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Dockets Management Branch
HFA-305, Room 1061
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

DOCKET NO. 01N-0078

**SUBJECT: COMMENT REQUEST: ASSESSMENT OF PHYSICIAN AND
PATIENT ATTITUDES TOWARD DIRECT-TO-CONSUMER
PROMOTION OF PRESCRIPTION DRUGS**

Dear Madam/Sir:

In response to FDA's announcement (*Federal Register*/Vol. 66, No. 53/Monday, March 19, 2001) of an opportunity to provide comments on two proposed collections of certain information, ie, surveys of physician and patients to examine the impact of direct-to-consumer (DTC) promotion of prescription drugs, we are pleased to provide the attached comments.

Please be advised that the material and data contained in this submission are considered to be confidential. The legal protection of such confidential commercial material is claimed under the applicable provisions of 18 U.S.C., Section 1905 or 21 U.S.C., Section 331(j) as well as the FDA regulations.

Sincerely,

Mary Jane Nehring
Senior Director, Marketed Products
Support and Training
Worldwide Regulatory Affairs

BAM:js
Attachment

01N-0078

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5/17/01 js

Comments on the Assessment of Physicians and Patient Attitudes towards Direct-to-Consumer Promotion of Prescription Drugs

In this memo we will:

1. Comment on ways (in our opinion) to enhance the quality, utility, and clarity of the information to be collected by making suggestions regarding the survey design.
2. Make suggestions that could help minimize the burden of the collection of information on respondents by utilizing an automated collection technique.

1. General Comments

Overall, the design of the study is solid. The questions are well written and most are easily understood. However, we see opportunities to improve the accuracy of the collection and are somewhat concerned about the potential for bias based upon the order of the questions. In all surveys, all respondents become biased as the survey progresses. The later the question in the survey, the more potential there is for responses to be influenced by the preceding questions. We therefore feel that it is essential to determine which questions are most important and those questions should be moved to the beginning of the questionnaire in order to achieve the most accurate and unbiased response.

Another important aspect of survey research is context. When the respondents report their attitudes about DTC advertising, it would be helpful to understand how they feel about advertising in general for all products. If respondents have a bias (either positive or negative) towards advertising in general, there is a good chance that their bias will impact their reaction to prescription DTC advertising. In order to accurately evaluate the results, we believe that these general attitude questions should be handled in the beginning of the survey within the appropriate context. We believe that this will make it easier to evaluate the results.

Physician Survey

Specific Comments/Suggestions

- Add two questions up front to understand in-going attitudes towards advertising, both in general (consumer products) and specific to prescription DTC
- Q4 - The list of responses may not be all-inclusive – consider adding an “other, please specify” option
- Prior to Q7 Physicians are asked to think about their most recent interaction with a patient who asked about a prescription drug – We think that a question needs to be added to establish first “I” they had an interaction with a patient who asked about a prescription drug for his or her health concern.
- Q8 responses should include “Something a Pharmacist said” and “Other, please specify”
- Q9 should also include “Something a Pharmacist said”
- Similar to Q7, we should first determine if a patient asked about a prescription drug that they saw advertised – otherwise an assumption is made that all physicians are asked about advertised prescription drugs – Q10 could be moved before the introduction to that section of the questionnaire to make it more accurate
- What is included in the Precoded list for Q14?
- We believe that a gateway question is also needed prior to Q17 – the introduction to this question assumes that physicians believe that “the fact that their patient saw an advertisement may have created both beneficial effects and problems for their interaction with that patient” - We should first determine “if “ they hold this belief - if they do, then they should proceed with Q17 – if they do not, then they should skip to Q20

- In the section that includes Q24 through Q30 there are four negative responses and three positive responses – We would like to suggest that you consider adding a question such as “The patient would benefit from the prescription product that he/she requested”
- We were happy to see that Q31 through Q45 would be rotated – we would like to suggest that you alternate positive and negative questions if possible
- Q32 assumes that patients have either been educated or confused – we suggest that this be separated into two questions for a more accurate response. The issue of confusion is also addressed in Q38.
- We would strongly suggest that Q45 be moved to the front of the questionnaire. We feel that this is a very central question and will be impacted by respondent bias if it is left in its current location.
- In the General Opinions about DTC – four out of the five questions are negative – we would like to see a more balanced opportunity for the physicians to respond including some of the positive aspects of DTC advertising.

