Health Care Professional Survey of Prescription Drug Promotion

0910-NEW

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

Regulatory Background

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

Description

The pharmaceutical industry spends millions of dollars a year promoting their products to American health care professionals and to consumers. FDA regulates the promotion of prescription drugs to both professionals and consumers. As such, FDA has an interest in determining the attitudes, perceptions, and opinions of health care professionals with prescribing authority regarding such promotion. Direct-to-consumer (DTC) advertising captures the most public attention, making it an important topic of interest to FDA; but the bulk of industry resources are spent in professional promotion, making this an equally important topic for investigation. The current research is designed to explore prescriber opinions of DTC advertising as well as other aspects of prescriber experience that relate to the promotion of prescription drugs.

The rise of DTC drug advertising and prescription drug promotion has affected health care professionals in a number of ways. First, health care professionals regularly encounter patients who have been exposed to DTC ads. Second, health care professionals also see and hear such ads directly as mass media consumers themselves. Since clarification of the adequate provision requirement for prescription drug broadcast ads in 1997, FDA has faced numerous questions about the influence of DTC pharmaceutical marketing because such advertising directly engages consumers and potentially affects interactions between patients and their physicians.[1] Those questions have grown more urgent with the growth of DTC advertising in recent years.[2] In 2002, FDA considered this form of promotion sufficiently important as a force in the physician-patient interaction that they surveyed both patients and physicians regarding their perceptions of DTC advertising.[3] Now, nearly a decade later, there are critical reasons to return to the field to gather more evidence on the influence of DTC advertising in the examination room and on the relationships between health care professionals and patients.

One of the most noteworthy aspects of the 2012 health care environment is the role now played by various physician extenders. Naylor and Kurtzman[4] recently noted that nurses are the single largest group of health care professionals in the United States, and they argue that nurse practitioners will play an increasingly vital role in primary care delivery. Similarly, physician assistants also bolster the ability of our health care system to offer some types of care at lower costs. The 2002 FDA study did not include nurse practitioners or physician assistants in the

[1] Fintor, L. "Direct-to-Consumer Marketing: How has it fared? *Journal of the National Cancer Institute*, vol. 94, pp. 329-331, 2002; Palumbo, F.B. and C.D. Mullins, "The Development of Direct-to-Consumer Prescription Drug Advertising Regulations, *Food and Drug Law Journal*, vol. 57, pp. 423-443, 2002.
[2] Curry, T.J., J. Jarosch, and S. Pacholok, "Are Direct to Consumer Advertisements of Prescription Drugs Educational? Comparing 1992 to 2002," *Journal of Drug Education*, vol. 35, pp. 217-223; Government Accountability Office (GAO), "Improvements Needed in FDA's Oversight of Direct-to-Consumer Advertising. GAO-07-54, Washington, DC: GAO, November 16, 2006.
[3] Aikin, K.J., J.L. Swasy, and A.C Braman, "Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs," Washington, DC: Food and Drug Administration, November 19, 2004.
[4] Naylor, M.D. and E.T. Kurtman, "The Role of Nurse Practitioners in Reinventing Primary Care," *Health Affairs*, vol. 29, pp. 893-899, 2010.

sample, instead focusing on general practitioners and specialists in several key areas targeted by DTC advertising. Murray and colleagues[5] also conducted a large-scale survey of U.S. physicians regarding their perceptions of DTC advertising, but they also did not include nurse practitioners or physician assistants in their sample. Because DTC advertising likely affects daily interactions between patients and nurse practitioners and physician assistants—similar to the 2002 FDA study that suggested the influence of advertising on physicians' work lives—including these groups in the new sample will further understanding of DTC advertising in the health care system.

Another limitation of the 2002 FDA study was the extent to which the results were nationally representative. As FDA has acknowledged, the initial set of results as reported were applicable to survey respondents but were not weighted to reflect national statistics on age, sex, and racial composition of the health care professional population. Similar to many types of surveys that have struggled in recent decades with declines in cooperation rates,[6] surveys of health care professionals in general often can benefit from weighting to reduce nonresponse bias. The current survey will include weighted responses from respondents that will reflect national demographic patterns.

Over the past decade, researchers have been able to better assess how DTC advertising has unfolded in the United States and determine the questions that warrant further survey work. For example, researchers have worried for a number of years that DTC advertising might produce adverse outcomes, such as clinically inappropriate patient requests for drugs or patient overestimation of the efficacy of advertised medications.[7] At the same time, the 2002 FDA

[5] Murray, E., B. Lo, L. Pollack, et al., "Direct-to-Consumer Advertising: Physicians' Views of It's Effects on Quality of Care and the Doctor-Patient Relationship," *Journal of the American Board of Family Practice*, vol. 16, pp. 513-524, 2003.
[6] Dey, E.L., "Working With Low Survey Response Rates: The Efficacy of Weighting Adjustments," *Research in Higher Education*, vol. 38, pp. 215-227, 1997.
[7] Aikin, K.J., J.L. Swasy, and A.C. Braman, "Patient and Physician Attitudes and Behaviors Associated with DTC

survey found that roughly as many physicians thought DTC advertising had a positive effect on their practice as those who thought there had been a negative influence. Moreover, the 2002 FDA survey found that roughly one-third of physicians surveyed thought that DTC advertising had essentially no influence on their practice. The question of whether a similar pattern will emerge now, despite the growth of DTC advertising, is a vital one.

