, greater risks)[8]. Indeed, the affect heuristic has been cited as an explanation for the documented inverse relationship between perceived risks and benefits[9]. In this study, the affect heuristic also has implications for the transference of evaluative judgments from one object (e.g., advertising character) to another object (e.g., advertisement, project).

Benefit Recall and Recognition

Hypothesis 1.1 Participants who see the rotoscoped ad will show lower recall and recognition of benefit information than those who see the nonhuman sufferer ad or the live-action ad (i.e., no animation).

Specific RQ 1.1 Will participants who see the nonhuman sufferer ad show greater recall and recognition of benefit information than those who see the live-action human sufferer ad (i.e., no animation)?

Risk Recall and Recognition

Hypothesis 1.2 Participants who see the rotoscoped ad will show lower recall and recognition of risk information than those who see the nonhuman sufferer ad or the live-action ad (i.e., no animation).

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[7] Eagly AH, Chaiken S. *The psychology of attitudes*. 1993. Ft. Worth, TX: Harcourt, Brace, & Janovich.

[8] An important assumption underlying this logic is that basing these risk and benefit judgments directly on the risk and benefit information given in the ad would require more effort than participants are able or willing to expend. The affect heuristic is less likely to come into play when, for example, risk and benefit information is readily available and people have sufficient ability and motivation to integrate that information when making a judgment about risk/benefit (e.g., Sloman SA. (2002). Two systems of reasoning In Gilovich T, Griffin D, Kahneman D (Eds.), *Heuristics and biases: The psychology of intuitive judgment.* 2002. Cambridge, UK: Cambridge University Press.).

[9] Alhakami AS, Slovic P. A psychological study of the inverse relationship between perceived risk and perceived benefit. Risk Analysis. 1994;14(6):1085-1096; Finucane ML, Alhakami A, Slovic P, Johnson SM. The affect heuristic in judgments of risks and benefits. J Behav Decision Making. 2000;13(1): 1-17.

Specific RQ 1.2 Will participants who see the nonhuman sufferer ad show greater recall and recognition of risk information than those who see the live-action human sufferer ad?

Overall ad comprehension

Hypothesis 1.3 Participants who see the nonhuman animated ad will show greater overall ad comprehension than those who see the live-action ad. Participants who see the rotoscoped ad will show lower comprehension than those who see the live-action ad.

Perceived Benefits

Hypothesis 1.4 Participants who see the nonhuman animated ad will have greater perceived benefit than those who see the live-action ad. Participants who see the rotoscoped ad will have lower perceived benefit than those who see the live-action ad.

Perceived Risks

Hypothesis 1.5 Participants who see the nonhuman animated ad will have lower perceived risk than those who see the live-action ad. Participants who see the rotoscoped ad will have greater perceived risk than those who see the live-action ad.

Attitudes

Hypothesis 1.6. Participants who see the nonhuman animated ad will show more positive attitudes toward the character, the ad, and the product than those who see the live-action ad. Participants who see the rotoscoped ad will show more negative attitudes toward these objects than those who see the live-action ad.

Intentions

Hypothesis 1.7. Participants who see the nonhuman animated ad will show greater product-related behavioral intentions than participants who see the live-action ad. Participants who see the rotoscoped ad will have lower intentions than those who see the live-action ad.

Experiment 2 Research Questions and Hypotheses

In Experiment 2 we will test the effects of different types of nonhuman personification in DTC advertisements on key message processing outcomes. Here nonhuman personification refers to the use of nonhuman animated characters to personify constructs related to prescription medication (i.e., sufferer, disease, benefit). These analyses will be designed in response to the following research questions:

Research Question 2A. Does nonhuman personification in DTC television advertisements influence processing of prescription drug information?

Research Question 2B. Does the impact of nonhuman personification on the processing of prescription drug information in DTC television advertisements vary by medical condition?

