4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-3516]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Disease Awareness and Prescription Drug Promotion on Television

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-NEW and title "Disease Awareness and Prescription Drug Promotion on Television." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRAStaff@fda.hhs.gov. For copies of the questionnaire

contact: Office of Prescription Drug Promotion (OPDP) Research Team, DTCresearch@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Disease Awareness and Prescription Drug Promotion on Television

OMB Control Number 0910--NEW

I. Background

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.

FDA's Center for Drug Evaluation and Research (CDER), Office of Prescription Drug Promotion (OPDP) is responsible for ensuring that prescription drug promotional materials are truthful, balanced, and accurately communicated. This project is being proposed as part of the research program of OPDP. 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 both target populations and advertising features.

Because we recognize the strength of data and the confidence in the robust nature of the findings is improved through the results of multiple converging studies, we continue to develop evidence to inform our thinking. We evaluate the results from our studies within the broader context of research and findings from other sources, and this larger body of knowledge collectively informs our policies as well as our research program. Our research is documented on our homepage, which can be found at: https://www.fda.gov/about-fda/center-drug-evaluation-and-research/office-prescription-drug-promotion-opdp-research. The website includes links to the latest *Federal Register* notices and peer-reviewed publications produced by our office. The website maintains information on studies we have conducted, dating back to a direct-to-consumer (DTC) survey conducted in 1999.

The present research concerns disease awareness and prescription drug promotion communications on television. When pharmaceutical companies market a new drug, they often also release disease awareness communications about the medical condition the new drug is intended to treat (Refs. 1 and 2). FDA is interested in whether and to what extent this practice may result in consumers confusing or otherwise misinterpreting the different information and claims presented in disease awareness communications and prescription drug promotion. Prior research has documented that in both print (Ref. 3) and online (Ref. 4) contexts, consumers tend to conflate the information presented in prescription drug promotional materials with information

presented in disease awareness communications. Specifically, the results of these studies suggest consumers incorrectly ascribe benefits to a prescription drug as a result of being exposed to information in a disease awareness communication that broadly describes the symptoms and negative consequences of the disease. There are ways in which this effect can be attenuated. For example, prior research has indicated that greater visual distinctiveness between the two ad types can ameliorate such confusion (Ref. 3). The present research seeks to extend previous studies of print and online promotion to the context of television promotion, and broadly examine the extent to which perceptual similarity between the two communication types, as well as their temporal proximity and exposure frequency, may lead to viewer confusion and the nature of that confusion.

This research is being conducted to determine how the similarity, temporal positioning, and frequency of exposure to disease awareness communications and prescription drug television promotion impact consumer perception and understanding of the benefits and risks of a prescription drug product. These objectives will be achieved using two experimental studies. The first study will explore the impact on consumer perception and comprehension of different levels of temporal separation between the disease awareness communication and prescription drug promotion within a single period of television programming, as well as the level of similarity versus distinctiveness between these communication types. Temporal separation is defined as the spacing or proximity between the disease awareness communication and prescription drug promotion in the hour-long programming, for example, if they are shown back-to-back or if they are separated by other ads or television programming.
Similarity/distinctiveness is defined by variations between the disease awareness communication and prescription drug promotion, including visual and presentation elements such as the setting,

actors, and colors. The second study will experimentally examine the impact of disease awareness communication temporal separation and exposure frequency on consumer perception and comprehension. Temporal separation in this second study again refers to the spacing or proximity between the disease awareness communication and prescription drug promotion but is operationally defined as either 1 day or 1 week. Exposure frequency is defined as the number of times that participants will view the disease awareness communication, either one, three, or six times. The results of this latter study will examine the practice of "seeding the market," in which pharmaceutical companies release disease awareness communications before releasing product promotion communications. Similarity versus distinctiveness will also be examined in this study.

We propose the following hypotheses for this research:

A. Study 1

H1: Increased perceptual similarity between a disease awareness communication and a prescription drug promotion will result in significantly more conflation of the information presented in both pieces.

H2: Increased temporal proximity between a disease awareness communication and a prescription drug promotion will result in significantly more conflation of the information presented in both pieces.