In addition, with the proliferation of social media platforms, the emergence of online pharmaceutical marketing, and the evolution of office detailing practices,[8] FDA will benefit by knowing more about health care professionals' awareness of new and emerging drug promotion sites and practices. The proposed survey will address these issues.[9]

2. Purpose and Use of the Information Collection

The present study aims to investigate the perspectives of health care professionals with prescribing privileges—including physicians, physician assistants, and nurse practitioners—regarding various aspects of prescription drug promotion. Specifically, the survey will address DTC advertising, professional promotion, use of new technologies including social media, and the Office of Prescription Drug Promotion's (OPDP's) Bad Ad program. This is the first such study to our knowledge that examines the beliefs of health care professionals other than physicians who now have prescribing privileges. The study findings will inform FDA of

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Promotion of Prescription Drugs," Washington, DC: Food and Drug Administration, November 19, 2004; Mintzes, B., M.L. Barer, R.L. Kravitz, et al, "Influence of Direct to Consumer Pharmaceutical Advertising and Patients' Requests on Prescribing Decisions: Two Site Cross Sectional Study, *British Medical Journal,* vol. 324, pp. 278-279, 2002; Mitra, A., J.LSwasy, and K. Aikin, "How Do Consumers Interpret Market Leadership Claims in Direct-to-Consumer Advertising of Prescription Drugs?," *Advances in Consumer Research,* vol. 33, pp. 381-387, 2006; Murray, E., B. Lo, L. Pollack, et al., "Direct-to-Consumer Advertising: Physicians' Views of Its Effects on Quality of Care and the Doctor-Patient Relationship, *Journal of the American Board of Family Practice,* vol. 16, pp. 513-524, 2003.

[8] Donohue, J.M., M. Cevasco, and MB. Rosenthal, "A Decade of Direct-to-Consumer Advertising of Prescription Drugs," *New England Journal of Medicine,* vol. 357, pp. 673-681; Chew, L.D., T.S. O'Young, T.K. Hazlet, et al., "A Physician Survey of the Effect of Drug Sample Availability on Physician's Behavior," *Journal of General Internal Medicine,* vol. 15, pp. 478-483, 2002.

[9] For a full discussion of the information to be collected, see Section B.2 and Appendix D. This satisfies section D.b.1 of the OMB Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002.

relevant issues and concerns relating to health care professional exposure to prescription drug promotion.

Data will be collected by an independent contractor and shared with FDA electronically. No personally identifiable information will be sent to FDA. All information that can identify individual respondents will be maintained by the independent contractor in a form that is separate from the data provided to FDA. The data shared with FDA will be used to answer the research questions. The proposed data collection should have no impact on privacy.[10]

3. Use of Improved Information Technology and Burden Reduction

Automated information technology will be used in the collection of information for this study. The contracted research firm will collect data through Internet administration. One hundred percent (100%) of participants will self-administer the Internet survey via a computer, which will record responses and provide appropriate probes when needed. In addition to its use in data collection, automated technology will be used in data reduction and analysis. Burden will be reduced by recording data on a one-time basis for each respondent and by keeping surveys to less than 20 minutes.

4. Efforts to Identify Duplication and Use of Similar Information

FDA conducted a survey of physicians in 2002 (OMB Control Number 0910-0479). Although that survey provided valuable information, there are a number of reasons to conduct another survey in 2012. The 2002 survey was limited to physicians, did not include questions about professional promotion, and occurred before the advent of Internet and social media capabilities and implementation of the Bad Ad program. Although *Prevention* magazine continues to conduct a yearly consumer study on DTC advertising,[11] their respondents are not

[10] This paragraph satisfies sections D.b.2 and D.b.3 of the OMB Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002.

[11] *Prevention* magazine. (2011). http://www.rodaleinc.com/newsroom/12th-annual-survey-iconsumer-reaction-dtc-advertising-prescription-drugsi-reveals. Last accessed March 29, 2012.

health care professionals. Thus, while we have some current knowledge of social media and other new technology usage among consumers, we do not have current data on the perspectives of health care professionals regarding prescription drug promotion.

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

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection.

6. Consequences of Collecting the Information Less Frequently

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

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

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

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

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of of January 17, 2012 (77 FR 2299). FDA received five public comment submissions which included over 50 comments embedded . In the following section, we outline the observations and suggestions raised in the comments and provide our responses:

(Comment 1) Two comments recommended surveying pharmacists in addition to the health care professionals described in the notice (i.e., general practitioners, specialists, nurse practitioners, and physician assistants).

