FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF FOCUS GROUPS & IN-DEPTH INTERVIEWS FOR THE FDA CDER RISK COMMUNICATIONS INITIATIVE (0910-0677)

TITLE OF INFORMATION COLLECTION: Focus Groups to Investigate Specific Terminology in Prescription Drug Promotion

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of need:

The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Office of Prescription Drug Promotion (OPDP) is seeking OMB approval under the generic clearance 0910-0677 for the focus group project, "Focus Groups to Investigate Specific Terminology in Prescription Drug Promotion," to examine consumer and healthcare professional interpretation of specific terminology used in direct-to-consumer (DTC) and professional advertising of prescription drugs.

The terms "natural" and "targeted" have been seen in prescription drug ads and may affect consumer and healthcare professional interpretations of the risk/benefit profile of a drug by implying reduced drug risk and/or increased drug benefit in certain contexts. We propose the current focus groups to gain a basic understanding of consumer and healthcare professional interpretations of these terms on their own and in relation to promotion and to guide future research on similar topics.

Our strategy for inquiring about participant interpretations of these terms involves an inverted pyramid, beginning with general thoughts about the term in question and ending with thoughts about the term in regard to prescription drug promotion.

Interpretation of "natural" claims. Previous literature demonstrates that the term "natural" is often interpreted positively across a variety of domains. For example, there is a body of literature on the perceived meaning of the word "natural" when it refers to ingredients in food or medical products among consumers. The general finding is that consumers show "naturalness" bias, preferring products that claim to contain natural ingredients. Specifically in relation to drugs, individuals prefer ones that claim to be made from natural ingredients over those made with synthetic ingredients, even if they are told that "natural" and "synthesized" chemicals are identical.[1] It is suggested that "natural" ingredients are perceived to be safer; thus, in the case of drugs, there is a strong potential for this word to influence the perception of risk. However, health care professionals may not be impressed with the "naturalness" of pharmaceutical agents. For example, based on a review of the media coverage of medical marijuana issues, health care professionals' arguments against medical marijuana often stressed the availability of synthetic THC (for example, Marinol[tm]) or more effective pharmaceuticals indicated for the medical conditions in question (Ulasevich, 2003).[2]

1 DiBonaventura, M., Chapman, G, B. (2008). Do decision biases predict bad decisions? Omission bias, naturalness bias and influenza vaccination. Medical Decision Making, 40, 1-8.

2 Ulasevich, A. (2002). Newspaper coverage of medical marijuana debate. Presentation at the 2002 American Public Health Association Conference, Philadelphia, PA.

We seek to gain additional understanding about consumer and healthcare professional interpretation of this term, particularly in a prescription drug promotion context, as well as to draw descriptive comparisons between these two populations.

Interpretation of "targeted" claims. It is possible that the term "targeted" can also influence perceptions of prescription drug efficacy and risk. For example, this term has been used in prescription drug ads to imply that a drug only affects the condition and does not have toxic effects on healthy cells, when that is not always the case. We seek to gain additional understanding about consumer and healthcare professional interpretation of this term, as well as to draw descriptive comparisons between these two populations.

Investigation into understanding of the indication statement. The indication statement of a drug refers to its intended purpose: the diseases and symptoms that may be treated by using a specific drug. In line with previous research examining the addition of quantitative information to the benefit information in promotion (OMB Control No. 0910-0663), OPDP is interested in what this statement means to viewers when it is not accompanied by additional information as well as when it is accompanied by other qualitative benefit statements. These focus groups represent the first step in determining where and how this research should focus.

2. Intended use of information:

OPDP has an active research program with funds committed for important projects. In order to maximize resources and anticipate future needs, it is necessary for OPDP to continuously explore avenues for future research. The qualitative focus group is a valuable tool for developing a future research agenda. The proposed focus groups will allow us to investigate consumer and healthcare professional interpretation of specific terminology including "natural" and "targeted" in DTC and professional advertising, as well as obtain some preliminary feedback on how people view indication statements. This information collection will inform development of future quantitative research studies.

3. Description of respondents:

FDA contracted with Ipsos Public Affairs (Ipsos) to conduct these in-person focus groups.

Focus groups will consist of 12 groups with a general population of consumers and 6 groups with healthcare providers. Respondents will be recruited and screened for eligibility according to the criteria in the attached participant screener. Table 1 shows the breakdown of participants. As shown, consumer groups will be split between high and low education groups, defined by graduation from high school or not.

Table 1. Participant Population and Group Breakdown			
Population	**City**	**Education Level**	**Groups**
General population consumers	Washington, DC metro area	High	2
		Low	2
	Chicago, IL	High	2
		Low	2
	Knoxville, TN	High	2
		Low	2
Healthcare Providers	Washington, DC metro area	N/A	2
	Chicago, IL		2
	Knoxville, TN		2

4. Date(s) to be conducted and location(s):

As shown in the Table 1, groups will be conducted in the metropolitan areas of Washington, DC; Chicago, Illinois; and Knoxville, Tennessee. Focus groups are planned for the winter and spring of 2013.

5. How the Information is being collected:

Recruitment Information

Staff from the focus group facilities will conduct subject recruitment for both consumer and healthcare professional groups using the participant screener (attached). The facilities' staff will book the proper focus group participants into the healthcare professional and non-healthcare professional groups. The facilities' staff will provide all necessary information and instructions to ensure participants arrive at the proper location on the agreed upon date and time. Facilities will recruit 12 participants for each session, to ensure a minimum of 9 participants "show."

The focus group facilities will send confirmation and reminder correspondences to recruited participants to help ensure attendance.