Our theoretical rationale for the Experiment 2 hypotheses focuses on advertising effects by different types of nonhuman personification. As in Experiment 1, analyses involving the medical-condition factor will be exploratory. We have no reason to expect that medical condition will moderate the effects of nonhuman personification on information processing outcomes.

In addition to psychological mechanisms outlined under Experiment 1, our hypotheses for Experiment 2 draw on outcomes related to identification with animated characters in an advertisement. Identification is a cognitive and emotional process whereby an audience member adopts a stance of empathy toward a character, takes on the character's perspective and goals, and experiences a temporary loss of self-awareness[10]. Identification with a character leads people to become deeply absorbed in a media text and take a less critical stance toward it[11]. One antecedent of identification noted by Cohen (2001) is the similarity of audience members to the character. For example, feelings of similarity may be brought about when an audience relates to a character by virtue of a common experience or situation, like suffering from the same medical condition. With this in mind, we expect identification to be higher in the sufferer condition than either the benefit or disease conditions. In turn, we would expect people who experience stronger identification to adopt a stance toward perceived drug risk and benefit that aligns with the character's point of view. In the broader context of direct-to-consumer advertising for prescription drugs, characters act in pursuit of finding relief from the signs, symptoms or consequences of a medical condition. Thus, we would expect stronger identification with a character in a prescription drug ad (e.g., adopting the character's goals and perspective) to orient the audience toward drug benefits and away from risks. Further, because stronger identification

[10] Cohen J. Defining identification: A theoretical look at the identification of audiences with media characters. Mass Communication Society. 2001;4(3):245-264.
[11] Fiske J. *Television culture.* 1989. London: Routledge.

is associated with greater action, we expect participants in the sufferer condition to have stronger drug-related behavioral intentions[12].

Identification with the Character

Hypothesis 2.1 Participants in the sufferer condition will show greater identification with the character than those in the benefit-personification or disease conditions.

Benefit Recall and Recognition

Hypothesis 2.2 Participants in the benefit-personification condition will show greater recall and recognition of benefit information than those in the sufferer or disease conditions.

Risk Recall and Recognition

Specific RQ 2.1 Will recall and recognition of risk information differ by nonhuman personification condition?

Overall Ad Comprehension

Specific RQ 2.2 Will overall ad comprehension differ by nonhuman personification condition?

Perceived Benefits

Hypothesis 2.3 Participants in the sufferer and benefit-personification conditions will show greater perceived benefit than those in the disease-personification condition.

Perceived Risks

Hypothesis 2.4 Participants in the sufferer and benefit-personification conditions will show lower perceived risk than those in the disease-personification condition.

[12] Basil MD. Identification as a mediator of celebrity effects. J Broadcasting Electronic Media. 1996;40: 478-495.

Attitudes

Hypothesis 2.5 Participants in the sufferer and benefit-personification conditions will show more positive attitudes toward the character, the ad, and the product than those in the disease-personification condition.

Intentions

Hypothesis 2.6 Participants in the sufferer condition will show greater product-related behavioral intentions than participants in the benefit-personification and disease conditions.

Analysis Plan

This analysis plan describes our approach to answering the study's research questions and exploring relationships between variables. The proposed analysis will consist of three steps: (1) descriptive data analysis, (2) hypothesis testing, and (3) multivariate modeling.

Descriptive Analysis

During descriptive analysis, we will calculate frequency distributions and check the apparent validity of the data (i.e., range checks, frequency of missing responses, or response distribution). For continuous/ordinal variables, statistical output will include means, medians, standard deviations, ranges, and counts. For categorical variables, output will include counts and percentages.

In addition to frequency distributions, we will conduct three other types of analyses during this step. First, we will calculate reliability of composite variables and multi-item scales to determine if the individual items hang together as composite measures. Specifically, we will calculate Cronbach's alpha for each composite variable. If alpha for a composite measure or scale does not meet our pre-established threshold of 0.75, we will discuss whether to use single-item measures rather than the composite or to consider such composites as indices (because of a theoretical reason to consider an aggregate measure regardless of item correspondence) in hypothesis testing.

