Request for OMB Review
Docket No. 2007-N-0461
OMB No

Supporting Statement for

Mental Models Study of Communicating with Health Care Providers about the Risks and Benefits of Prescription Drug Use for Pregnant and Nursing Women with Chronic Conditions

Submitted by:

Office of Policy and Planning
Office of the Commissioner
Food and Drug Administration
Department of Health and Human Services

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The authority for FDA to collect the information derives from the FDA Commissioner's authority, as specified in section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (the Act, 21 U.S.C. 393(d)(2)) to conduct education and public information programs relating to the FDA's responsibilities, including that the public health is protected by ensuring that human drugs are safe and effective.

Under the above section of the Act, FDA engages in a variety of communication activities to ensure that patients and health care providers have the information they need to make informed decisions about treatment options, including the use of prescription drugs. FDA regulations (21 CFR § 201.57) describe the content of required product labeling, and FDA reviewers ensure that labeling contains accurate and complete information about the known risks and benefits of each drug. The requested data collection and analysis will provide FDA with insight for evaluating and improving current procedures. It is designed to identify knowledge gaps that FDA could then address, which would ultimately improve decision making and hence the health outcomes of the affected patients. In addition to identifying specific opportunities to redress misperceptions or gaps in health care providers' knowledge regarding treating pregnant and nursing women, the data from this study may also help more generally to guide FDA's communications efforts to focus on areas of misinformation in health care providers' mental models regarding treatment decisions for all patients.

2. Purpose and Use of the Information Collection

As mentioned above, this data collection will provide FDA with insight for evaluating and improving current communication procedures. It is designed to identify knowledge gaps for FDA to address, which would ultimately improve practitioner decision making and hence the health

outcomes of the affected patients. This new information collection uses Mental Modeling, a qualitative research method that compares a model of the decision-making processes of a group or groups to a model of the same process developed from expert knowledge and experience. In this study, the decision models of health care providers (HCPs) concerning treatment options for pregnant and nursing women will be compared to a model derived from the knowledge and experience of FDA employees who review product labeling for the purpose of ensuring that prescribers get the information they need to make optimal prescribing decisions. FDA will use telephone interviews to determine from the health care providers the factors that influence their treatment decisions for pregnant and nursing women with chronic conditions. Comparing expert and health care provider models based on the collected information will identify any significant gaps in health care providers' knowledge and misperceptions about prescription drug labeling and will contribute to a greater understanding of HCPs' risk/benefit decisions regarding prescription drug use during pregnancy and nursing. FDA can use this greater understanding to review its communication vehicles and to examine whether such vehicles could address any identified gaps or inconsistent perceptions in HCPs' decision-making mental models.

The qualitative data resulting from this research project will provide a preliminary framework and help FDA decide whether it would be useful to pursue quantitative studies to test the extent of any knowledge gaps and whether changes to FDA communications, including prescription drug labeling, would decrease or eliminate these knowledge gaps and misperceptions. In the long run, we expect this work to facilitate improved decision making by HCPs and their patients and thereby to improve public health.

FDA has contracted with Decision Partners to develop and conduct the Mental Models study, which they will do with the aid and input of FDA experts in social science research. Decision Partners has already completed the first phase needed for a Mental Models study. For this

phase, Decision Partners solicited the necessary insight from FDA study investigators, an internal FDA Project Advisory Group, and a workshop with a set of FDA expert reviewers to develop an Expert Model of "How Best to Communicate to Health Care Providers about the Risks and Benefits of Prescription Drug Use for Pregnant and Nursing Women." FDA elected to narrow the scope of this model to HCPs' treatment decisions for women with chronic conditions who are pregnant or nursing in order to focus the expert model development. The expert model is used as a base to develop the protocol for the next phase of the Mental Models study.

Mental models research is typically conducted with ***cohorts*** of respondents who represent categories of people whose mental models are to be compared, both individually with the expert model and between cohorts, identifying the potential for significant differences among cohorts. For the research in question, Decision Partners will work under FDA's direction to conduct interviews with 48-60 health care providers to develop a mental model describing how each of two cohorts makes treatment decisions relating to prescription drug use in pregnant or nursing women. The cohorts are as follows:

1) Healthcare providers who provide direct care to pregnant and nursing women. This cohort includes practitioners in: obstetrics, obstetrics/gynecology, nurse midwives, and primary care (general practice, family practice, and internal medicine).
2) Healthcare providers who provide care to women of reproductive age who have chronic health problems. This cohort includes practitioners in four specialty areas: allergy/pulmonology, cardiology, neurology, and psychiatry.