B. Study 2

H1: Increased frequency of exposure to a disease awareness communication before exposure to a prescription drug promotion will result in significantly more conflation of the information presented in both pieces.

H2: Increased temporal proximity between a disease awareness communication and a prescription drug promotion will result in significantly more conflation of the information presented in both pieces.

H3: Increased perceptual similarity between a disease awareness communication and a prescription drug promotion will result in significantly more conflation of the information presented in both pieces.

In each instance, conflation is defined as the extent to which an individual remembers and attributes benefits to a product that is based on information presented in a disease awareness communication and not in the drug promotion.

To address these hypotheses, Study 1 will employ a 3x4 factorial design in which participants are randomly assigned to one disease awareness communication condition, plus one control condition where participants will not view a disease awareness communication. The extent to which the disease awareness communication is perceptually similar to the product promotion communication will vary, as will the temporal separation of the disease awareness communication and product promotion communication. Table 1 depicts our design visually.

Table 1.--Study 1 Experimental Design

Disease Awareness Ad	Perceptual Similarity to Product Ad	Disease Awareness and Product Ad Temporal Separation			
		Back to back	Within same commercial pod[1]	In neighboring commercial pods	In non-neighboring commercial pods
Yes	Similar. Semi-similar. Distinct.				
No	N/A				

[1]A commercial pod refers to a group of ads into which the test ad is inserted, designed to simulate an advertising break during a television program. As depicted in table 2, by neighboring commercial pods, we mean commercial pods separated only by television programming and no other commercial pods. By non-neighboring commercial pods, we mean commercial pods separated by both television programming and one or more (one, as studied here) other commercial pods.

Table 2.--Study 1 Sequence

Condition	Sequence														
	6min[1]	2min[2]	5min[1]	2min[2]	5min[1]	2min[2]	5min[1]	2min[2]	6min[1]	2min[2]	5min[1]	2min[2]	5min[1]	2min[2]	5min[1]
Back to back		DA, P[3]												DA, P	
Same pod		DA, P												DA, P	
Neighboring pods		DA		P								DA		P	
Non-neighboring pods		DA				P				DA				P	
Control		P												P	

[1]TV Program.
[2]Commercial Pod.
[3]DA = Disease Awareness Communication; P = Product Promotion.

Study 2 will employ a 2x2x3 factorial design in which participants are randomly assigned to one disease awareness communication condition. The varying factors in Study 2 are the temporal separation between the disease awareness and product promotion communication, the number of exposures to the disease awareness communication, and the perceptual similarity of the disease awareness communication to the product promotion communication. Table 3 visually depicts our design. Of note, to reduce the overall number of experimental conditions for Study 2, no semi-similar experimental condition is used.

Table 3.--Study 2 Experimental Design

Time Delay Until Product Ad Exposure (Temporal Separation)	Perceptual Similarity of Ads	Exposures to Disease Awareness Ad		
		One Exposure	Three Exposures	Six Exposures
One Day	Similar.			
	Distinct.			
One Week	Similar.			
	Distinct.			

Table 4.--Study 2 Sequence

			Disease Awareness Ad Exposure Phase						Product Ad Exposure Phase							
			Day →													
			1	2	5	6	9	10	11	12	13	14	15	16	17
	Delay	Similarity														
Six Exposures	1 day	similar	x	x	x	x	x	x	x						
		distinct	x	x	x	x	x	x	x						
	1 week	similar	x	x	x	x	x	x							x
		distinct	x	x	x	x	x	x							x
Three Exposures	1 day	similar				x	x	x	x						
		distinct				x	x	x	x						
	1 week	similar				x	x	x							x
		distinct				x	x	x							x
One Exposure	1 day	similar						x	x						
		distinct						x	x						
	1 week	similar						x							x
		distinct						x							x

Study 1 and 2 Sample. The targeted voluntary sample for both studies will comprise adults who self-report a current asthma diagnosis, a lifetime incidence of asthma, or experience a large number of asthma symptoms. These groups are believed to be very likely to be targeted by disease awareness and product promotion communications for asthma. The combined incidence rate of these groups is 22.2 percent (Refs. 5 and 6). In addition, several exclusion criteria are specified. These include: (1) training or employment as a healthcare professional, (2) employment with a pharmaceutical company, an advertising agency, a market research company, or the Department of Health and Human Services, and (3) participation in market research within the past 3 months on the topic of prescription drugs. Pretest participants will also be ineligible for the main study.