(Response) We respectfully acknowledge the large role played by pharmacists in the health care system. However, the purpose of our survey is to query health care professionals with prescribing privileges. One comment noted that pharmacists have some limited prescribing privileges in certain states. This is true; pharmacists have certain privileges in Florida, can prescribe controlled substances under Collaborative Drug Therapy Management agreements in seven states, and with specific advanced training can prescribe within the Veterans Administration system. This contrasts with the nearly universal prescribing privileges of nurse practitioners and physician assistants, with varying levels of physician supervision. To maximize our resources, we propose to maintain our current distribution of health care professionals. Given the variety of prescribing privilege rights among physician extenders in different states, however, we will add a screening question to ensure that our respondents do have prescribing privileges.

(Comment 2) One comment mentioned adding a variety of different types of prescribers to our sample, including dentists, doctors of osteopathy, and podiatrists.

(Response) The comment incorrectly notes that the 2002 survey did not include a variety of prescribers. Contrary to the comment, the 2002 survey did include a range of specialties, reflecting those therapeutic areas with the highest amount of DTC advertising at that time. The current survey will include specialists who practice in therapeutic areas for which DTC advertising is or has recently been active: dermatologists; endocrinologists; allergists/pulmonologists, psychiatrists (all of whom were sampled in 2002); rheumatologists; cardiologists; ear, nose, and throat doctors; urologists; neurologists; and pain specialists.

(Comment 3) One comment recommended that demographic questions be added to the beginning of the survey to attain adequate representation, instead of occurring at the end.

(Response) The Internet panel from which this data will be collected already contains much of the demographic information we need to ensure that participants represent a balanced stratification of demographic variables. When relevant information is not available from the panel, screening questions will be asked prior to the questionnaire to obtain the desired information. We prefer to keep other demographic variables at the end of the survey to avoid distracting participants with questions about personal information before they have answered substantive survey questions. We also prefer to ask our most important questions first to avoid any respondent fatigue that may occur throughout the survey. We expect that respondents will have an easier time answering questions about themselves; therefore, these questions will be less subject to participant fatigue.

(Comment 4) One comment recommended adding open-ended questions in several locations in the survey.

(Response) We appreciate this suggestion and agree that open-ended questions could provide extra, unprompted information from respondents. However, given the current length of the survey, it is likely that adding many open-ended questions would increase respondent demand and, therefore, result in more respondents quitting before completion. Moreover, the addition of several open-ended questions would increase coding burden without adding a commensurate value to our data. Thus, we do not plan to incorporate additional open-ended questions. If we find data that we would like to pursue further, we can incorporate this approach into future studies.

(Comment 5) One comment recommended that we provide “don’t know” and “it depends” responses for many questions.

(Response) We understand the value of providing such responses for items of a factual nature and for items to which health care professionals might not know the answer (our items fall into the second category). The drawback to providing such response options, however, is that we may lose information by allowing respondents to choose an easy response instead of giving the item some thought. Research by Krosnick et al. (2002)[12] demonstrated that providing "no opinion" options likely results in the loss of data without any corresponding increase in the data quality. Thus, we prefer not to add these options to the survey. We plan to cognitively test the questionnaire before fielding the survey, so we will observe whether participants have particular difficulty with any of the questions.

(Comment 6) A comment recommended interpreting the results of this survey cautiously and in tandem with other ongoing research areas.

(Response) We agree that careful interpretation of the data is crucial. We plan to apply the most rigorous standards of analysis and to interpret the findings based on those analyses alone. When relevant, we will assimilate the findings from this project with other research projects we conduct.

(Comment 7) One comment suggested that Q2 (now Q1) be asked as a screening question.

(Response) We intend to screen based on percentage of time prescribers spend with patients. We do not believe additional screening based on the number of patients seen per week is necessary. We will ask only one of the three options provided in the draft questionnaire. Other comments have recommended asking respondents to recall the last *week* in time, so we will use that question to assess their patient volume.

[12] Krosnick, J.A., A.L. Holbrook, M.K. Berent, et al., "The Impact of "No Opinion" Response Options on Data Quality: Non-Attitude Reduction or An Invitation to Satisfice?", *Public Opinion Quarterly*, vol. 66, pp. 371-403, 2002.

(Comment 8) One comment recommended asking about "*health and lifestyle changes*" as an additional question in Q3 (now Q2).

(Response) We have added this item to the questionnaire.

(Comment 9) This comment recommended eliminating the "almost always" option from Q3 (now Q2) because it may confuse respondents in terms of exactly what we are asking.

(Response) We have removed this option and have changed the other responses so now the only responses are "never," "rarely," "sometimes," and "often." We believe this better represents the range of options available to answer this question and will make the question easier to answer.

