changing organizational structures and information dissemination channels in the managed care setting on the agency's responsibilities to regulate drug marketing and promotion. The agency is particularly interested in exploring the issues surrounding new modes and techniques of drug information dissemination (e.g., the communication of cost-effectiveness claims) and the formation of alliances between manufacturers and prescription benefit management companies (PBM's).

DATES: The public hearing will be held on October 19, 1995, from 1:30 p.m. to

on October 19, 1995, from 1:30 p.m. to 5:30 p.m., and October 20, 1995, from 8:30 a.m. to 5:30 p.m. Submit written notices of participation by September 15, 1995. Written comments will be accepted until December 29, 1995.

ADDRESSES: The public hearing will be held at the Quality Hotel-Silver Spring, 8727 Colesville Rd., Silver Spring, MD 20910. Submit written notices of participation and comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with docket number 95N-0228. Transcripts of the hearing will be available for review at the Dockets Management Branch (address above).

FOR FURTHER INFORMATION CONTACT: Lee L. Zwanziger, Center for Drug Evaluation and Research (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4695.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Federal Food, Drug, and Cosmetic Act, FDA has responsibility for regulating the labeling and advertising of prescription drugs. Specifically, the agency reviews promotional materials disseminated by, or on behalf of, prescription drug manufacturers for consistency with approved drug product labeling, and to ensure that these materials are accurate, contain proper disclosures, and "fair balance" in terms of benefit and risk information. Underlying this responsibility is a public health concern that health care professionals and patients base their decisions about drug products on sound scientific data and information.

Traditionally, health care providers, patients, pharmacists, and pharmaceutical manufacturers have been separate entities with independent functions. However, the relationships

among health care providers, pharmaceutical manufacturers, and health benefits managers are changing. The rapid growth of managed health care, with its emphasis on managing the quality of care while controlling costs, has dramatically changed pharmaceutical purchasing. Consequently, pharmaceutical marketing has also changed to emphasize value in addition to safety and effectiveness. Direct comparative effectiveness, safety, and costeffectiveness information has become more prevalent as a basis for promotional claims.

Furthermore, the audience for prescription drug promotion has also changed. The importance of institutional decisionmakers as recipients of marketing communications has increased. Over the past several months, several pharmaceutical manufacturers have formed business relationships with or have purchased companies that manage pharmacy benefits (i.e., PBM's). FDA has received reports that these entities are disseminating information to formulary decisionmakers, prescribers, and users about the allied manufacturer's drug products. Moreover, pharmacist employees of certain PBM's have telephoned prescribers to request that they switch their patients to the drug products of their employer's allied manufacturer.

Several pharmaceutical manufacturers have approached FDA about its policies regarding the dissemination of pharmacoeconomic information, especially comparative costeffectiveness analyses of pharmaceutical products. In response to these inquiries, FDA has stated that "effectiveness" elements of cost-effectiveness claims must be based on adequate and wellcontrolled studies and cost elements should be substantiated by adequate disclosure of both prices and methods used to derive the cost estimates. In addition, the Division of Drug Marketing, Advertising and Communications (DDMAC) has circulated a draft set of principles for use in evaluating pharmacoeconomic

Some have asserted that the dissemination of information by the pharmaceutical industry to managed care providers (e.g., formulary managers) need not meet traditional standards of substantiation because the audience is highly educated and able to regulate the process by creating a demand for supporting studies that display scientific rigor.

In addition, they maintain that these audiences may impose corrective

measures (e.g., formulary exclusions), which would drive up the quality of pharmacoeconomic analyses. However, the proponents also suggest that the increased costs and time needed to conduct multiple studies with sufficient methodological rigor are prohibitive and that their customers are demanding information that, in some instances, may only be provided by the use of less expensive techniques such as administrative data base analysis and modeling.

The agency recognizes that these issues affect both the manufacturers' desire to provide drug information and the managed health care industry's need for this information. Accordingly, FDA seeks to investigate the implications of these issues on its regulatory responsibilities.

II. Scope of the Hearing

In light of the many complex scientific and public health issues raised by the evolution of the health care environment, FDA is soliciting broad public participation and comment on the potential implications of these changes on pharmaceutical regulation. The agency encourages individuals with information relevant to these changes to respond to this notice. FDA is interested in a broad range of issues including:

(1) Changing business relationships. What are the implications of the changing health care market on pharmaceutical communications and promotion? Should FDA regulations be modified? If yes, how should the agency's regulations be modified? How would these modifications affect FDA's public health responsibilities?

(2) Changing marketing claims. How are pharmacoeconomic claims different from traditional comparative claims between therapeutically similar drugs or therapies? What should be FDA's goal in monitoring cost-effectiveness claims? What level of support is necessary to substantiate cost-effectiveness claims?

(3) Changing audiences for industry-supplied pharmaceutical information. Who is receiving/asking for industry-supplied pharmaceutical information? Is this audience more sophisticated (highly educated) than traditional audiences? What type of comparative information is sought? How is this comparative information utilized and interpreted? What should be FDA's goal in monitoring the communication of comparative drug information to healthcare providers and patients within managed care organizations?

(4) Changing channels for communication of pharmaceutical information. What constitutes sufficient evidence of "independence" to give