Passback questions and responses

1. What response rate does FDA expect to achieve? How many individuals will FDA contact to attain the required number of participants?

Our Contractor expects that we could get a rather high response rate for this type of work. While they have not recruited exactly this way before, they cite Kellerman and Herrold (2001; American Journal of Preventive Medicine) in asserting that similar research can achieve response rates of 40-60% or higher, and given the incentive and the FDA request, they may expect to be on the high end of that or greater.

However, our Contractor also notes that response rates are typically not an appropriate measure for mental models research because, as we are in this study, we are interested in learning from healthcare providers who are sufficiently interested the topic to give us an hour of their time, on order to capture the full-range of thinking among them. Further, this methodology does not involve the type of quantitative analyses that lend themselves to analyses of non-response. If we decide to do more structured surveys to capture prevalence's we would be more concerned about non-response bias.

FDA will send out invites to randomly selected healthcare providers (from the AMA's Physician Masterfile, which tracks **all** physicians practicing in the United States) in batches of 250 until we reach the quotas for each practice type within each of the 2 cohorts. The nurse midwives are being contacted through an eNewsletter being sent out from their professional association (American College of Nurse Midwives). Because we are not screening (i.e., not requesting information from) these individuals, we have not included them in the overall burden estimate.

2. Given the qualitative nature of this research, as we discussed on our call, can FDA revise the language in the response to #2 of the supporting statement to stress that this study will yield largely formative data, that the results will not be generalized to the entire universe of healthcare providers, and that further research would be necessary to test messages crafted from these results or to inform policy or regulation? The language in #2 seems to convey a higher level of precision or definitiveness (e.g. on page 3, the supporting statement says "FDA will use these telephone interviews to determine from the health care providers the factors that influence their treatment decisions…" and "comparing expert and consumer models… will determine whether these gaps could be addressed in specific labels").

See attached for changes in redline on page 3. Among other changes, we specify that 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." Our sense is that the above changes concur with your position that this is formative data and that further research would be necessary to test messages crafted from these results or to inform policy or regulation.

<<OMB ICR Pregnancy and Nursing MM study revised 10-29-08.doc>>

3. Can FDA add information as to why the 24-30 practitioners per cohort is the appropriate number of interviewees?

Following norms developed in ethnographic and other qualitative research, mental models studies often include 25-30 individuals. Although the prevalence of individual beliefs will be estimated with less precision than with a larger sample, the nature of those beliefs will be understood better than with a larger sample structured survey that restricts the respondents' abilities to express themselves. The immediate need for this study is to achieve a better understanding of the nature of the providers' beliefs. Mental models research also lends itself to informing the design of more structured surveys that can be administered to a larger sample if greater precision is needed. Examples of similar sample size employed in mental models research are in the references below.

References:

- Byram, S., Fischhoff, B., Embrey, M., Bruine de Bruin, W., & Thorne, S. (2001). Mental models of women with breast implants regarding local complications. *Behavioral Medicine, 27*, 4-14.

- Darisi T., Thorne, S., & Iacobelli, C. (2005). "Influences on decision-making for undergoing plastic surgery: a mental models and quantitative assessment." Plastic Surgery, 116, 907-16.

- Downs, J. S., Bruine de Bruin, W., & Fischhoff, B. (2008). Parents' vaccination comprehension and decisions. *Vaccine, 26*, 1595-1607.

4. FDA is providing assurance of confidentiality. If FDA were to be FOIA'd on this particular study, would FDA be able to withhold the information?

The contractor will not give the names of the interviewees to FDA. This is standard procedure for our social science research studies to ensure confidentiality. Because the names will not be part of FDA's records, we cannot divulge them under the FOI Act. Further, the interview questions do not ask for personally identifiable information. Therefore, even if the contractor gives us quotes or interviews we will not be able to identify the interviewee not to provide that information under the FOI Act.

5. The mental models final report lists a number of criteria that are important in guiding the sampling for this study. Will FDA, for example, ensure that there is adequate representation from rural providers and a good mix of practice types, both in terms of demographic diversity as well as # of patients served and years of experience)?

The focus of our research is understanding healthcare providers' decisions and informational needs rather than the decisions and informational needs of their patients. In discussing the sampling frame with the project team and the Contractor, we determined that having an appropriate range of professional types (general OB/GYN, nurse midwives, specialties, etc.) whom our internal experts believe are most likely to treat women who are or may become pregnant and are nursing. We also determined that minimal level of experience (8 years of practice) were essential criteria. At that time we established quotas on practice types and set a minimum for years of practice because we hypothesized these would be the factors that would be most likely to influence the healthcare providers' mental models of treatment decisions.

No other target criteria were set for populations served. The nature of the data collection does not permit it to ensure true “representativeness” in the quantitative sense of the term. However, depending on responses to the invitation, the Contractor may be able, from comparison of zip code information to Census data, to provide target ranges for geographic locations, rural/urban communities and populations served (average income level and % minority). They will try to do this to ensure that they capture the thinking of healthcare providers who serve across the range of locations and populations.