Pretesting. Pretesting will take place before the main studies to evaluate the procedures used in the main studies. Each of the two pretests will have the same design as its respective main study (pretest 1 for Study 1 and pretest 2 for Study 2). The purpose of both pretests will be to: (1) ensure that the mock stimuli are understandable, viewable, and delivering intended messages; (2) identify and eliminate any challenges to embedding the mock stimuli within the online survey; (3) ensure that survey questions are appropriate and meet the analytical goals of the research; and (4) pilot test the methods, including examining response rates and timing of survey. The two pretests will be conducted simultaneously.[1] Based on pretest findings, we will refine the mock stimuli, survey questions, and data collection process, as necessary, to optimize the full-scale study conditions.

[1] Pretesting will be preceded by cognitive interviewing, not described here. Cognitive interviews are used to probe a small sample of participants on how and why they responded to various questions as they did, resulting in strong measurement instruments.

Measurement. Our planned analyses are designed to address the key hypotheses. For both Study 1 and Study 2, we anticipate that the primary analysis will be analysis of variance to compare the main and interaction effects of the experimental factors.

The focal dependent variable will be *conflation*--a measure of memory and perceptions regarding the promoted drug relative to the information presented in the disease awareness communication. Conflation will be measured by using the number of benefits that are incorrectly attributed to the prescription drug product based on responses to a number of both open-ended and closed-ended items.

Other key dependent variables will reflect perceptions and attitudes toward the product ad. These include measures of:

1. Perception of product promotion effectiveness;
2. Behavioral intentions toward the drug;
3. Perceived efficacy of the drug; and
4. Perceived risks of the drug.

In addition to the primary variables of interest, we have also identified potential covariates that will be included in the analyses:

1. Knowledge about asthma;
2. Health literacy; and
3. Perceived ad effectiveness.

We expect that knowledge about asthma and increased health literacy may moderate any conflation that results from ad similarity, temporal proximity, and frequency of exposure. Perceptions of promotion effectiveness, on the other hand, can be examined both as an outcome/dependent variable but also as a covariate that examines involvement with the product

promotion. Greater involvement may attenuate conflation in that it directs more in-depth processing of both the disease awareness communication and product promotion, and therefore more correct understanding of the claims in each (Refs. 7 to 9).

In the *Federal Register* of October 17, 2018 (83 FR 52472), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received six comments that were PRA related. Within those submissions, FDA received multiple comments that the Agency has addressed. Two additional comments were received that were not responsive to the four collection of information topics solicited and therefore are not discussed in this document.

(Comment 1) Four comments suggested that FDA provide copies of stimuli in the *Federal Register* for public comment. Relatedly, one comment requested a copy of the participant consent documents.

(Response) We have described the purpose of the study, the design, the population of interest, and have provided the questionnaire to numerous individuals upon request. Our full stimuli are under development during the PRA process. We do not make draft stimuli public during this time because of concerns that this may contaminate our participant pool and compromise the research. The consent form is available as part of the information collection submission to OMB.

(Comment 2) Three comments expressed support for FDA's determination to take an evidence-informed approach to its regulation of sponsor communications.

(Response) We appreciate this support.

(Comment 3) Three comments suggested that selecting asthma sufferers as the target population limits the applicability of the results, or that asthma sufferers' prior knowledge regarding asthma may bias their responses.

(Response) Researching each medical condition, or general population sample, requires significant resources. We are committed to conducting this research using our available resources while ensuring the integrity of the research by collecting data on a high prevalence condition (i.e., > 20% incidence rate) for which participants might be thought of as sufficiently representative of the average consumer, thus allowing us to draw conclusions about broad perceptual and cognitive processing outcomes.

(Comment 4) Three comments suggested that use of mock advertisements, products, and environments do not represent what happens in the real world.