(Comment 10) One comment recommended that we add a response option to Q4 for in-office programming that occurs in waiting rooms.

(Response) We have deleted this question entirely because of survey time constraints.

(Comment 11) Two comments stated that one week is a reasonable amount of time to ask prescribers to recall information in Q5 (now Q3).

(Response) As we have done in the screener and as suggested by these comments, we will use one week as the time period.

(Comment 12) This comment recommended that we use a more specific probe in Q6 (now Q4) to gather information on why prescribers feel positively or negatively about patients mentioning advertised prescription drugs.

(Response) We have added a follow-up probe (Q4a) to address why respondents chose their answer.

(Comment 13) This comment recommended asking prescribers how their patients reference advertisements, for example, whether they specifically mention the drug's name, the condition the drug treats, or some element in the ad such as a butterfly or bee (Q8; now Q5).

(Response) While this is a very interesting question, it is more relevant to marketers of these products and outside the scope of what FDA hopes to accomplish with this survey. Given the number of questions in the survey, we respectfully decline to add this question.

(Comment 14) This comment recommended shortening the time frame in Q9 (now Q6) from one month to one week.

(Response) Given the feedback from this and other comments, we agree that one week is a reasonable amount of time to reference when answering these questions, and we have adjusted the questionnaire to reflect this change.

(Comment 15) One comment recommended wording changes to Q7.

(Response) Q7 has been deleted because of survey time constraints.

(Comment 16) This comment asked that the nature of the request also be added to Q10 (now Q7).

(Response) Although we agree that asking about the nature of the request would be interesting, additional questions would increase the burden on respondents, and we think that other areas of inquiry are more relevant at this time. Please note that we have altered the response option in this one question, which will yield additional information.

(Comment 17) One comment recommended specifying in Q10 (now Q7) that patients have requested a drug after seeing it advertised.

(Response) The purpose of the question is to assess the prescribing behavior of the prescriber, not the source of the patient's request, so we prefer to keep the question as is.

(Comment 18) This comment recommended a change in the response options in Q10 (now Q7) to further delineate the prescriber's behavior.

(Response) We agree that this is a useful change and have implemented this response format. We have made further changes based on peer review comments.

(Comment 19) Two comments indicated that it may be difficult for health care professionals to answer Q12 (now Q9) as written.

(Response) We agree that it might be difficult for prescribers to reliably assess the feelings and emotions of members of another group. We have changed the emphasis in this question from the patient's expectation to the health care professional's feeling of obligation, thus eliminating the issue over response options in the original item. We have altered the question to put the focus back on what prescribers feel rather than what their patients feel. Please note that we have also altered the response options for this question to make the question easier to answer.

(Comment 20) This comment recommended emphasizing the part of the stem of Q13 and Q14 (now Q11) that states, "As a result of discussion about advertised prescription drugs."

(Response) Given the survey length, we have deleted original Q13, but this comment applies to current Q11. We have attempted to emphasize the appropriate part of the stem in this question and will be cognizant of this issue when working with the programmers of the actual survey. We will use bolding techniques and color as necessary to make sure that this part of the question is highlighted.

(Comment 22) One comment questioned the utility of asking prescribers about a variety of behaviors they engage in as a result of a conversation about advertised drugs (Q14; now Q11).

Their argument is that the prescriber may respond "never" because the subject did not come up, not because they did not want to provide that action.

(Response) We agree that this is a possible interpretation of that response and will be careful to include that in interpretations of the data. Nevertheless, we are interested in obtaining information on the number of times these behaviors occur and believe this is a useful measure.

(Comment 23) One comment recommended changing Q14 (now Q11) from "provided a brochure for the drug" to "provided a *patient education* brochure for the drug."

(Response) We respectfully decline to add this phrase because not all brochures may be considered patient education brochures, and the addition does not improve or clarify the question.

(Comment 24) One comment recommended making Q15 (now Q12) more specific.

(Response) The purpose of this question is to get a general reaction to DTC advertising. Although we cannot statistically compare the results of this survey to FDA's 2002 physician survey for a number of reasons, we plan to descriptively compare results from the new survey with data obtained in 2002; thus, we prefer to keep the question as is. Although we did not make the question more specific, we have altered the wording slightly to make it clearer.

(Comment 25) This comment recommended the addition of several questions about what happens in the prescriber-patient relationship when patients are exposed to advertised prescription drugs (Q16; now Q13).

(Response) We agree that these are useful questions and have revised the questionnaire accordingly.

(Comment 26) One comment suggested adding a question to Q16 (now Q13) about whether DTC advertising increases the likelihood of conversations that the prescriber would not have otherwise had with his or her patients.

(Response) We have included this suggestion in the revised questionnaire.

(Comment 27) This comment recommended that we add, "the patient requests to be taken off the prescribed medicine" to Q17 (now Q10).

