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AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS*

Pharmacists in health systems helping people make the best use of medications

June 26, 1998

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Division of Drug Marketing, Advertising
and Communications
Center for Drug Evaluation and Research
Food and Drug Administration
HFD-40, Room 17B04
5600 Fishers Lane
Rockville, MD 20857

3014 98 JUL 16 AM 11:11

RE: Guidance for Industry -- Promotional Use of Health Care Economic Information Under Section 114 of the Food and Drug Administration Modernization Act (FDAMA)

Dear Ms. Burke:

The American Society of Health-System Pharmacists (ASHP) understands that the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) will soon provide the Food and Drug Administration (FDA) a draft "Guidance for Industry -- Promotional Use of Health Care Economic Information Under Section 114 of the Food and Drug Administration Modernization Act" that was developed by a working group of ISPOR organizations. ASHP is the 30,000-member national professional association representing pharmacists who practice in hospitals, health maintenance organizations, long-term care facilities, home care organizations, and other components of health care systems. ASHP was one of the organizations participating in ISPOR's development of the draft guidance.

ASHP has not yet seen the final draft of ISPOR's proposed guideline, but in terms of previous drafts and discussions among the ISPOR groups, we would like to bring to your attention some concerns that we believe need to be addressed by the FDA.

Our major concern relates to possible recommendations about the expertise of the audience that is to receive pharmacoeconomic information. Section 114 of the Food and Drug Administration Modernization Act states that health care economic information can be "provided to a formulary committee, or other similar entity." The House Committee on Commerce Report on the legislation (H.Rept. 105-310, p. 65) expands the list of examples of the types of entities that may receive such information to include "formulary committees, drug information centers, and other multidisciplinary committees within health care organizations that review scientific studies and technology assessments and recommend drug acquisition and treatment guidelines."

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ASHP believes that the assumption that a high level of expertise exists among such professionals to adequately interpret the value and limitations of economic studies may be exaggerated. In October 1995, ASHP testified before an FDA public hearing on "Pharmaceutical Marketing and Information Exchange in Managed Care Environments." At that time, we presented the results of a brief survey of ASHP members who are involved in drug product purchasing or formulary system management in managed care organizations. That survey showed that while almost 94% of the members surveyed believed that their managed care organizations planned to increase their use of pharmacoeconomic studies, only 60% of those practitioners believed that their organizations were well equipped to critically analyze the comparative pharmacoeconomic claims of drug manufacturers. Although more formulary committees and similar entities may be adding such expertise, we caution FDA not to aim too low in determining the burden of evidence that must be provided by pharmaceutical manufacturers.

That same 1995 survey of members indicated strong support for the FDA's review of pharmacoeconomic claims. Over 89% of those responding to the survey believed that the agency should apply the same degree of rigor in assessing a manufacturer's pharmacoeconomic claims as it does in assessing clinical claims. This does not mean that FDA should use the same standards for pharmacoeconomic claims as it does for clinical claims. Section 114 of FDAMA replaces the more restrictive standard applied to clinical information conveyed in prescription drug labeling and advertising with the Federal Trade Commission's (FTC) less restrictive "competent and reliable" standard. While ASHP believes that the use of the FTC standard is appropriate for pharmacoeconomic information, we also believe that FDA must rigorously review that information to ascertain that it is indeed "competent and reliable scientific evidence," as required by FDAMA.

ASHP appreciates the opportunity to provide these comments to the FDA prior to the agency's issuance of its own draft guidance document on promotional use of health care economic information. We look forward to providing comments to the FDA on the specific guidance document that the agency develops. Feel free to contact me if you have any questions regarding our comments.

Sincerely,



Gary C. Stein, Ph.D.
Senior Government Affairs Associate

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