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Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852



**RE: Docket No. 03N-0344
Consumer-Directed Promotion**

Merck & Co., Inc. is a leading worldwide human health product company. Merck's corporate strategy — to discover new medicines through breakthrough research — encourages us to spend nearly \$3 billion annually on worldwide Research and Development (R&D). Through a combination of the best science and state-of-the-art medicine, Merck's R&D pipeline has produced many of the important pharmaceutical and biological products on the market today.

As a leading health care company, we support communication with patients through the dissemination of consumer-directed educational information and through advertisements directed to consumers; also known as Direct-to-Consumer (DTC) promotion. We routinely provide patient education materials to physicians for distribution to patients. In addition, we have worked closely with the Division of Drug Marketing, Advertising, and Communications (DDMAC) to implement many consumer-directed print and broadcast campaigns for a variety of products and diseases such as osteoporosis, hypercholesterolemia, arthritis, benign prostatic hyperplasia, and HIV infection. We believe this relationship has resulted in DTC programs that provide clear, balanced, product and disease information for consumers and encourage consumers to interact with healthcare providers (HCPs). Hence, we are very interested in and welcome the opportunity to comment on DTC promotion. This response contains general comments regarding DTC advertising following the FDA-sponsored public hearing that was held on September 22-23, 2003.

General DTC Comments

Merck supports FDA's approach to ensuring that important public policy decisions affecting patient health outcomes are driven by research and data. Several large and rigorous studies presented during the hearing (particularly those conducted by DDMAC and *Prevention* magazine) provide strong evidence that the current regulatory approach to DTC advertising results in a positive impact on health outcomes. Specifically that:

- DTC advertising stimulates appropriate patient-initiated conversations with HCPs.
- DTC advertising makes patients aware of disease states and possible treatments, more involved in their health care, and leads them to ask better questions.
- Most HCPs do not feel compelled to prescribe the advertised medication, nor do patients routinely demand to receive a particular medication.

Thus, the data presented at the hearing support the continuation of DTC advertising under the current regulations as a means to provide patients with information on disease states and the products available to treat those diseases. In addition, the hearing served to identify aspects of DTC advertising that could benefit from additional research.

DTC Television Advertising

Manufacturers employ a variety of communication vehicles to disseminate product information to varied audiences and each vehicle carries a unique set of communication characteristics. DTC advertising is most appropriately evaluated as a single element of a manufacturer's total effort to educate patients and HCPs about medical conditions and pharmaceutical products available to treat them.

DTC television advertising is often the most visible component of these efforts, but does not exist in isolation. Television ads are part of a larger campaign through which product- and disease-specific information are concurrently disseminated. Television is best utilized when the intent is to reach a large audience with a relatively simple set of messages. DTC television ads are employed to increase disease awareness, inform consumers about the availability of a particular product, and to encourage consumers to ask their HCP whether a product is right for them, thereby increasing consumer/HCP interactions with a positive impact on health outcomes.

Consumer Information Sources

In addition to DTC TV ads, manufacturers provide additional information to consumers in the forms of print ads, direct mail, internet web sites, product and disease brochures, and toll-free phone lines. These additional sources of information provide opportunities for consumers to gain more detailed information about the product.

Consumers are exposed to pharmaceutical information through the various communications media with which they are in contact. Pharmaceutical information dissemination programs are best designed to ensure that detailed information is available to any consumer *who desires that information* in a format that is acceptable to that consumer. For consumers who seek additional information, the communication channels available through *adequate provision*¹ are better suited to delivering often complex information in a form appropriate for consumers than is a brief television ad.

¹ FDA Guidance for Industry, *Consumer-Directed Broadcast Advertisements*, August 1999.

Learned Intermediary

The single most important goal of consumer-directed communication is to encourage consumers to engage in conversations with their HCPs about medical conditions and available treatments, when appropriate. For consumers who act on DTC ads, the HCP remains the learned intermediary, the primary information source for patients, and retains control over the prescribing decision. HCPs are in the best position to assess the presenting symptoms, the appropriateness of available treatments, and the information needs of individuals. The conversation between the HCP and consumer should be viewed as the most important communication to the patient about a particular product.

Suggestions for Additional Research

Existing research shows that DTC advertising increases both disease awareness and awareness of treatment options while encouraging appropriate physician/patient discussion. One area that remains open to further research is how to best communicate the benefit and risk information in each of the various DTC channels, both in content and format.

Future research might also focus on the question of the consumer's ability to absorb and retain information when delivered in brief television formats. Questions to be answered may include:

- What amount and type of risk information are productive/counterproductive to consumer understanding in the context of TV advertising?
- Does embedding less/more information in DTC television ads result in better/worse comprehension and retention by consumers?
- In the context of TV ads, what is the contribution of other information sources to improve the patient/HCP interaction when the patient inquires about prescription products?

Lastly, future research might focus on the role of the internet in communicating benefit/risk information to consumers and how the internet optimally can be used for this purpose. Although manufacturers routinely sponsor product-specific web sites, there is variability in the information provided and how it is presented. Therefore, it may be worthwhile to evaluate alternative approaches to using the internet as a tool through which to provide benefit/risk information directly to consumers.

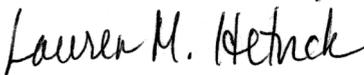
- Currently most web sites are based on communication methods used in print advertising. How effective are these methods when used on-line? Should the internet offer benefit/risk information in a different way?
- Current FDA guidances for internet advertising are based on traditional advertising that "pushes" information to consumers. However, the internet is a "pull" channel that does not operate like TV or print media. Are there ways in

which sponsors can take advantage of the unique “pull” aspects of the internet to educate consumers?

Conclusions

Merck supports the continuation of DTC advertising. At a time when patients are increasingly interested in health care information, the goal of DTC advertising is to generate a productive discussion between patient and HCP. Through the use of mass media print and broadcast ads, manufacturers provide the general public with access to disease and product information that may help patients identify and report symptoms to their HCP, thereby resulting in undiagnosed or at-risk patients seeking advice. Appropriate DTC promotion can facilitate a dialogue between patient and HCP to identify and support the treatment plan.

Sincerely,



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