(Response) We agree this is a useful addition and have added it to the revised questionnaire.

(Comment 28) The comment agreed that the item in Q17 (now Q10) asking about patient recall of aspects of advertised drugs they discuss with their prescribers is valuable, but questions whether the item as worded will yield interpretable results.

(Response) We have revised the question and response options and will pay close attention to this when we conduct cognitive testing with nine participants prior to pretesting the instrument.

(Comment 29) The comment recommended removal of the series of questions in Q17 (now Q10) because many factors may enter into the responses to each question. Specifically, the comment refers to personal characteristics of a patient that may influence these answers.

(Response) We agree that patient characteristics may play a role, but we are interested in the overall responses of prescribers to these questions. Other surveys capture patient characteristics that may influence this question.[13] We have made minor improvements in the wording of these items based on peer review comments.

[13] *Prevention* magazine. (2011). http://www.rodaleinc.com/newsroom/12th-annual-survey-iconsumer-reaction-dtc-advertising-prescription-drugsi-reveals. Last accessed March 29, 2012.

(Comment 30) Two comments recommended adding questions to Q18, one of which referred to the effect of DTC advertising on prescription drugs patients are already taking.

(Response) We have added questions on these topics to Q18 (now Q14).

(Comment 31) The comment recommended the addition of several items related to cost to Q21 (now Q17).

(Response) These questions are outside the scope of the current project because FDA does not have authority over the cost of prescription drugs. Given the current length of the survey, we have chosen not to include these recommendations.

(Comment 32) One comment recommended the addition of two questions to the question series for Q22.

(Response) We have included the recommendation in Q14 of the revised questionnaire.

(Comment 33) This comment encouraged FDA to cautiously interpret the results of Q22 (now Q14), which asks whether prescribers believe that DTC advertising caused their patients to think drugs work better than they actually do.

(Response) We agree that all responses should be interpreted cautiously and will take care to avoid overinterpreting beyond the data.(Comment 34) The comment suggested removing the concept of "less expensive treatments" from Q22 (now Q15) about whether prescribers

thought DTC advertising caused patients to want advertised drugs over others.

(Response) Although we have heard this complaint frequently in focus groups, we have modified this question so that instead of the comparator in the question being "less expensive treatments," the comparator is "other recommended treatments."

(Comment 35) This comment recommended deleting the question about the cost of prescription drugs (Q22).

(Response) We have deleted this question from the questionnaire.

(Comment 36) One comment suggested a change in wording to Q23 (now Q16).

(Response) We have replaced the word "diagnoses" with the word "treatment," as suggested by the comment.

(Comment 37) This comment refers to Q23 (now Q18) and the questions following it that inquire about patients bringing coupons to their doctors for specific prescription drugs. Coupons and other incentives are frequently used in DTC promotion. This comment recommended rewording the question to assess whether patients are more likely to ask prescribers for drugs with coupons rather than those without.

(Response) We are unsure how prescribers would know this information because they are likely not current with the range of active advertising campaigns at any given time. We maintain that the currently worded question is a useful measure for assessing prescribers' general opinions about the use of incentives in DTC promotion.

(Comment 38) The comment expressed concern about Q23-25 (now Q18-20) because they believe that without clarification we may miss important nuances such as the possibility that a coupon may initiate a quality conversation about an illness.

(Response) As with all questions in this survey, we will carefully interpret the data, making sure not to draw conclusions not supported by the data. Nevertheless, we believe that if the presentation of a coupon resulted in a good doctor-patient conversation, the respondent would indeed select a positive answer to this question.

(Comment 39) Two comments stated that Q25 (now Q20) repeats Q24 (now Q19) in the questionnaire.

(Response) Q24 (now Q19), asked only of respondents who *have* encountered a patient with a coupon, asks how they *did* feel about that. Q25 (now Q20), asked only of respondents who have *not* encountered a patient with a coupon, asks how they *would* feel about that. Respondents will only see one of these two questions, depending on whether a patient has ever asked them about a prescription drug that has been advertised with a coupon. We like the suggested wording in one comment for Q24 (Q19) and have applied it to both questions.

(Comment 40) The comment suggested modifying Q26 to ask whether prescribers have ever had patients become concerned about their medication after seeing an ad for it.

(Response) We believe this would have been a good introductory question for the former Q26; however, because of survey time constraints, we were forced to limit the number of questions in this area. Based on peer review comments, we replaced these questions with a question that more directly asks whether prescribers have ever had a patient refuse to take or to stop taking their medication for these reasons (now Q21).

(Comment 41) One comment recommended adding a response of "*depends on the condition*" to the question of whether there should be more or less information about medical conditions in DTC advertising (Q27).

(Response) Because of survey time constraints, this question has been deleted.

(Comment 42) One comment recommended changing the order of Q28 and Q29.

(Response) Because of survey time constraints, all questions in this series have been deleted except Q29b (now Q22).