Focus Group Discussions

Ipsos staff members will serve as moderators for all focus groups. OPDP staff members will observe most, if not all,of the sessions from the observation rooms at the focus group facilities or remotely using streaming technology. The focus group facilities will make audio recordings of the group events to ensure a verbatim record of the proceedings is captured. Transcripts will be created to facilitate the moderator's reporting of the groups.

The moderator will use the attached moderator guide to ensure that all relevant topic areas are addressed.

The Contractor will comply with safeguards for ensuring participant information is kept private to the extent permitted by law. The last names of the participants will not appear

on any focus group materials. Verbatim quotes included in the final report will not be attributed to any individual.

6. **Number of focus groups:**
   FDA Personnel Focus Groups/Interviews

   Healthcare Professionals: 6 focus groups
   Non-Healthcare Professionals: 12 focus groups

   See Table 1 for greater detail.

7. **Amount and justification for any proposed incentive:**

Our experience in conducting focus group research indicates that offering an incentive that is below the accepted rate will result in increased costs that exceed the amount saved on a reduced incentive. The consequences of an insufficient incentive include the following.

- Increased time and cost of recruitment
- Increased likelihood of "no-shows" (which may result in methodologically unsound focus groups with small numbers of participants)
- Increased probability that a focus group may need to be cancelled or postponed due to insufficient numbers recruited by the scheduled date of the focus group. This incurs additional costs and puts additional burden on the recruited participants who have to reschedule their participation in the focus group

In preparation for these focus groups, Ipsos consulted with facilities that host focus groups to determine incentive rates. The contractor informed us that proposal of lower incentives resulted in the facilities refusing to accept the job. Given this information, we propose an incentive of $75 to ensure that we are able to attract a reasonable cross-section of general population participants.

Healthcare professionals are even more difficult to recruit for participation in research, RTI International, a non-profit research organization, conducted a review of the provider incentive literature and found the following.

Research on surveys with physicians suggests such surveys are typically characterized by low response rates.[3] As a result, numerous studies have been conducted to determine methods for improving such response rates. As a result of that research and practical experience, the general consensus among researchers in non-profit, government, and academic institutions who conduct surveys with physicians and other healthcare providers is that incentives are necessary to ensure acceptable response rates.

A number of studies have been published demonstrating the effects of incentives on increasing response rates:

3 VanGeest, J., Johnson, T., & Welch, V. (2007). Methodologies for improving response rates in surveys of physicians: A systematic review. *Evaluation and the Health Professions*, 30, 303-321.

- **Dykema, Stevenson, Day, Sellers, & Bonham, 2011.**[4] 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, $200 lottery, $50 incentive, or $100 incentive). Response rates were highest in the groups with the $50 and $100 incentives.

- **Martins et al., 2012.**[5] 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.**[6] 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.**[1] 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 impact 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 & Johnson , 2011.**[7] 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, even when small, were beneficial in boosting response rates.

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4 Dykema, J., Stevenson, J., Day, B., Sellers, S., & Bonham, V. (2011). Effects of incentives and prenotification on response rates and costs in a national web survey of physicians. *Evaluation and the Health Professions*, 34, 434-447.

5 Martins, Y., Lederman, R., Lowenstein, C., Joffe, S., Hastings, B., & Abel, G. (2012). Increasing response rates from physicians in oncology research: A structured literature review and data from a recent physician survey. *British Journal of Cancer*, 106(6), 1021-6.

6 Thorpe, C., Ryan, B., McLean, S., Burt, A., Stewart, M., Brown, J., Reid, G., & Harris, S. 2008. How to obtain excellent response rates when surveying physicians. *Family Practice*, 26(1), 65-68.

7 VanGeest, J., & Johnson, T. (2011). Surveying nurses: Identifying strategies to improve participation. *Evaluation and the Health Professions*, 34(4), 487-511.

Furthermore, there is some evidence that using incentives can actually reduce nonresponse bias in some situations by bringing in a more representative set of respondents.[8] [9][10] This may be particularly effective in reducing nonresponse bias due to topic saliency.[11] However, none of these studies were conducted with physicians or other healthcare providers, and it is unclear if the same results would hold true.

Ipsos polled focus group facilities and found that several facilities refused to accept jobs when healthcare professionals were offered incentives lower than $275. Given the research that RTI uncovered in 2011 and the additional inflation that has occurred since then, we propose a compromise incentive of $200 for healthcare professionals to attract a reasonable selection of such individuals.

8. Questions of a Sensitive Nature:

None.

9. Description of Statistical Methods (i.e., Sample Size & Method of Selection):

The facilities' staff will provide all necessary information and instructions to ensure participants arrive at the proper location on the agreed upon date and time. Facilities will recruit 12 participants for each session, to ensure a minimum of 9 participants "show."

Table 2 shows the estimated annual reporting burden for the groups, assuming 9 participants per group.

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
General Population	108	105*108	189
Healthcare Professionals	54	105*54	95

8 Castiglioni, L., & Pforr, K. (2007). The effect of incentives in reducing non-response bias in a multi-actor survey. *Presented at the 2nd annual European Survey Research Association Conference*, Prague, Czech Republic, June, 2007.

9 Singer, E. (2002). The Use of Incentives to Reduce Nonresponse in Household Surveys. (R. M. Groves, D. A. Dillman, J. L. Eltinge, & R. J. A. Little, Eds.) *Survey nonresponse*, (051), 163 -178. University of Michigan Institute for Social Research. Retrieved from http://www.isr.umich.edu/src/smp/Electronic.

10 Singer, E. (2006). Nonresponse bias in household surveys. *Public Opinion Quarterly*, 70(5), 637-645.

11 Groves, R., Couper, M., Presser, S., Singer, E., Tourangeau, R., Acosta, G., & Nelson, L. (2006). Experiments in producing nonresponse bias. *Public Opinion Quarterly*, 70(5), 720-736.

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