(Response) In response to *Federal Register* notices for prior research under our research program, commenters have suggested the opposite, which is that use of real materials (i.e., existing drug ads) could have confounding results due to consumer familiarity with medicines and drug classes used to treat their existing condition. We sought to address this concern by utilizing realistic mock materials. Additionally, utilizing mock materials allows for precise manipulation of the stimuli fitting with our research questions and is the most common practice in the field.

(Comment 5) Two comments expressed concern about use of "conflation" as a dependent variable.

(Response) The present research seeks to extend previous studies of print and online promotion to the context of television promotion and as such utilizes many of the same dependent measures, including the key dependent measure of "conflation." Conflation as

defined in this notice reflects the key outcome of interest given the research questions posed and therefore has been retained.

(Comment 6) Two comments suggested that the open-ended response questions are open to interpretation and data variability and encouraged FDA to revise these to close-ended questions.

(Response) The purpose of the open-ended items is to measure unaided participant recall of claims made in the prescription drug promotion. These responses will be content coded using an inductive approach and numeric codes will be assigned to the open-ended responses. Quantifying open-ended responses provides structure and reduces the interpretation associated with a qualitative coding scheme. After sanitizing open-ended comments (removing obscenities, proper names, and any case-specific information), two reviewers will read the responses and develop a coding scheme to establish theme descriptions, numeric codes, and coding rules. Two coders will receive training and will code 25 percent of the responses. After achieving high inter-coder reliability (e.g., κappa = .75), the remaining responses will be divided between the coders. Open-ended coding will then be merged with the data set for analysis. Additionally, we have tested these response options in cognitive interviewing and found them to be effective for their intended purpose. We have also received positive feedback on these measures from our consultations with expert peer reviewers. These measures have therefore been retained.

(Comment 7) Two comments suggested adding a control condition to Study 2 whereby participants only see the prescription drug product ad before completing the survey.

(Response) For Study 2, the primary questions are related to both frequency of exposure and delay. A control condition that features no disease awareness communications makes the

delay factor redundant, and comparisons can be made between no exposure and repeated exposure. Therefore, a control condition for Study 2 is unnecessary given the current design.

(Comment 8) Two comments suggested that Studies 1 and 2 are highly similar and thus only one study needs to be conducted. One of these comments suggested dropping Study 2 and utilizing the resources that would have been allotted to instead create different iterations of temporal separation for Study 1.

(Response) Studies 1 and 2 include overlap in their independent and dependent variables. However, they are unique in that Study 1 will explore outcomes within a single period of television programming, whereas Study 2 will examine outcomes over time mirroring the practice of "seeding the market," in which pharmaceutical companies release disease awareness communications before releasing product promotion communications. Both studies offer significant and unique value to FDA and therefore both studies have been retained.

(Comment 9) One comment suggested separating recall of the ad from recall of the product into separate questions.

(Response) The question reads, "Do you recall seeing a commercial for [Drug X], a prescription product for asthma?" This question is intended to assess recall of the commercial for [Drug X] and is not intended to assess recall for this fictitious product beyond this commercial. We hope this clarification is helpful for understanding why we intend to retain the present version of this question.

(Comment 10) One comment suggested that pretesting be conducted to ensure that stimuli reflect the intended manipulations.

(Response) FDA intends to conduct both cognitive interviewing and pretesting to ensure the stimuli reflect the intended manipulations.

(Comment 11) One comment suggests that the proposed research overlooks the positive aspects of disease awareness campaigns, and to address this, steps can be taken such as adding questions about behavioral intentions to the questionnaire.

(Response) FDA acknowledges that there are positive aspects of disease awareness campaigns. This research is intended to evaluate specific research questions as outlined in the 60-day *Federal Register* notice and therefore dependent measures align with these research questions. As an overall strategy to reduce participant burden, we do not intend to ask questions that do not inform these research questions.

(Comment 12) One comment suggested relocating non-terminating screening questions to the end of the questionnaire to reduce participant fatigue.

(Response) The purpose of including the screening items at the beginning of the questionnaire is to ensure a diverse sample using predetermined quotas, and for required statistical analyses following completion of the data collection. Retaining the screening items at the beginning of the questionnaire will allow for comparisons between non-respondents and respondents.

