**DEPARTMENT OF HEALTH & HUMAN SERVICES**
Administration

Public Health Service
Food and Drug

# Memorandum

Date December 10, 2009 (Revised October 22, 2010)

From PRA Specialist, Paperwork Reduction and Records Management Staff, Office of Information Management

Subject Request for Approval of FDA Focus Group, "Investigation of Consumer and Physician Beliefs about Direct-to-Consumer (DTC) Advertising"; OMB Control No. 0910-0497

To Human Resources and Housing Branch
Office of Information and Regulatory Affairs, OMB
Through: HHS Reports Clearance Officer_____

The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER)/Division of Drug Marketing, Advertising, and Communications (DDMAC) is seeking OMB approval under the generic clearance 0910-0497 to conduct a focus group, "Investigation of Consumer and Physician Beliefs about Direct-to-Consumer (DTC) Advertising," to explore how consumers and physicians feel about various aspects of direct-to-consumer (DTC) advertising of prescription drugs. This information will be critical in our development of future quantitative research studies.

Purpose of the Focus Group

The qualitative focus group is a valuable tool for developing a future research agenda. Currently, DDMAC has an active research program with funds committed for important projects. In order to maximize resources and anticipate future needs, it is necessary for DDMAC to explore avenues for future research so that a solid research plan is in place. Focus groups will allow us to investigate three areas of interest to DDMAC and to sharpen the focus of the research questions for later quantitative studies.

DDMAC proposes two focus group sets of non-physicians and one focus group set of physicians.

For the parents and teachers (non-physicians), we propose an incentive of $75. According to Karen Sollod of OMR Market Research and Focus Groups based in Washington, DC, $75 had been the industry standard until two or three years ago. At that time, facilities in Washington, DC, Philadelphia, Dallas, and Seattle began to offer a $100 incentive for consumers. According to these facilities, with the current cost of gas and other travel expenses, $100 is the new standard for ensuring participation in qualitative research. Given this information, we propose a $75 incentive to ensure that we are able to attract a reasonable cross-section of consumers.

For the physicians, we propose an incentive of $150. Physicians are a difficult group to recruit for participation in research.[1] Sudman (1985)[2] described five reasons why they may be difficult to recruit:

1) lack of time
2) perceived importance of the study
3) confidentiality concerns
4) past response experiences
5) gatekeepers (e.g., receptionists, nurses)

These reasons have been supported in more recent studies.[3] VanGeest et al. (2007) conducted a systematic review to determine what methods, if any, increased the participation of physicians. They found that monetary compensation increased participation compared with nonmonetary incentives, and that personal payment increased participation compared with donation to charity or other non-personal incentive.[4] Although VanGeest et al.'s review found that monetary amounts ranging from $1 to $50 did not produce different levels of participation, they found no studies examining larger incentives. In 2007, the professional focus group industry rate for physicians ranged from $250-$400, so these studies do not reflect an examination of the rates physicians are accustomed to being offered.

The literature suggests that physicians must be paid to induce adequate participation. Physicians are extremely busy and have maintained a wall of protection between themselves and researchers. In order to recruit them, adequate monetary incentives must be provided. Although $150 is well

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1 VanGeest, J.B., Johnson, T.P., & Welch, V.L. (2007). Methodologies for improving response rates in surveys of physicians: A systematic review. *Evaluation of Health Professionals, 30*, 303-322.

2 Sudman, S. (1985). Mail surveys of reluctant professionals. *Evaluation Review, 9*, 349-360.

3 See, for example, Heywood, A., Mudge, P., Ring, I., & Saonson-Fisher, R. (1995). Reducing systematic bias in studies of general practitioners: The use of a medical peer in the recruitment of general practitioners in research. *Family Practice, 12*, 227-231; Kaner, E.F., Haighton, C.A., & McAvoy, B.R. (1998). "So much post, so busy with practice—so, no time!": A telephone survey of general practitioners' reasons for not participating in postal questionnaire surveys. *British Journal of General Practice, 48*, 1067-1069; MacPherson, I., & Bisset, A. (1995). Not another questionnaire!: Eliciting the views of general practitioners. *Family Practice, 12*, 335-338.

4 Deehan, A., Templeton, L., Taylor, C., Drummond, C., & Strang, J. (1997). The effect of cash and other financial inducements on the response rate of general practitioners in a national postal survey. *British Journal of General Practice, 47*, 87-90; Gattellari, M., & Ward, J.E. (2001). Will donations to their learned college increase surgeons' participation in surveys? A randomized trial. *Journal of Clinical Epidemiology, 54*, 467-491.

below the industry standard of professional focus group organizations for this group of participants, we believe that we can attempt to recruit physicians using this rate.

