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

Re: Docket No. 01N-0078

May 8, 2001

To Whom It May Concern,

We are pleased to have the opportunity to comment on the proposed data collection concerning physician and patient attitudes toward direct-to-consumer (DTC) promotion of prescription drugs. We believe this endeavor is important and hope that the next round of data collection may provide more insights into the impact of DTC promotion on the physician-patient relationship.

We have reviewed the draft of the consumer survey and have noted that it is comprehensive with respect to consumer attitudes and prevalence information (e.g., the percent of those surveyed that remember seeing advertisements and that ask their physician about an advertised drug). It also includes some basic variables predictive of consumer behavior (e.g., income, age and gender). We believe that the survey would be strengthened if it included additional variables predictive of consumer behavior. This addition would permit more complex analyses of the associations between consumer characteristics and actions (i.e., initiating a discussion with a physician and/or requesting specific prescription drugs). Such analyses would provide insights into the types of individuals who respond to these promotions and would lay the groundwork for future investigations regarding the effects of DTC promotion on physician-patient relationships. To our knowledge, such information is not currently available to the public, especially not at the national level.

Below is an example of a model of consumer behavior taken from a highly regarded general marketing text. Should you decide to add more consumer behavior-related questions, this model and the thorough discussion about it presented in the text may be helpful.

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Factors Influencing Consumer Behavior

Cultural ⇒

- Culture
- Subculture
- Social Class

Social \Rightarrow

- Reference groups
- Family
- Roles/status

Personal ⇒

- Age/life-cycle stage
- Occupation
- Economic situation
- Lifestyle
- Personality/selfconcept

Psychological \Rightarrow Buyer*

- Motivation
- Perception
- Learning
- Beliefs/attitudes

Source: Kotler, P. and G. Armstrong (1999). Principles of Marketing. Upper Saddle River, NJ, Prentice Hall.

We realize that your resources are limited and that the inclusion of too many questions could negatively impact the response rate. That said, the inclusion of measures with theoretical underpinnings would be valuable in advancing our limited understanding of consumers' responses to DTC advertisements and how these responses affect physician-patient relationships.

Separate from our suggestions above, we would also like to recommend that a very clear distinction be made in your questions regarding consumers' actions following exposure to DTC promotion. We propose that the survey ask two questions regarding consumers' actions: one that emphasizes asking <u>about</u> and one that emphasizes asking <u>for</u> a specific advertised prescription drug. The former implies a simple, non-demanding inquiry, while the latter implies demand for a certain brand; the distinction is important to understanding the type of patient action prompted by the advertisements.

Additionally, more information about the physician's response to a consumer's inquiry would be informative. We recommend structuring this series of questions in the following way: a first question would ask the consumer: "Did you ask your physician about/for the advertised drug?" If the answer to this question is affirmative, then another question would be asked: "Did your physician write a prescription for the drug?" If the answer to this question is negative, then another question would be asked: "Did your physician discuss why the drug was inappropriate for you?" This information would assist in better understanding the dynamic between the physician and patient with regard to DTC promotion.

Should you find it helpful, we are happy to discuss these comments further with you. You may contact Ms. Teleki via email, telephone or mail, as noted above. Many thanks in advance for your consideration.

Sincerely,

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^{*} In the case of prescription drugs which require physician sanction for purchase, the endpoint of a buyer in this model is more accurately thought of as a patient asking about and/or for an advertised drug.

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