Second, we will conduct a content analysis of responses to the open-ended risk and benefit recall questions. We will develop a codebook to guide classification of responses based on their match with risk and benefit claims made in the chronic dry eye and psoriasis ads. To ensure consistent and reliable coding of open-ended data, we will develop and implement an inter-rater reliability protocol before proceeding to code the full content.

Finally, we will conduct a non-response analysis to determine if individuals who do not respond to the study's invitation differ from those who complete the study. We will compare responding individuals to invited but non-responsive individuals on key demographics—such as age, sex, race, and education—to see if significant differences exist. Specifically, we will conduct t-tests comparing the proportions of respondents and non-respondents using a standard significance threshold of p=0.05.

Hypothesis Testing

We will test hypothesized relationships implied by our central research questions by conducting one of several statistical tests as outlined below. In most cases, we plan to conduct an overall test of the relationship between the independent and dependent variables and then conduct hypothesis-specific planned comparisons to assess whether the data support predicted differences among experimental groups. We do not have specific hypotheses concerning interaction effects by medical condition with type of animation or nonhuman personification. If a significant interaction is observed, we will conduct follow-up analyses to describe the interaction. Foremost, we will test for the predicted pattern of means across manipulated experimental conditions (i.e., type of animation in Experiment 1; nonhuman personification in Experiment 2) in each medical condition. We will develop planned contrast equations for this purpose corresponding to each of our research hypotheses.

For hypotheses examining continuous or scale outcomes (e.g., perceived benefit, behavioral intentions), we will conduct two-way ANOVAs to detect significant relationships. For Experiment 1, we will test for effects by type of animation (animated nonhuman sufferer, rotoscoped human sufferer, live-action human sufferer), medical condition (CDE, psoriasis), and their interaction. Experiment 2 will test for effects by nonhuman personification (sufferer, benefit, disease), medical condition (CDE, psoriasis), and their interaction. Statistical output will include F statistics, degrees of freedom, p values, mean differences, and standardized effect sizes (e.g., Cohen's d) for the main effects of each independent variable as well as any interaction effects. We will conduct planned comparisons based on hypothesized relationships to identify significant differences between specific experimental groups. An example template for ANOVA output is shown in ***Exhibit 4***.

Multivariate Modeling

Our descriptive analyses may reveal opportunities for exploring whether the effects of type of animation (Experiment 1) and nonhuman personification (Experiment 2) are influenced by additional variables. Specific plans for multivariate models that control for additional variables, test for complex moderation, or test for mediation will be discussed with FDA based on the hypothesis testing results. The plans will include a rationale for selecting potential covariates, mediators and/or moderators, procedures for verifying statistical assumptions (e.g.,

normal distribution, homogeneity of variance, parallel regression lines), and a description of the proposed modeling approach.

Power

The following assumptions were made in deriving the sample size for the main studies: (1) 0.90 power, (2) 0.05 alpha level for main effects and interactions or 0.008 for post-hoc pairwise comparisons, and (3) a small-to-medium effect size. We use Cohen's conventional thresholds for interpreting the magnitude of effect sizes[13]. Effects with *f* values in the order of 0.40 and greater are large, from 0.25 to but not including 0.40 are medium, and from 0.10 to but not including 0.25 are small. Corresponding effects measured with *d* statistics equal to or greater than 0.80 are large, from 0.50 to but not including 0.80 are medium, and from 0.20 to but not including 0.50 are small. For continuous dependent variables in the main study experiments, we will conduct a set of two-way analyses of variance (ANOVAs) and planned contrasts to test for significant differences among the six experimental groups in a 2 × 3 factorial design. Results from a sensitivity analysis suggests that, with 150 participants in each experimental group (N = 900 per experiment), omnibus F tests will be able to detect moderately small differences among groups (f = 0.14). The main study design is also sensitive to detect moderately small differences for up to six non-orthogonal planned contrasts (f = 0.13) or six post-hoc pairwise comparisons (d = .46), assuming a Bonferroni-adjusted alpha of 0.0083.