(Comment 43) This comment has taken a subsection of the questions about awareness of the Bad Ad program (Q31-37; now Q23-30) and claimed that FDA is using this forum as a way to inform prescribers about the Bad Ad program.

(Response) Looking at the entire set of questions, it is clear that the goal of this series is to assess whether prescribers have heard about the program and to explore their opinions about it. A description of the Bad Ad program is provided in current Q24 because we want to ask the subsequent questions of all respondents and can only do so if they know about the program. This survey provides a logical vehicle for assessing opinions about the Bad Ad program. Furthermore, because the Bad Ad program is directly related to prescription drug promotion, we believe it is clearly within the scope of the survey. We recognize, however, that we did not make this clear in the introductory section of the Federal Register notice, and we have included additional verbiage to remedy this omission. We note that no other comments expressed concern about these questions.

(Comment 44) One comment recommended wording changes to the follow-up open-ended item about the Bad Ad program (Q34a; now Q27).

(Response) We agree that the revised wording is preferable and have incorporated it into the questionnaire.

(Comment 45) One comment recommended wording changes to Q36/Q37 (now Q29/Q30).

(Response) We agree that changing the wording of these two questions may make them easier for respondents to understand and have done so in the questionnaire.

(Comment 46) This comment recommended deleting Q38-43 (now Q31-36) regarding social media membership and participation, citing the justification that the survey is about DTC advertising and these questions are irrelevant.

(Response) We reiterate that the purpose of the survey is to obtain opinions and responses from a variety of prescribers regarding prescription drug promotion. This topic encompasses both professional and DTC advertising and labeling and a variety of different media through which this promotion occurs. The Agency has an interest in determining the extent of promotion in emerging technologies such as social media, and various stakeholders have pressed the Agency to produce guidance related to new technologies. This survey provides an opportunity to explore prescribers' use of social media sites in order to assess whether future research is warranted regarding these emerging and potentially promotional venues. We have added language to the introduction section to clarify the scope of the survey.

(Comment 47) One comment recommended that we change the word "post" to "comment" in Q42/Q43 (now Q35/36).

(Response) We have made this change in these two questions. Please note that we have also added a time period to help respondents answer the questions more easily.

(Comment 48) One comment recommended the addition of Internet search engines to Q44 (now Q37a and 37b).

(Response) We have added search engines as an option for this question. We have also separated the question into two parts based on peer review comments to avoid a cognitively demanding ranking task.

(Comment 49) This comment expressed support for FDA's data collection from health care professionals regarding prescription drug promotion. One general issue raised by this comment was the exclusion and inclusion criteria for prescribers.

(Response) Prescribers must see patients at least 50 percent of the time in a non-hospital or non-inpatient setting. Primary care physicians will include internists, general practitioners, family practitioners, and obstetricians/gynecologists (all of whom were sampled in 2002). We will exclude pediatricians because relatively little DTC advertising is aimed at children or their parents. Specialists will include those who practice in therapeutic areas for which DTC advertising is or has recently been active: dermatologists; endocrinologists; allergists/pulmonologists; psychiatrists (all of whom were sampled in 2002); rheumatologists; cardiologists; ear, nose, and throat doctors; urologists; neurologists; and pain specialists. Nurse practitioners and physician assistants must have prescribing privileges.

(Comment 50) One comment raised the issue of weighting.

(Response) Although we did not provide details on weighting in the 60-day Federal Register notice, we agree and have implemented all suggestions provided by this comment. For example, this comment noted that FDA did not explain at what level results will be reported (i.e., aggregate versus each group as a separate sample). Results will be reported both in aggregate and for each group separately, and weights will be adjusted to produce national-level estimates.

(Comment 51) This comment supported FDA's use of equal-sized samples of four different types of health care professionals (general practitioners, specialists, nurse practitioners, and physician assistants) although it suggests that the artificial nature of equal-sized samples may make it difficult to find population parameters and targets to use for weighting purposes.

(Response) We note that the target population is all health care professionals with prescribing authority in the United States. This is considered the inferential population, which is rarely achieved. The proposed sample will be selected from the "responding population." The final survey weights will be constructed to reduce the coverage error and to compensate for nonresponse error and unequal probability of selection to represent the target population.

(Comment 52) This comment expressed skepticism that sample weighting can adjust or correct for noncoverage that results from inadequacies in sampling frames.

(Response) We agree that frame undercoverage cannot completely eliminate noncoverage bias in an estimator completely but will apply poststratification as the primary method for dealing with this undercoverage.[14] We believe that poststratification should reduce this bias to some extent for the same reasons that weighting adjustment reduces nonresponse bias. We will consider trimming extreme weights and redistributing them to avoid losses in precision. Details on weighting procedures used can be found on page 31.

