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

Subject: Docket No. 01N-0078: Comments on a survey, *Altitudinal and behavioral effects of direct-to-consumer (DTC) promotion of prescription drugs*

To Whom It May Concern:

This letter is written to submit our comments on your survey entitled, *Altitudinal and behavioral effects of direct-to-consumer (DTC) promotion of prescription drugs.* Please find enclosed a copy of our responses.

If you have any questions or need any further information, please feel free to contact us. Our mailing address, phone numbers, and e-mails are provided below.

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Sincerely,

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Responses for the Food and Drug Administration's consumer survey:

Attitudinal and Behavioral Effects of
Direct-to-Consumer (DTC) Promotion of Prescription Drug

By the College of Pharmacy, University of Michigan
Division of Social and Administrative Sciences

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The *Attitudinal and Behavioral Effects of Direct-to-Consumer Promotion of Prescription Drug* survey[1] reflects that the Food and Drug Administration (FDA) closely monitors the effects of Direct-To-Consumer prescription drug Advertising (DTCA) on the public. A two-phase survey (a telephone interview and a follow up survey) is a strength of your study, as extensive and specific effects of DTCA are simultaneously investigated. The telephone interview assesses overall effects of DTCA on consumers' attitudes and behavior, as well as on consumer-provider relationships. The follow up survey assesses consumers' recognition and understanding of DTCA information by exposing them to particular drug advertisements.

Reviewing the survey, we arrive at three major observations/suggestions that are probably useful for your future research. Two observations are related to the telephone interview, and the remaining one is associated with the follow up survey. These three observations are described as follows.

The telephone interview

The content of the telephone interview suggests that consumers' reactions and attitudes toward DTCA can be viewed as a function of how they process advertising information. This assumption is based on the Elaboration Likelihood Model (ELM).[2]

According to the ELM, highly involved people are those who feel that advertising information is relevant to them (such as people who have related illness presented in DTCA). They are more likely to pay extensive attention and scrutinize the product-relevant information presented in the advertisement. They may read small print information in a brief summary. If they perceive such information to be cogent and persuasive, they will form favorable attitudes. If information is specious, less favorable attitudes will result.[3]

In contrast, less-involved people are those who feel that advertising information is probably irrelevant to them (such as people who do not have related illness presented in DTCA). They are less likely to pay attention to product-relevant information. They may not read small print information in a brief summary. They are more likely to use other types of product information such as a prestige of product endorsers or a credibility of informational sources to generate their favorable or unfavorable attitudes toward the advertisement and the product.[3]

Thus, we propose that consumers' health condition and a credibility of informational source should be included in the survey to understand consumers' attitudes and behavior toward DTCA, which sequentially influence interactions with their doctors.

Observation 1. Health condition as an indicator for self-relevance and involvement

In the survey, doctor visit (Q2) and current prescription drug use (Q20) are used to determine consumers' level of self-relevance and involvement when they are exposed to DTCA. However, both of these items are behavioral measures. We think that subjective measure such as consumers' perceptions is also very important to determine how they interact with DTCA information. The presence or absence of illnesses reported by consumers[4-6] is usually used to determine consumers' perception of self-relevance and involvement. People who have an illness are more likely to recall seeing DTCA (i.e. increase an awareness of DTCA)[6] and to talk with doctors about the advertised drug (i.e. perform *information-seeking* behavior).[5]

Suggestions:

Examples of questions to assess consumers' health condition are presented in the Exhibit A.

Exhibit A: Health condition

Q1: I will read a list of health conditions, please indicate whether you have any of them or not. I may start reading a list now. First, [INSERT ITEM – ROTATE] do you have this condition?

a. Allergies
b. Arthritis
c. Asthma
d. Depression
e. High blood pressure or hypertension
f. High cholesterol
g. Migraine
h. Osteoporosis

Categories

01	Yes
02	No
98	Don't know
99	Refuse

Q2: Is there any other illnesses or conditions you have and I did not read? (Please specify)

_____

Justifications

1. We propose both close-ended and open-ended questions to obtain information about illness conditions among consumers. The close-ended question (Q1) facilitates ease in answering the question. This question is modified from a 1998 national survey, conducted by *Prevention* magazine.[6] However, the *Prevention* survey includes only eight illness conditions (items a-h in the Exhibit A). Some other important conditions such as diabetes and heart conditions are left undetectable. The open-ended question (Q2) helps us to obtain more information about other possible health conditions of consumers.