(Comment 13) One comment suggested adding a "Don't know" response option wherever applicable.

(Response) We understand the value of providing such responses for items of a factual nature. The drawback to providing such response options to these questions, however, is that we may lose information by allowing respondents to choose an easy response instead of giving the item some thought. Research has demonstrated that providing "no opinion" options likely results in the loss of data without any corresponding increase in the quality of the data. Thus, we prefer not to add these options to the survey.

(Comment 14) One comment suggested that FDA develop a clear, overarching research agenda and provide a comprehensive list of its prescription drug promotion studies.

(Response) The 60-day *Federal Register* notice for this study describes OPDP's research agenda, how this study fits into that agenda, and provides the web address of OPDP's research page, which includes links to the latest *Federal Register* notices and peer-reviewed publications produced by our office. The website maintains information on studies we have conducted, dating back to a DTC survey conducted in 1999.

(Comment 15) One comment suggested that the current research duplicates prior work conducted in online and print contexts.

(Response) The present research seeks to extend previous studies of print and online promotion to the context of television promotion. In previous *Federal Register* notices under our research program, we have been advised by commenters that findings for one form of advertising should not be assumed to broadly apply to other forms of advertising. Additionally, we note that the present research includes unique elements beyond advertising format that have not previously been studied. An example of this is assessment of "seeding the market" in Study 2 whereby sponsors initially release a disease awareness ad for a period of time, followed by release of a product promotion ad.

(Comment 16) One comment suggested that the time commitment required for participation may result in a self-selected sample of individuals with more time available (e.g., students).

(Response) Participants will be recruited through online panels, which include a diverse range of participants in regard to age, race/ethnicity, income, education, and employment. We also have proposed the use of soft quotas to further ensure that we will recruit a diverse sample.

Finally, we were able to recruit a diverse sample for cognitive interviewing and although a smaller sample size than will be recruited for the pretests and main studies, the sample was not overrepresented in any demographic categories.

(Comment 17) One comment suggested that the calculated burden is appropriate but requested additional detail about other requirements that may add to burden in addition to the time in the study itself.

(Response) Data collection will occur online, so the burden estimate reflects time spent answering the screener, stimuli viewing, survey completion, thus reflecting overall study time and requirements.

(Comment 18) One comment identified errors in the questionnaire.

(Response) Thank you for noting these errors. All identified errors have been fixed.

(Comment 19) One comment suggested adding intermediate response values to questions that omitted them (e.g., 1 = no improvement, to 6 = substantial improvement).

(Response) These questions were developed through scale validation research. We did not encounter any confusion on the part of respondents during cognitive testing of the questionnaire. We will retain these questions in their original form.

(Comment 20) One comment suggested that because "prescription drug information" has become a political topic in recent years, the introduction to the questionnaire should be revised to avoid saying that "[w]e will use your feedback to…improve prescription drug information for people like you." The concern is that this information may bias responses depending on participant views of "prescription drug information."

(Response) The proposed research concerns prescription drug information and so we need to provide this context to participants to orient them to the questions that follow. Moreover,

institutional review boards typically require transparency about the topic of the research. We have therefore retained this language in our study materials.

(Comment 21) One comment noted that "[p]erceptions of promotion effectiveness" is described as both a dependent variable and a covariate, and to avoid distortion in the model, recommends selection of a different covariate.

(Response) Perception of promotion effectiveness is described as a dependent variable, differing from perceived ad effectiveness, which measures perception of the disease awareness communications. The purpose of including perceived ad effectiveness as a covariate is that perception of the disease awareness communications may directly affect conflation, which could require statistical adjustment.

(Comment 22) One comment suggested expanding the participant exclusion criteria to include individuals studying health fields and product marketing (beyond pharmaceuticals).

(Response) We currently exclude individuals who work for a pharmaceutical company, an advertising agency, a market research company, or the Department of Health and Human Services. These criteria exclude individuals working in advertising or market research beyond pharmaceuticals, but do not necessarily exclude students studying these fields. To ensure a diverse sample, we generally aim to limit our exclusion criteria. However, please note that random assignment to experimental condition should ensure that these individuals are approximately evenly distributed across conditions.

