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December 21, 1995

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Docket Management Branch (HFA-305)
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RE: Docket No. 95N-0228
"Pharmaceutical Marketing and Information Exchange in
Managed Care Environments"

Sirs:

Thank you for the opportunity to comment on the issue of pharmaceutical marketing and information exchange in managed care environments. The American College of Clinical Pharmacy (ACCP) is a national professional and scientific society of clinical pharmacists dedicated to optimal drug therapy outcomes in the pharmaceutical care of patients.

It is clear that pharmaceutical marketing is changing to emphasize value in addition to safety and efficacy. While most health professionals are reasonably well-equipped to evaluate marketing claims regarding safety and efficacy, most are currently unprepared to evaluate those relative to cost-effectiveness. Also, the expanding influence of managed care is rapidly changing the traditional patient-physician-pharmacist relationship.

We offer the following considerations and recommendations:

- 1) With specific regard to drug therapy, the expanding influence of managed care has meant that a smaller number of individuals are controlling drug product selection for larger and larger groups of patients. Pharmaceutical marketing is clearly changing. The focus of promotional efforts by manufacturers is shifting from individual practitioners to system-wide decision makers or prescription drug benefit managers. Pharmacoeconomic-based claims receive greater emphasis in these promotional efforts.

These changing relationships do not mandate any modification of FDA's regulations concerning drug safety and effectiveness. While ACCP encourages the application of pharmacoeconomic principles and information to the drug therapy process, we do not believe that such information should be a required component of

the new drug approval process. Requiring such at this point would needlessly prolong the drug approval process. Manufacturers will voluntarily develop such data if it is needed to construct an effective marketing plan for their new drug. However, if pharmacoeconomic data are used as part of drug promotional activities, they should meet FDA guidelines for such data.

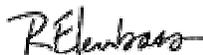
2. The pharmaceutical industry is placing increasing importance on economic-based claims as part of its marketing efforts. However, most consumers of this information are relatively unskilled in its evaluation and application, in contrast to their ability to evaluate marketing claims related to drug safety and efficacy.

FDA and the professions thus each have a responsibility in this area. FDA can assist by assuring that pharmacoeconomic information distributed by manufacturers derives from appropriately designed studies, whether prospective, retrospective, or model based. Professional organizations such as ACCP can assist by educating our members in the performance and application of pharmacoeconomic studies.

3. The audiences for economic-based marketing claims are widely varied. They range from individual healthcare providers making therapy decisions for individual patients, to members of Pharmacy and Therapeutics Committees making formulary decisions and guiding institutional drug use, to prescription drug benefit program managers who influence vast numbers of patients. The level of sophistication of these different audiences varies markedly, but with few exceptions most are relatively unsophisticated at the present time.
4. ACCP is concerned about efforts by manufacturer-owned prescription drug benefit programs (PBMs) to switch patients from one product to another therapeutic or generic equivalent produced by the parent pharmaceutical company. However, ACCP believes that regulation of the relationship among PBMs, the patient, and the healthcare professional is beyond the FDA's scope of authority. These issues are more appropriately dealt with by individual state boards of pharmacy or healing arts, or by the Federal Trade Commission. FDA's regulatory authority does not extend to the actual practice of pharmacy, medicine, or any other health profession.

Again, we appreciate this opportunity to comment.

Sincerely,



Robert M. Elenbaas, Pharm.D., FCCP
Executive Director