Within each cohort, 24-30 practitioners will be interviewed by trained interviewers in one-on-one in-depth telephone interviews. The interviews will take approximately one hour. Each HCP participant will receive $150 - $200.

Potential physician participants will be randomly identified through a purchased list based on the American Medical Association's (AMA) Physician Masterfile. This list tracks all physicians (MDs and DOs) practicing in the US, not only members of the AMA. Potential nurse midwives will be identified through their professional association.

3. **Use of Improved Information Technology and Burden Reduction**

Qualitative interview guides are often unstructured. The questions are generally open-ended, allowing interviewees to respond without restriction. As opposed to structured questionnaires, the goal of a qualitative inquiry is to discover the range of meaningful themes and categories – often used in follow-up, quantitative research. Typically, a qualitative interview requires some interaction between the respondent and the interviewer. While for some qualitative studies it may be appropriate to engage in an electronic interaction – through a computer interface - mental modeling interviews rely on the subtleties than can only be detected through verbal conversation. The consumer interviews for this research are conducted over the telephone, which minimizes respondent burden that would be incurred through the time and travel that would be needed to conduct the interviews in person. Past experience has shown that telephone interviews are sufficient to provide the necessary connection and rapport to result in useful data.

4. **Efforts to Identify Duplication and Use of Similar Information**

We are unaware of any other groups that are conducting this kind of research or are even engaged in trying to determine what factors health care providers use in making treatment decisions for pregnant or nursing women. Because we have held a number of public meetings regarding pregnancy labeling we expect that we would be aware of such work if it existed.

5. **Impact on Small Businesses or Other Small Entities**

This study will not have a significant impact on small businesses or other small entities. The information collection is completely voluntary and healthcare providers can complete the interview whenever they wish.

6. Consequences of Collecting the Information Less Frequently

This is a one time information collection. Without the data collection, FDA would not have the knowledge or understanding of how HCPs make risk/benefit decisions regarding prescription drug use during pregnancy and nursing.

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

The information collected from the interviewees is confidential. Please see section 10 below for a discussion on confidentiality.

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

In accordance with 5 CFR 1320.8(d), on December 11, 2007 (72 FR 70328), FDA published a 60-day notice in the *Federal Register* requesting public comment on the information collection provisions. No comments were received.

Dr. Baruch Fischhoff, Howard Heinz University Professor, Carnegie Mellon University, Pittsburgh, PA, reviewed the protocol for the information collection. Dr. Fischhoff is a primary co-author of the (to-date) definitive work on Mental Models and is internationally known in this field. The contractor, Decision Partners, is a leader in research in this field as well. Dr. Anthony Scialli, adjunct Professor of Obstetrics and Gynecology, and Biochemistry and Molecular Biology at Georgetown University Medical Center, was also involved in the process of putting together the Mental Models protocol.

9. Explanation of any Payment/Gift to Respondent

Decision Partners typically offers an honorarium to interviewees for participation in a research project. While honoraria for lay participants is generally on the order of between $25-$30, for the interviewees in this study Decision Partners has suggested that honoraria be between $150 - $200, depending on the specialty of the health care provider. Their experience has been that physicians expect to be compensated more generously, especially given that they may be contributing up to an hour of their time.

10. Assurance of Confidentiality Provided to Respondents

The contractor collects information for the sample list for the sole purpose of inviting people to participate in an interview. The information is stored securely and will not be used unless the person opts to participate in an interview. Under no circumstance is contact information ever released to a third-party.

The information collected from healthcare providers (HCPs) in this research is considered confidential. This study has been reviewed by FDA's Institutional Review Board (Research Involving Human Subjects Committee - RIHSC) Director and has been determined to be exempt from RIHSC review under 45 CFR 46.101(b)(2). This exemption states that although participants may be identified, disclosure of information could not place them at risk of civil or criminal liability or be damaging to their financial standing, employability, or reputation. Despite this exemption, the contract specifies that identifying information will stripped from the data and that appropriate security procedures are in place.

11. Justification for Sensitive Questions

No questions of a sensitive nature are asked in this information collection. Further, we are only asking respondents to speak within the context of their professional capacities.

12. Estimates of Annualized Burden Hours and Costs

The time required for screening and participation will be 1 hour per respondent. There will be a total of no more than 60respondents. The total estimated respondent burden is 60 hours.