(Comment 23) One comment requested information about how learning effects would be controlled for given the multiple exposures.

(Response) For Study 2, learning effects are accounted for by the exposure frequency manipulation. Participants are randomly assigned to see the disease awareness ad once, three

times, or six times. For Study 1, all participants see the ads the same number of times, except participants randomly assigned to the control condition who do not see the disease awareness ad.

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

Table 5.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Study 1 Pretest screener	385	1	385	0.08 (~5 minutes)	31
Study 2 Pretest screener	329	1	329	0.08 (~5 minutes)	26
Study 1 screener	3,007	1	3,007	0.08 (~5 minutes)	241
Study 2 screener	2,643	1	2,643	0.08 (~5 minutes)	211
Study 1 Pretest	270	1	270	1.33 (~1 hour 20 minutes)	360
Study 2 Pretest	158	1	158	0.53 (~32 minutes)	84
Study 1	2,105	1	2,105	1.33 (~1hour 20 minutes)	2,800
Study 2	1,269	1	1,269	0.53 (~32 minutes)	673
Total					4,426

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

II. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at https://www.regulations.gov. References without asterisks are not on public display at https://www.regulations.gov_because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the

Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. Bulik, B.S. (March 11, 2018). "Unbranded Pharma Ads--What Are They Good For? Actually Quite a Bit, Marketing Panelists Say." Available at https://www.fiercepharma.com/marketing/unbranded-pharma-ad-what-are-they-good-for-actually-quite-a-bit-marketer-panelists-say?mkt_tok=eyJpIjoiWkRnelpUSmlORFpoWkdNMSIsInQiOiJPaENIUERpT0tnUmt6Y1BPMk9LTnpreUI3bUtPOVRzRnh1RzNuWUtYQmp0cWJhcW05UFhlcllwTzI3V0RJSndjVkZLR3NGUHBLamJOZmJSK2FZeWtIVXczeFRFcmtEV0NFaVdCSjArUmx4dUlRVHZpUzFFOWlVY0dNb1RzOU9XayJ9&mrkid=20932234. Accessed on April 12th, 2019.

2. Bulik, B.S. (December 21, 2016). "Avanir Shelves Danny Glover PBA Awareness Ad in Favor of Branded Nuedexta Effort." Available at https://www.fiercepharma.com/marketing/avanir-launches-nuedexta-brand-campaign-retires-danny-glover-pba-disease-awareness-ad. Accessed on April 12, 2019.

3. * Aikin, K.J., H.W. Sullivan, and K.R. Betts, "Disease Information in Direct-to-Consumer Prescription Drug Print Ads." *Journal of Health Communication*, 21:228-239, 2016.

4. * Sullivan, H.W., A.C. O'Donoghue, D.J. Rupert, et al., "Are Disease Awareness Links on Prescription Drug Websites Misleading? A Randomized Study." *Journal of Health Communication,* 21:1198-1207, 2016.

5. * Centers for Disease Control and Prevention. (2018a, May 18). "2016 National Health Interview Survey (NHIS) Data." Retrieved from https://www.cdc.gov/asthma/nhis/2016/table2-1.htm.

6. * Centers for Disease Control and Prevention. (2018b, May 15). "Most Recent Asthma Data." Retrieved from https://www.cdc.gov/asthma/most_recent_data.htm.

7. Petty, R.E. and J.T. Cacioppo, "Issue Involvement Can Increase or Decrease Persuasion by Enhancing Message-Relevant Cognitive Responses." *Journal of Personality and Social Psychology,* 37:1915-1926, 1979. doi: 10.1037/0022-3514.37.10.1915.

8. Petty, R.E. and J.T. Cacioppo, "The Elaboration Likelihood Model of Persuasion." *Advances in Experimental Social Psychology,* 19:123-205, 1986. doi: 10.1016/S0065-2601(08)60214-2.

9. Petty, R.E., J.T. Cacioppo, and R. Goldman, "Personal Involvement as a Determinant of Argument-Based Persuasion." *Journal of Personality and Social Psychology,* 41:847-855, 1981. doi: 10.1037/0022-3514.41.5.847.

Dated: June 24, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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