Consumer Questionnaire Comments

- We would like to suggest that any consumers who work in a medically related (Physician, Health Care provider, Pharmaceutical Company, Market Research, Advertising Agency, Government etc) be screened out.
- Add two questions up front to understand in-going attitudes towards advertising both in general and specific to prescription DTC
- We would like to suggest that a parallel question Q45 of the physician questionnaire regarding the overall impact of DTC on the quality of patient/physician interactions be asked up-front in the consumer questionnaire as well.
- Q6 could include: outdoor advertising (billboards, buses, trains etc) and In-store Pharmacy advertising as well as events such as: Golf, Baseball, Hockey signage or other sponsorships etc.
- Q7 – response 05 (what to do in case of an overdose) seems very unusual.
- Q8 is an extremely difficult question to answer – you may consider shortening the time period to get a more accurate response.
- Q9 is also difficult because if confusion exists, consumers may be unaware that they are confused – you may want to consider giving them a list of Rx and OTC products that are currently advertised and asking them if they know the status of each – you then could deduce the level of confusion.
- Q11 and Q12 – we are assuming that you are referring to the brief summary in these two questions. Since there is large and small print in the context of the ad itself, we suggest that the question be more descriptive (e.g. One or two columns of black and white small print adjacent (or next to) the ad)
- Also you may want to determine among those who do read the brief summary, whether or not they generally understand what they have read.
- Q19 television and radio responses should be separated in response (01)
- Q23 – the consumer probably will not know the physician’s motivations in each of these cases
- After Q25 you may want to ask in an unaided fashion where they heard about the prescription product
- If the respondent answers no to Q26 they should skip to Q31
- Prior to Q27, you may want to ask questions similar to Q12, Q15, Q16 Q24, Q26, Q28, and Q29 in the physician’s survey in order to assess patient reactions to the physician/patient interaction.
- Q30 – add the response – “your managed health care plan does not cover the prescription”
- Q32 – this question asks the consumer to project how the physicians would react – they may not be able to do this
- Q44 also would be a question that consumers probably won’t be able to answer
- Q48 makes the assumption that all consumers use the Internet – this should probably have a gateway question that establishes if the consumer uses the Internet prior to asking them how many hours per day they use it.

2. *Suggestions to Minimize the Burden of the Collection*

The Internet may provide an alternative to the telephone survey for the physicians. We have conducted a number of studies among physicians on the Internet and have been pleased with the results. Some of the benefits of Internet research include:

- Very rich and detailed verbatim responses
- Timely – much quicker turnaround
- Allows flexibility for respondents – they can answer the survey 24/7. In a recent survey that we conducted among 352 physicians, we found that 20% completed the survey on the weekend and another 58% completed the survey between 7:00 PM and 7:00 AM. Therefore it may be easier to reach physicians because they can answer the survey at their convenience.
- You can target specific respondents
- Tight security
- Some suppliers offer a totally Web-based process that lets you analyze results, as they come in.
- Conservatively at least 65% of physicians use the Internet

If you decide to field the survey on the Internet, we would recommend working with a supplier that has experience conducting surveys in this manner.

In addition, you will want to indicate in the invitation to participate (which could be by mail or e-mail) that respondents can participate on a first come first serve basis and that the total sample size is limited. You can shut down the survey after you achieve the sample size that you desire and limit the risk of having to pay additional honoraria if a very large body of participants accept the offer.

However, there is debate about whether or not the Internet population is nationally representative or projectable. We would be more concerned about skews or bias in the consumer population. At this point in time a telephone survey among consumers may be more appropriate.

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