Each set of focus groups is explained below.

1. Role of DTC Promotion in Diagnosis and Treatment of Subjectively Diagnosed Conditions: Attention Deficit Hyperactivity Disorder (ADHD) and Fibromyalgia

Some critics of DTC have charged that DTC advertising contributes to the medicalization of normal behavior.[5] This is perhaps especially relevant to medical conditions for which diagnosis is based on clinical judgment and not objective biological markers. The purpose of this project is to explore the role of DTC in two such medical conditions, ADHD and fibromyalgia.

ADHD is a medical condition characterized by a "…chronic level of inattention, impulsive hyperactivity or both, such that daily functioning is compromised" (Centers for Disease Control, 2005). This disorder is thought to affect between 3%-7% of children (and 4% of adults, but we will focus on children for the purposes of this study) and pharmaceutical treatments for it are frequently advertised. We propose twelve focus groups to talk with parents and teachers to determine what role DTC has played (if any) in their experiences with ADHD. We propose to involve teachers because they are in a unique position to exert influence on parents given their first-hand experience with children in an academic setting on a daily basis. The goal of the groups is to establish whether there is sufficient qualitative evidence to mount a quantitative study of the influence of DTC in this or other subjectively diagnosed medical conditions. This particular condition was chosen because of the vulnerable population (children) involved and the widespread use of DTC advertising in the class of drugs that treat ADHD.

This part of the project will involve twelve groups of consumer focus group participants. Six groups will consist of parents whose children have been diagnosed with ADHD and six groups will consist of teachers who have had in their classes at least three students with a diagnosis of ADHD. Six of the groups (three parent groups, three teacher groups) will be local to the Washington, DC metropolitan area. The other six groups will be located in other places across the United States outside of the Washington, DC metropolitan area.

Fibromyalgia is another medical condition that is subjectively diagnosed, involving widespread pain, abnormal pain processing, sleep disturbances, and often psychological problems.[6] It is believed that approximately 2% of people suffer from this condition, more commonly women (3.4%) than men (0.5%). The diagnosis of this condition is one of exclusion, as objective laboratory results often return normal.[7] Unlike ADHD, this is a disorder of adulthood. Pharmaceutical treatments for fibromyalgia are currently advertised. We propose eight focus groups to talk with persons who have been diagnosed with fibromyalgia to investigate the role of DTC in their treatment.

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5 Mintzes, B. (2002). For and against: Direct to consumer advertising is medicalising normal human experience. *British Medical Journal*, *324*(7342), 908-909.

6 http://www.cdc.gov/arthritis/arthritis/fibromyalgia.htm

7 http://www.mayoclinic.com/health/fibromyalgia-symptoms/AR00054

This part of the project will involve eight groups of consumer focus group participants who have been diagnosed with or are at risk for fibromyalgia or are suffering from otherwise unexplained chronic pain. Four of the groups will be local to the Washington, DC metropolitan area. The other four groups will be located in other places across the United States outside of the Washington, DC metropolitan area.

2. Understanding of Major Statement in Oral Contraceptive DTC Advertising

The prescription drug advertising regulations (21 CFR 202.1) distinguish between print and broadcast advertisements. Print advertisements must include a brief summary of the product's risks, which generally contains each of the risk concepts from the product's approved package labeling. Advertisements broadcast through media such as television, radio, or telephone communications systems must disclose all of the product's major risks in either the audio or audio and visual parts of the presentation; this is sometimes called the *major statement*.

The labeling for combined oral contraceptives has been standardized.[8] As a result, the major statement of risks in television ads and the brief summary in print ads for combined oral contraceptives has been consistent for many years. During that time, no research has examined how well consumers understand the standardized description of these risks. Given the active promotion of these products to consumers, DDMAC wants to ensure that this language adequately conveys appropriate information about the risks of these products. We will conduct twelve focus groups of women between the ages of 18 and 40 to explore the issue of whether these focus group participants understand the risks as stated and whether learning about the additional risks from the product labels alters their perception of the appropriateness of the risk statements in the ads.

This project will involve twelve groups of female consumer focus group participants ranging in age from 18 to 40. Six of the groups will consist of women who are considering or have considered taking oral contraceptives but are not currently on treatment. The other six groups will consist of women who are currently taking oral contraceptives and have been for at least six months. Six of the groups (three of current users and three of prospective users) will be local to the Washington, DC metropolitan area and the other six groups will be located in another city outside of the Washington, DC area.