For analyses involving discrete outcome variables (e.g., correctly understood risks vs. incorrectly understood risks), the proposed main-study sample size will allow detection of an absolute difference of 18 percentage points in group-to-group comparisons (e.g., a difference between 68% in one experimental group versus 50% in another) with a power of 0.90. In this calculation, we assumed equal-sized samples in each arm (n = 150), a design effect equal to 1, an alpha level of 0.05, a two-sided Fisher's exact test, and an underlying proportion of study participants in a particular response category equal to 0.50. An underlying proportion of 0.50 is the most conservative estimate and overestimates the sample size relative to alternate proportions.

We will conduct the pretests with a smaller sample size than the main study. The objective of the pretest is to confirm that the entire survey process runs smoothly and that the stimulus will be effective for the study design, not to test the hypotheses. The sample size will be large enough to pretest the stimuli and data collection process thoroughly. The pretest experiments – assuming the same power and alpha levels as the main study – omnibus F tests and up to six non-orthogonal planned contrasts will be sensitive to detect medium-to-large effects (f = 0.31 and f = 0.30, respectively).

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

[13] Cohen J. A power primer. Psychol Bull. 1992;112:155-9.

Both the pretests and main survey will use an existing Internet panel to draw a sample. The panel (described in B.1) comprises individuals who share their opinions via the Internet regularly. 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);
- Administer the survey over the Internet, allowing respondents to answer questions at a time and location of their choosing;
- Email a reminder to the respondents who do not complete the protocol within 24 hours of the original invitation to participate.

In the absence of additional information, response rates are often used alone as a proxy measure for survey quality, with lower response rates indicating poorer quality. However, lower response rates are not always associated with greater nonresponse bias[14]. Total survey error is a function of many factors, including nonsampling errors that may arise from both responders and nonresponders[15]. A nonresponse bias analysis can be used to determine the potential for nonresponse bias in the survey estimates from the main data collection.

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[16]. For the proposed project, we will perform two steps: comparing response rates on subgroups and comparing responders and nonresponders on frame variables.

We will first identify the subgroups of interest, such as age and gender. At the end of the data collection, we will calculate response rates by subgroup. If the response rates are the same within subgroups, then nonresponse bias should not affect the results related to those group categories. For example, if the response rate for males and females is the same, then there will not be a large nonresponse bias in the survey estimates for gender.

To the extent that information is available about all sample cases on the frame and that information is associated with the key survey estimates, this approach can provide additional information about the potential for nonresponse bias. At the end of data collection, we will review the sampling frame to determine if any variables are associated with the key survey estimates, such as age. We will then compare the frame information for the full sample compared

[14] Groves R. Nonresponse rates and nonresponse bias in households. Public Opinion Quarterly. 2006;70(5): 646–675.
[15] Biemer P, Lyberg, L. Introduction to survey quality. 2003. New York: Wiley.
[16] Office of Management and Budget, *Standards and Guidelines for Statistical Surveys*, September, 2006. www.whitehouse.gov/sites/default/files/omb/inforeg/statpc. Last accessed April 18, 2013.

with respondents only. Differences between the full sample and the respondents are an indicator of potential bias.

4. Test of Procedures or Methods to be Undertaken

Eighteen (2 waves of 9 each) cognitive interviews will have been conducted to assess questionnaire flow and wording. After this round of cognitive testing, we plan to conduct pretests on a larger scale to ensure the main study will run smoothly. We propose to test 300 individuals in the pretest.

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

The contractor, RTI, will collect and analyze the data on behalf of FDA as a task order under Contract HHSF223201510002B. Bridget Kelly, Ph.D., 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.