

II. Scope of the Meeting

In light of the many complex public health issues raised by DTC prescription drug promotion, the agency stated, in previous **Federal Register** notices that it needed rigorous studies to assess the actual effects of DTC promotion and to help guide future policy. The agency is soliciting feedback on the results of such research for presentation at this public meeting. The meeting will give parties who have conducted rigorous research an opportunity to present their findings to FDA and the public. The agency will consider its own research and the research of others to explore whether, and, if so, how, the agency's current regulatory approach should be modified, including whether the guidance on DTC broadcast advertisements should be withdrawn, continued, or modified to reflect the agency's current thinking.

FDA is interested in research related to the promotion and advertising of prescription drugs, both DTC advertising and the interaction of DTC and health care professional-oriented promotion. The research may be either broadly defined or specific, and narrowly focused, but it must meet accepted standards for rigorous research. Specific topics of interest include, but are not limited to, the following:

1. What is known about the effects of DTC promotion on patient and physician behavior, and what effects, if any, does DTC promotion have on public health? What measurements should be used as indicators of the influence of DTC promotion, and which are most important?

2. Drugs ads used in DTC promotion include full-product advertisements, which include risk and benefit information, and shorter "reminder" ads. These shorter advertisements do not provide contextual and risk information. In what ways do consumers differ in their processing of full product advertisements and drug promotions, such as reminder ads, that do not provide contextual and risk information?

3. Does DTC promotion oversimplify the safety and effectiveness of prescription drugs? If so, what effect does such oversimplification have on public health? Specifically, what effect does it have on consumer understanding of and use of prescription drugs?

4. What impact does DTC promotion have on how patients interact with their health care professionals? Does this interaction affect health care providers' prescribing decisions?

5. Can consumers understand and accurately assess claims regarding the efficacy of prescription drugs? Can consumers understand and accurately assess claims regarding the safety of prescription drugs? Do consumers understand the qualifiers in efficacy and safety claims that represent distinctions about the degree of scientific uncertainty and causality associated with a claim, such as "may cause," "risk factors include," "individual results may vary," and other similar qualifiers? Given the fact that prescription drug use requires participation of a learned intermediary, how important is imperfect understanding?

6. What kind of additional information, if any, should be required in the presentation of comparative drug claims to help consumers understand and critically evaluate them? What kind of additional information, if any, should be required in the presentation of comparative cost claims? Should this information vary if prescription drugs are compared to other prescription drugs, over-the counter drugs, or other types of treatments?

7. Current regulations require inclusion of a "brief summary" of prescribing information (side effects, contraindications, and effectiveness) in print advertisements. Does this form of disclosure effectively communicate to consumers? Is it informative? Should there be alternate requirements for risk disclosure, and, if so, what should they be? Current regulations require that broadcast advertisements present a "brief summary" of prescribing information unless adequate provision is made for the dissemination of the approved product labeling. Also required is a statement of the major risks of the product. Are these disclosure requirements effective and informative for consumers? Are there alternate types of risk disclosures that would be more effective or informative? If so, what are the strengths and limitations of these alternative types of risk disclosures?

8. The agency issued final guidance in 1999 on how pharmaceutical companies could meet the regulatory requirements to disseminate approved labeling for a prescription product in lieu of a scrolling "brief summary" in broadcast advertisements. Are consumers making use of this method for obtaining brief summary information? What, if any, factors hinder effective use of this information, especially among consumer segments most needing it, such as those with limited knowledge of the brand and medical condition?

9. New technologies have spurred the growth of computer-based promotional vehicles, such as the Internet, electronic

bulletin boards, and kiosks in pharmacies. These promotions are neither purely print nor broadcast. What kind and format of information is necessary to ensure that these vehicles appropriately communicate risks and benefits of the product.

10. "Infomercials" are program-length television or radio programs that promote prescription drugs to consumers. How well do consumers understand the sponsorship of consumer-oriented "information" promotions that differ in character from traditional promotion formats (15-, 30-, and 60-second ads)? How well do consumers understand the difference between benefit and risk claims based upon anecdotal evidence, such as a series of testimonials and product claims based upon scientific evidence?

11. To help ensure that advertisements contain "fair balance," FDA currently requests disclosure of key risk and/or limitations of efficacy information, i.e., critical messages, in DTC prescription drug promotion. In general, are such disclosures effective and informative for this audience? What kinds of information should be disclosed?

12. Promotional materials that are disseminated directly by or on behalf of a pharmaceutical company (promotional labeling) are required to include the approved product labeling instead of a brief summary. How do consumers use product labeling, whether it is written for professionals or patients, and how does consumer use of labeling compare to consumer use of the brief summary?

13. Some manufacturer-supported DTC promotion appears to be sponsored by independent, third-party services, such as mailings from, or Web sites posted by, disease-specific foundations or disease management support services. What kind of disclosures would help consumers understand the source of the communication?

14. What additional research is needed to examine the effect of DTC advertising on public health and other DTC advertising issues? Is there research that the agency should conduct, and if so, what should be the focus of that research?

FDA is planning this public meeting to present the findings of its surveys and to hear the results of DTC research conducted by individuals, associations, organizations, academia, and companies. The objective of the meeting is for FDA to gather information to help the agency explore whether, and, if so, how, the agency's current regulatory approach to DTC prescription drug promotion should be modified. The agency believes presentations of