The final focus group project will involve general practice physicians.

3. Role of DTC Promotion in the Doctor-Patient Interaction

FDA last queried physicians about DTC advertising in focus groups that took place in 2004. Since that time, the landscape has changed, including rampant increases in internet utilization, more frustration about health care coverage, and several changes in the tone of DTC advertisements. This project is designed to update our understanding about the role of DTC advertising in the doctor-patient interaction. Recent studies have shown that few people visit a

8 Guidance for Industry: Labeling for Combined Oral Contraceptives. Center for Drug Evaluation and Research. Available at http://www.fda.gov/cder/guidance/5197dft.pdf (last accessed March 17, 2009).

doctor because of a DTC advertisement,[9] yet anecdotally, it appears that physicians still dislike DTC advertising. What happens when a patient does visit a doctor about an advertised medication? How often is that information found on the internet? What coping strategies have physicians developed to deal with the time pressures that this discussion entails?

This project will include six focus groups of general practitioners, including internal medicine, family practice, and OB/GYN who see patients at least 50% of the time, have been in practice at least three years, and who do not practice exclusively in a hospital setting. Three of the focus groups will be conducted locally in the Washington, DC area and the other three will be located outside of the Washington, DC area. If recruitment becomes problematic, FDA will consider the use of new technological solutions, such as video conferencing, to collect a proper sample of physicians.

Summary

The purpose of this project is to assess consumer and physician focus group participants' thoughts and perceptions about the role of DTC advertising in three specific areas of interest, as outlined above. These issues will be explored with consumer focus group participants in 32 focus groups of 9 individuals each and with physician focus group participants in 6 focus groups of 9 individuals each. The objective of this focus group project is to apply social science techniques to elicit information about DTC advertising in different areas of interest to better understand how consumer and physician focus group participants view such information. Partially from these discussions, FDA will determine whether quantitative research further delving into these three areas is necessary to fulfill the needs of the Division. The consumer and physician responses gained through the focus groups will be used to help the FDA team develop dependent measures for subsequent studies.

Table 1. Participants and focus group locations.

| | Participants | # Groups | # Participants per Group | Location |
|---|---|---|---|---|
| Ia | Parent-ADHD | 3 | 9 | DC Metro |
| Ib | Parent-ADHD | 3 | 9 | US City |
| Ic | Teacher-ADHD | 3 | 9 | DC Metro |
| Id | Teacher-ADHD | 3 | 9 | US City |
| IIa | Fibromyalgia patient | 4 | 9 | DC Metro |
| IIb | Fibromyalgia patient | 4 | 9 | US City |
| IIIa | Oral | 3 | 9 | DC Metro |

9Parnes, B., Smith, P.C., Gilroy, C., Quintela, J., Emsermann, C.B., Dickinson, L.M., & Westfall, J.M. (2009). Lack of impact of direct-to-consumer advertising on the physician-patient encounter in primary care: a SNOCAP report. *Annals of Family Medicine, 7(1)*, 41-6.

| | | | | |
|---|---|---|---|---|
| | contraceptive -no | | | |
| IIIb | Oral contraceptive -no | 3 | 9 | US City |
| IIIc | Oral contraceptive -yes | 3 | 9 | DC Metro |
| IIId | Oral contraceptive -yes | 3 | 9 | US City |
| IVa | General practitioner | 3 | 9 | DC Metro |
| IV b | General practitioner | 3 | 9 | US City |
| | **Total** | 38 | 342 | |

Table 2. Estimated Annual Reporting Burden for Selected Respondents[1]

| Number of respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|
| 513 (screener) | 1 | 513 | 2/60 | 15 |
| 342 (focus groups) | 1 | 342 | 1 ½ | 513 |
| | | | | 528 |

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Depending on the results of the focus group, we plan to develop up to three quantitative study series on: 1) the role of DTC advertising in subjectively diagnosed populations, 2) the wording of the oral contraceptive class risk information, and 3) the role of DTC advertising in the doctor-patient relationship.

We plan to conduct most of these focus groups during fiscal year 2010, except during the Census blackout between March and August. If we receive OMB approval by mid-

January, we expect that we will be able to conduct a third of the focus groups by February 28th, 2010. The remaining focus groups will be conducted in September and October of 2010.

If you have any questions, please contact Elizabeth Berbakos at 301-796-3792.

Attachments