(Comment 53) With regard to the questionnaire, this comment recommended adding specific questions about the prescriber's practice, including the size of the practice, whether it is part of a managed care organization, whether it is part of an integrated health system that involves hospitals, and whether the practice has a low- or no-access policy with regard to pharmaceutical sales representatives.

(Response) We agree that these may be relevant variables, and these questions are represented in the demographic section.

(Comment 54) One comment suggested adding a series of questions to assess the market dynamics that may affect prescribing decisions.

[14] Korn, E.L. and B.I. Graubard, "Analysis of Health Surveys, John Wiley and Sons: New York, NY, 1999.

(Response) Although these are interesting questions, they are outside the scope of the current project. Many of the suggested questions deal with issues of cost and reimbursement, which FDA does not regulate.

(Comment 55) One comment recommended that we should ask particular questions of nurse practitioners and physician assistants to assess their characteristics.

(Response) We agree with the comment and have several questions in the questionnaire, asked of all respondents, that will address some of these questions. We have added a question to the screener to ensure that all respondents have at least some prescribing authority, and we have added a question to the questionnaire to delve further into how much authority respondents have. We will also ask all respondents how many prescriptions they write in one week.

(Comment 56) One comment suggested reexamining the questionnaire from OPDP's online DTC promotion study (Docket No. FDA-2011-N-0230) in light of this survey to explore the possibility of comparing responses on similar questions.

(Response) We appreciate this suggestion and will examine the data from both studies to see if any descriptive comparisons can be made.

Please note that in response to all comments received, whether we have adapted the suggestions or not, we will specifically examine the items mentioned in cognitive testing. During this testing, nine respondents will participate in the survey while explaining why and how they have chosen their answers and which questions they find difficult to respond to or to understand.

External Reviewers

In addition to inviting public comment, OPDP sent materials to three individuals for external peer review. Two individuals provided comments:

Lila Finney Rutten, Ph.D., M.P.H.
Behavioral Scientist
Health Communication and Informatics Research Branch
National Cancer Institute

Cary Silvers
Director of Consumer Insight
Rodale, Inc.

9. Explanation of Any Payment or Gift to Respondents

The two partners Knowledge Networks is using for recruiting have different incentive policies. The Primary Care Network (PCN) panel provides cash incentives to physicians who complete the survey, which vary depending on the physician group. Primary care professionals receive $55; specialists $75. For this survey, nurse practitioners and physician assistants will also receive cash incentives: NPs $50; PAs $50. The OptIn panel is not providing any physicians for the survey but is helping to supplement the NP and PA groups. The OptIn panel partners with different companies that have rewards programs (e.g., Ticketmaster, Pizza Hut, Blockbuster) and invites people to join the panel and earn "rewards currency" for their time.

The use of an incentive is consistent with OMB standards for incentive use because the incentive will help improve coverage of specialized respondents (i.e., health care professionals). Participants receive incentives as part of the normal operating costs of online panels, so the incentive is not a separate cost to the Federal Government. The following studies have examined the influence of incentives on health care professional participation in research:

Dykema, Stevenson, Day, Sellers, and Bonham, 2011.[15] The authors conducted an incentive experiment on a survey of physicians selected from the American Medical Association's Physician Masterfile. Physicians were randomly assigned to one of four treatment groups: no incentive (6.2% response rate), $200 lottery (8.6% response rate),

[15] Dykema, J., J. Stevenson, B. Day, et al., "Effects of Incentives and Prenotification on Response Rates and Costs in a National Web Survey of Physicians," *Evaluation and the Health Professions*, vol. 34, pp. 434-447, 2011.

$50 incentive (15.4% response rate), or $100 incentive (25.4% response rate). As shown, response rates were highest in the groups with $50 and $100 incentives**.**

Martins et al., 2012.[16] The authors conducted a review of published oncology-focused studies to investigate methods for improving response rates. The meta-analysis showed that monetary incentives were effective at increasing response rates.

Thorpe et al., 2008.[17] The authors conducted several studies with physicians in Canada. They found that when they applied the Dillman tailored design approach and used monetary incentives (gift certificates), their response rates increased from 48% to 74–76%.

VanGeest, Johnson, and Welch, 2007.[18] The authors conducted a meta-analysis on methodologies for improving response rates in physician surveys. They examined 21 studies published between 1981 and 2006 that investigated the effect of monetary incentives on response rates in surveys of physicians. Looking at the results from all studies, the odds of responding to a survey with an incentive were 2.13 times greater than responding to a survey without incentives.

VanGeest and Johnson, 2011.[19] Similar to the meta-analysis conducted with physicians, the authors examined 22 published reports on strategies for increasing response rates with nurses. The authors found that monetary incentives were beneficial in boosting response rates.

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[16] Martins, Y., R. Lederman, C. Lowenstein, et al., "Increasing Response Rates From Physicians in Oncology Research: A Structured Literature Review and Data From a Recent Physician Survey," *British Journal of Cancer*, vol. 106(6), pp. 1021-6, 2012.