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
60	1	1	1.0	60.0
Total				60.0

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no other annual costs or operating and maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

The total cost to the Federal government for this data collection is approximately $1,000 to account for the mailing costs of sending recruitment letters to physicians.

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA intends to make at least a summary of the results available on its Web site and to write up the results for publication in peer-reviewed professional journals.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB Approval date will be displayed on all materials associated with the study.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the Certification for Paperwork Reduction Act Submissions for this proposed research.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

This information collection will not employ statistical methods. It is a qualitative data collection that provides data that do not depend on either random selection or random assignment to experimental conditions. Regardless, we include below information about the sample and how it will be selected, as well as discuss, as appropriate, the methodology in general.

1. Respondent Universe and Sampling Methods

Mental models research is typically conducted with ***cohorts*** of respondents who represent categories of people whose mental models are to be compared, both individually with the expert model and between cohorts, identifying the potential for significant differences among cohorts. For the research in question, Decision Partners will work under FDA's direction to conduct interviews with 48-60 health care providers to develop a mental model describing how each of two cohorts makes treatment decisions relating to prescription drug use in pregnant or nursing women. The cohorts are as follows:

- Healthcare providers who provide direct care to pregnant and nursing women. This cohort includes practitioners in: obstetrics, obstetrics/gynecology, nurse midwives, and primary care (general practice, family practice, and internal medicine).
- Healthcare providers who provide care to women of reproductive age who have chronic health problems. This cohort includes practitioners in four specialty areas: allergy/pulmonology, cardiology, neurology, and psychiatry.

Potential physician participants will be randomly identified through a purchased list based on the American Medical Association's (AMA) Physician Masterfile. This list tracks all physicians (MDs and DOs) practicing in the US, not only members of the AMA. Potential nurse midwives will be identified through their professional association.

Within each cohort, 24-30 practitioners will be interviewed by trained interviewers in one-on-one in-depth telephone interviews. Cohorts will be identified and recruited to represent a reasonable range of geographic locations (urban/suburban/rural), practice settings and age.

2. Procedures for the Collection of Information

The mental models interviews of approximately one hour in length will be conducted by trained researcher interviewers from Decision Partners. The interviews will take place by telephone and will be recorded, without any identifying information attributed to the respondents. The interview protocol is in Attachment A. The remarks from the recorded interviews will be transcribed, coded and consolidated into a report.

3. Methods to Maximize Response Rates and Deal with Nonresponse

Physicians and other healthcare providers are known to be exceptionally busy professionals who generally employ office managers, receptionists, secretaries, or nurses as "gatekeepers" to screen mail and telephone contacts. Because they are considered difficult to reach, the following procedures will be employed to maximize the response rates for the physician/health care provider respondents.

(1) *Pre-notification letters.* Literature and practical experience have shown that "cold calling" physicians for survey participation has a low chance of success. Instead, we will pre-notify potential respondents through a letter (Attachment B) which the FDA will send to the physicians. The letter describes the purpose of the research and will be signed by the Director of FDA's Office of Women's Health. Interested persons will be asked to call, email or write back to a designated person at Decision Partners who will then contact them to schedule an interview.

(2) *Callbacks.* After the initial contact, additional callbacks will be employed in an attempt to reach the physician. A negative response from the "gatekeeper" will not be accepted as a termination. If the respondent is not available, an appointment for a callback will be made with the

gatekeeper, and the respondent will be contacted at the designated appointment time. If it is not possible to schedule an appointment, the interviewer will leave a telephone number for the respondent to schedule an appointment to conduct the interview.

(3) *Incentives for physicians.* Each physician will receive an honorarium of $150 to $200 (depending on whether the respondent is a primary care or a specialty physician) as incentive for participation. Our experience has shown that physicians expect to be compensated generously, given that they may be contributing up to an hour of their time.

4. Test of Procedures or Methods to be Undertaken

The contractor, expert in the field of Mental Models research, has reviewed the questionnaire (interview protocol – Attachment A). This questionnaire was also reviewed by FDA individuals who are highly experienced with telephone survey design. A total of six (6) pre-test Mental Models interviews were conducted as an initial test of procedures and respondent understanding of terminology and questions. Three were conducted before the interview protocol (questionnaire) was revised, and three after revision. Following the pre-test, a number of questionnaire items were simplified in response to feedback received by both interviewers and physician/HCP respondents.

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

Because this is a qualitative study, there are no statistics that will be employed to analyze the data. The contractor, Decision Partners, will qualitatively code and interpret the data and prepare a report for FDA that contains the analysis and recommendations.