2. Although a social desirability issue possibly occurs because of consumers' unwillingness to reveal their illnesses, this issue may be minimized by assuring anonymity and confidentiality before the survey.

Observation 2. Credibility and popularity of drug information sources

A. Popularity of information source

Our second observation is based on the questions # 13-14 of the survey. It is known that DTCA leads some consumers to seek additional information about the advertised drug or health conditions.[1,5-7] However, simply knowing about sources of additional information[1,6]may not be as informative as knowing about how often consumers use such informational sources as a result of seeing DTCA. In other words, we assess a popularity of drug information sources to know what types of information sources consumers use most often.

Suggestion:

The measurement power of the question #14 in the survey may increase by slightly changing a measure scale from a yes/no scale to a 5-point frequency scale. An example of revised version for the question #14 is presented in the Exhibit B.

Exhibit B: Popularity of information sources

Q14a: (ASK IF Q13 = 1) How often do you [INSERT ITEM – ROTATE] to obtain additional information about the prescription drug you have seen advertised? Would you say always, often, sometimes, rarely or never?

a. Use a reference book
b. Use a magazine
c. Use a newspaper
d. Use the Internet
e. Ask a friend, relative, or neighbor
f. Call the 1-800 number in the advertisement
g. Talk to a pharmacist
h. Talk to a nurse
i. Talk to YOUR doctor
j. Talk to a doctor other than your own doctor
k. Do something else, please specify _____

Categories

01	Always
02	Often
03	Sometimes
04	Rarely
05	Never
98	Don't know
99	Refuse

B. Credibility of information source

As stated in earlier discussions, a credibility of information source should be included in the survey because it influences consumers' information processing of DTCA, which sequentially affects their attitudes and behavior.

Suggestions:

We propose to add a question to assess consumers' perception of credibility of information sources. An example of the question is shown in the Exhibit C.

Exhibit C: Credibility of information sources

Q: For each of following informational sources, please indicate your level of trust regarding prescription drug information. Would you say [INSERT ITEM – ROTATE] is very trustful, trustful, somewhat trustful, little trustful, or not trustful at all?

a. Reference book
b. Magazine
c. Newspaper
d. Internet
e. Friend, relative, or neighbor
f. Advertisement
g. Pharmacist
h. Nurse
i. YOUR doctor
j. A doctor other than your own doctor

Categories

01	Very trustful
02	Trustful
03	Somewhat trustful
04	Little trustful
05	Not trustful at all
98	Don't know
99	Refuse

Justifications

1. The questions assessing credibility and popularity of information sources (Exhibits B and C) should contain a same list of sources of information (items a-j) because obtained data can be then used to construct a credibility-popularity matrix or to assess correlations between credibility and popularity dimensions for each information source.
2. The questions assessing credibility and popularity of information sources (Exhibits B and C) should not be next to each other because a sequent position of these two questions may produce an order effect.[8] For example, when respondents are asked how often they use these information sources and then are asked how trustful these sources are, the respondents may associate their frequency of use with the credibility of the sources and vice versa.

The follow up survey

In the follow up survey, consumers were exposed with 12 photos of prescription drug advertisements and instructed, "...You do not need to read the words in the advertisement. We would just like to know if you recognize any of them..." A series of questions asked consumers to indicate a) whether they have seen these advertisements before, b) where they have seen them, and c) what conditions these drug are used for.

Observation 3. The role of informational and emotional appeals in the advertisements

According to the survey content and instructions, the FDA presents interest in assessing a) effects of ad images on consumers' recognition of the particular advertisements and b) consumes' understanding in indications of the advertised drugs. This suggests that the FDA do not only monitor the ad content, the substance, and the written words, but it also considers the consequences of ad images (or emotional appeals) on consumers.

Our observation is also supported by a recent report about the FDA's vigilant action on DTCA. The FDA has exercised the *fair balance* regulation to regulate both informational and emotional appeals in prescription drug advertising. Recently, the FDA announces a television advertisement for Celebrex as misleading because its totality of images (such as the music and audio statements) overstates its efficacy.[9] Other evidence shows that some drug companies have used emotional appeals to manipulate consumers' risk perception about the advertised drug. For example, the major statement about side effects and contraindication is often presented along with some positive emotional images such as people engaging in life-affirmative activities or picking flowers with a child in a grassy field.[10]

Current situations suggest that although the advertisement contains fair-balanced messages about risk-benefit information, the "informed" public is probably still vulnerable to harmful treatment decisions resulting from persuasion of emotional appeals in the advertisements. Especially, if doctors are less effective gatekeepers, the inappropriate use of medicines and treatment costs due to drug misadventures may be the results.