[17] Thorpe, C., B. Ryan, S. McLean, et al., "How to Obtain Excellent Response Rates When Surveying Physicians," *Family Practice*, vol. 26(1), pp. 65-68, 2008.

[18] VanGeest, J., T. Johnson, and V. Welch, "Methodologies for Improving Response Rates in Surveys of Physicians: A Systematic Review, *Evaluation and the Health Professions*, vol. 30, pp. 303-321, 2007.

[19] VanGeest, J. and T. Johnson, "Surveying Nurses: Identifying Strategies to Improve Participation, *Evaluation and the Health Professions*, vol. 34(4), pp. 487-511, 2011.

10. Assurance of Confidentiality Provided to Respondents

No personally identifiable information will be sent to FDA. All information that can identify individual respondents will be maintained by the independent contractor in a form that is separate from the data provided to FDA. The information will be kept in a secured fashion that will not permit unauthorized access. Confidentiality 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 20.63).[20] These methods will all be approved by FDA's Institutional Review Board (Research Involving Human Subjects Committee (RIHSC)) prior to collecting any information.

All respondents information will be kept confidential to the extent permitted by law. The Internet panel includes a panel privacy policy that is easily accessible from any page on the site. A link to the privacy policy will be included on all survey invitations. The panel complies with established industry guidelines and states that members' personally identifiable information will never be rented, sold, or revealed to third parties except in cases where required by law. These standards and codes of conduct comply with those set forth by the American Marketing Association, the Council of American Survey Research Organizations, and others. In addition, a consent form will be displayed before participants begin the survey (Appendix D). The consent form states that participation is voluntary.[21]

[20] This section states: "(a) The names or other information which would identify patients or research subjects in any medical or similar report, test, study, or other research project shall be deleted before the record is made available for public disclosure. (b) The names and other information which would identify patients or research subjects should be deleted from any record before it is submitted to the Food and Drug Administration. If the Food and Drug Administration subsequently needs the names of such individuals, a separate request will be made."

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

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

All electronic data will be maintained in a manner consistent with the Department of Health and Human Services' ADP Systems Security Policy as described in the DHHS ADP Systems Manual, Part 6, chapters 6-30 and 6-35.[22] All data will also be maintained consistent with the FDA Privacy Act System of Records #09-10-0009 (Special Studies and Surveys on FDA-Regulated Products).[23]

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

The total annual estimated burden imposed by this one-time collection of information is 773 hours.

Table 1.--Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Screener	3,500	1	3,500	0.03	105
Informed Consent	2,025	1	2,025	0.03	60
Pretest	25	1	25	0.33	8
Main Study	2,000	1	2,000	0.3	600
Total					773

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

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

12.b. Annualized Cost Burden Estimate

Type ofRespondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Physicians	396	$46.50[1]	$18,414
Physician Assistants	198	$30.50[2]	$6,039
Nurse Practitioners	198	$36.53[3]	$7,232
Total			$31,685

[1]Based on the 2011 median weekly income of $1,860 for physicians and surgeons of both sexes, as reported by the Department of Labor, http://www.bls.gov/cps/cpsaat39.pdf
[2]Based on the 2011 median weekly income of $1,220 for physician assistants of both sexes, as reported by the Department of Labor, http://www.bls.gov/cps/cpsaat39.pdf
[3]Based on the 2011 median weekly income of $1,461 for nurse practitioners of both sexes, as reported by the Department of Labor, http://www.bls.gov/cps/cpsaat39.pdf

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

There are no capital operating and maintenance costs.

14. Annualized Cost to the Federal Government

The total annual estimated cost to the Federal Government for the collection is $364,588($729,175 for two years). This includes costs paid to the contractor to create measurement instruments, program the study, draw the sample, collect the data, and create a database of the results ($649,175). The task order was awarded as a result of competition. Specific cost information other than the award amount is proprietary to the contractor and is not public information. The cost also includes FDA staff time to design and manage the study, analyze the results, and draft a report ($80,000; 15 hours per week for 2 years).

15. Explanation for Programs Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Conventional statistical techniques for survey data, including descriptive statistics such as proportions and percentages, will be used to describe the data. Additionally, analysis of variance and regression models will be used to analyze comparisons between occupational and demographic groups. (See section B below for detailed information on the design, hypotheses, and analysis plan.) The Agency anticipates disseminating the results of the study after 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 postings.

Project Timetable:

Task	**Estimated Completion Date**
External Peer Review	April 2012
RIHSC Review	August 2012
30-day FR notice publication	September 2012
OMB Review of PRA package	December 2012
Data Collection	January/February 2013
Receipt of Data and Methods Report from Contractor	May 2013
Data Analysis	July 2013
Draft Report	August 2013
Internal Review of Draft Report	November 2013
Revisions	December 2013
Final Report	January 2014

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.