Hi Brenda,

Please see Nancy Ostrove's responses to your questions/comments. Nancy is providing these written answers but can telecon if you need more information upon review. If you would like to schedule a call on this, please let me know.

Thanks,
Jonna

From: Aguilar, Brenda [mailto:Brenda_Aguilar@omb.eop.gov]
Sent: Friday, December 14, 2007 3:24 PM
To: Capezzuto, JonnaLynn; Berbakos, Elizabeth G; Presley, Denver
Subject: OMB Comments Physician Risk (ICR Ref No.: 200707-0910-006)
Importance: High

All -

Please see below and attached for OMB questions/comments on the Physician Risk Communication ICR. The biggest obstacle to clearance is the lack of Part B of the supporting statement. I can't find it in ROCIS if it was submitted and I can't clear without it. I can be available for a conference call with the program folks next week (other than Monday) if they think that would be helpful in moving clearance forward. However, I would want to have a chance to review Part B before the call took place to ensure we could wrap everything up.

Please advise,
Brenda

Comments on Supporting Statement

1. Part B of the Supporting Statement is missing, please provide ASAP.
2. P. 2 of the Supporting Statement (Part A) discusses as part of the key information to be collected, "The Impact on physicians, their patients, and their practices of the disclosure of still uncertain, emerging risks associated with medical products." That bullet may overstate the capability of the survey somewhat. Tt doesn't appear that the impact of disclosure of emerging risk information on physicians, patients and practices could be evaluated based on this survey. The survey appears to be more geared towards physician preferences w/r/t obtaining such risk information (timing, use of FDA's website, etc.) and physician perceptions of their ongoing relationship with patients who have obtained such information elsewhere. Perhaps that first bullet could be revised accordingly.
   Insert term “perceived” prior to “impact on physicians” and see questions 27-37 which address this key issue. There is more discussion on these questions below.

Comments on Questionnaire

1. Q's 3-16 ask respondents to evaluate a number of potential sources of information on emerging risk information. Did FDA consider adding a question prior to that one simply asking where the physician went for trusted information on emerging risks, or which source of information on emerging risks he/she trusted most?
   We did think about this. However, there are both cost and time implications of including open-ended questions in individual interviews, which is why we try to limit them. The sources in questions 3-16 were drafted following the results of the physician focus groups we conducted (in April-May 2006) to help with

questionnaire construction. We addressed the open-ended question suggested by OMB in those groups. The other concern about asking this in an open-ended fashion in the current interview is that, because of availability biases, we might get respondents' "top of mind" responses about what source they tend to use first, which doesn't necessarily get at what source they find to be most trustworthy. In fact, they might tend to not think of their most trustworthy source because they don't hear from it very often.

2. Q 24 contains the term, "non-risk associated alternatives." What does that term mean? Is it a medical term of art that doctors will understand?
That's a good question. It is not a medical term of art. It was meant to get at alternative treatments that could be substituted for the "problematic" product – treatments that are not associated with the same emerging risk. But we did not test this item with many of the cognitively interviewed physicians (n=8) because it was added during the interviewing process. Looking at it again, it is not clear to me that they would interpret it as intended. An alternative could be:
Would mentioning alternative treatments that don't currently show the emerging risk be very ….
3. Q 26 asks about what national newspaper the doctor reads at least weekly. What is the rationale for that question?
This is meant to give us practical direction regarding with what newspapers we could establish proactive working relationships, with the goal of encouraging these often consulted news sources to pay special attention to emerging risk press notifications. Ultimately, the goal is to facilitate getting the notices out to the targeted audiences (the physicians).
4. Q 27 asks about a patient that has gotten information on emerging risks from a source other than their doctor. The question (and the next few that follow it) assume that the information received was accurate. Oftentimes information received through the media or by word of mouth may be distorted, inaccurate, or out of context. Did FDA consider this in its development of these questions? Would the addition of some language in the existing question or the addition of a separate question help to clarify this?
This question does not necessarily assume that the information was accurate or inaccurate. In fact, in discussing this issue with the physician focus groups, they made it clear that patients will often get information from public sources that is not complete and hence may be misleading. It is a good suggestion to add a question about their most recent experience, which would allow us to co-vary the accuracy of the response with the reported effect on the physician-patient interaction. In response, I suggest inserting the following prior to question 37:
On a scale of 1 to 5, would you say that the information your patient got about this newly emerging risk was accurate or inaccurate, with 1 indicating that it was completely accurate and 5 indicating that it was completely inaccurate?
5. Q27-37 When taken in totality (and in light of the concern raised above) it appears that this section could be leading to the respondent and put them on the defensive with regard to the situation where their patient received information on emerging risks from an "outside" source. Is FDA concerned that it might bias doctors answers toward saying that they want more information on emerging risks sooner than they might actually use in practice? Does FDA account for this possibility in other ways? Please explain.
This is a reasonable concern. In act, the reason that this set of questions **follows** the set of questions that address their sources of, and preferences for when they receive, emerging information, is so that there is no possibility that our questions (or their responses) about their experiences with patients having received information from another source will influence their responses on those

items. The items that follow the questions concerning patient-physician interactions are fairly objective in nature (whether they used particular internet-based information sources and whether they reported adverse events) and not likely to be affected by any bias due to questions 27-37. However, in the 8 cognitive interviews we held, there was no suggestion that the patient interaction questions was in any way “leading” to the respondent. Their major expressed concern was with getting emerging information before the press gets it so that they can respond in an informed fashion to patients’ questions.