We propose that the follow up survey should expand its scope to investigate the effects of information and emotion interplay of these advertisements on consumers' attitudes and purchasing intent. Obtained information will be very helpful when used adjunctively with the content analysis of the advertisements to judge the totality of elements and images. It may provide useful information for establishing future prescription drug advertising policies as well.

Suggestions:

We propose to add three questions. The first question assesses consumers' attitudes toward the advertisements. The second question assesses consumers' perception of drug safety, and the last question measures the effects of the advertisements on consumers' purchasing intent. Examples of these three questions are presented in the Exhibit D.

Exhibit D: Attitudes and purchasing intent on a particular advertisement

Q: Please consider this advertisement as a whole, please indicate how much you like or dislike this advertisement. (Attitude toward the advertisement)

Dislike very much	**-4**	**-3**	**-2**	**-1**	**0**	**1**	**2**	**3**	**4**	**Like very much**

Q: Please consider this advertisement as a whole, please indicate how likely or unlikely you think the drug is safe. (Perception of drug safety)

Very unsafe	**-4**	**-3**	**-2**	**-1**	**0**	**1**	**2**	**3**	**4**	**Very safe**

Q: If you or somebody you know are suffering from an illness that this drug is a treatment choice, please indicate how likely or unlikely you will use or recommend the person to use this drug. (Purchasing intent)

Very unlikely to recommend or use it	**-4**	**-3**	**-2**	**-1**	**0**	**1**	**2**	**3**	**4**	**Very likely to recommend or use it**

Justification:

1. Attitude toward the advertisement and perception of drug safety may influence consumers' decision making to use or recommend the advertised drug to others.[11-12]
2. The question about purchasing intent is modified from a study of Davis (2000),[12] who investigates the effects of the completeness of risk statements in prescription drug advertisements on consumers' perceptions and purchasing intent.

Thank you for the opportunity for reviewing this survey. If you have any questions or concerns, please feel free to contact us.

References

1. Food and Drug Administration/Center for Drug Evaluation and Research. Attitudinal and Behavioral Effects of Direct-To-Consumer (DTC) Promotion of Prescription Drugs. URL: http://www.fda.gov/cder/ddmac/research.htm

2. Petty R, Cacioppo R. The elaboration likelihood model of persuasion. Berkowitz L. *Advanced in Experimental Social Psychology*. New York: Academic Press; 1986:124-203.

3. Christensen T, Ascione F, Bagozzi R. Understanding how elderly patients process drug information: A test of a theory of information processing. *Pharmaceutical Research.* 1997;14:1589-1596.

4. Morris L, Brinberg D, Klimberg R. The attitudes of consumers toward direct advertising of prescription drugs. *Public Health Reports.* 1986;101:82-89.

5. Perri M, Nelson AA. An exploratory analysis of consumer recognition of direct-to-consumer advertising of prescription medications. *Journal of Health Care Marketing.* 1987;7:9-17.

6. Prevention. National Survey of Consumer Reaction to Direct-to-consumer Advertising. Emmaus RP1998.

7. Williams JR, Hensel PJ. Direct-to-consumer advertising of prescription drugs. *Journal of Health Care Marketing.* 1995;15:35-41.

8. Sudman S, Bradburn NM; *Asking Questions: A Practical Guide to Questionnaire Design.* San Francisco, CA: Jossey-Bass Publishers; 1982.

9. Adams C, Grimes A. FDA faults 'misleading' drug-ad images. *The Wall Street Journal.* May 4, 2001;B8.

10. Reeves KN. Direct-to-consumer broadcast advertising: empowering the consumer or manipulating a vulnerable population? *Food and Drug Law Journal.* 1998;53:661-679.

11. Ajzen I, Fishbein M; *Understanding Attitudes and Predicting Social Behavior.* NJ: Prentice Hall; 1980.

12. Davis JJ. Riskier than we think? The relationships between risk statement completeness and perceptions of direct to consumer advertised prescription drugs. *Journal of Health Communication.* 2000;5:349-369.