December 19, 1996

Letter prepared by Margaret Garikes, Ext. 409

The Honorable Donna E. Shalala
Secretary
Department of Health and Human Services
200 Independence Avenue, SW -- Room 615-F
Washington, DC 20201

Dear Secretary Shalala:

The Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Information submitted an Action Plan to you on December 13, 1996. The undersigned medical specialty organizations are writing to comment on the Action Plan.

Our organizations are supportive of the goals outlined in the Proposed Rule of the Food and Drug Administration (FDA) on Prescription Drug Product Labeling: Medication Guide Requirement (MedGuide)." Goals consistent with the proposed rule are the distribution of useful written information to 75 percent of individuals receiving new prescriptions by the year 2000 to 95 percent by the year 2006. Physicians have a responsibility to counsel their patients about their prescription medicines to encourage compliance and help the patient identify adverse events associated with the drug therapy. Our goal is to improve the health outcomes of our patients.

Our organizations, however, cannot support the Action Plan submitted by the Steering Committee. We are concerned that the Action Plan as outlined will harm the quality of care to our patients. In addition, we believe that the Action Plan goes beyond the boundaries of a "voluntary" plan. We also contend that the manner in which oral counseling is addressed in the Action Plan is inappropriate.

Below you will find a detailed outline of our concerns:

1. Steering Committee Composition

Organizations representing practicing physicians were clearly under-represented on the Steering Committee. Only three physician organizations -- the American Medical Association, the American Academy of Family Physicians, and the American College of Obstetricians and Gynecologists -- were allowed to serve on the committee, despite a request for additional physician representation. In contrast, at least six pharmacy organizations and at least thirteen consumer organizations served on the Steering Committee. Of these "consumer" organizations, few represented voluntary health organizations of patients with a particular disease. Thus, the dynamics of the committee were such that physicians, who write more than 95% of all prescriptions and who have the primary responsibility to counsel and educate their patients about prescription medicines, were a small minority whose voice was consequently limited.

2. Off-label Uses

The Steering Committee does a great disservice by not promoting the disclosure of accepted life saving and essential off-label uses of drugs to patients. Today, in important medical specialties like oncology and pediatrics, more than half of the drug treatment of patients are off-label uses. Yet, these off-label uses are the standard of care. If the Action Plan denies such valuable information to our patients, we would oppose it for this reason alone.

3. Lack of Fair Balance in Written Information

Physicians believe that written information about prescription medicines should serve two purposes:

C to encourage patients to adhere to the medication regimen so as to optimize therapeutic outcomes; and

C to help patients identify, and report to their physicians, serious adverse events associated with drug therapy.

To achieve these two goals requires that written information be fairly balanced in presenting both positive and negative information about a particular medicine.

Unfortunately, some members of the Steering Committee contended that the chief focus of written information should be on the harm a medication can cause, with essentially no emphasis on promoting compliance. The physician organizations raise the concern that if written information is so weighted toward the potential harm a prescription medicine presents (i.e., emphasis on warnings, contraindications, adverse reactions, overdose, dependence, etc.), then the written information, itself, may well do more harm than good. Such biased information may frighten many concerned patients to the point of noncompliance with their medications, resulting in poor therapeutic outcomes.

4. Financial Incentives for Pharmacists

The pharmacy organizations have made a strong effort to use the Action Plan to legitimize one of their chief legislative and regulatory goals, which is to gain reimbursement for pharmacists' "cognitive services." There is little evidence that retail pharmacists are routinely providing cognitive (patient counseling) services or, in fact, are capable of providing these services. Expecting patients and third-party payers to reimburse for these activities will increase the overall costs of health care and encourage the inappropriate practice of medicine by pharmacists who might otherwise not go beyond the limits of their competence.

5. Oral Counseling

Physicians have a responsibility to provide their patients with sufficient and balanced information about prescription medicines to both encourage compliance and help identify adverse events associated with drug therapy. Ultimately, our goal is to improve the health outcomes of our patients. However, given physicians' limited voice on the Steering Committee, we must strongly oppose nonphysician members defining what physicians should do or say when orally counseling their patients about prescription medicines. This is a professional practice issue that falls clearly within the purview of physician professional associations and State Boards of Medicine. While acknowledging the statutory terms guiding the Steering Committee, the physician representatives nevertheless believe that addressing the issue of "oral counseling" in both the Steering Committee and the subsequent Action Plan is unacceptable because it extends beyond the scope of the FDA's jurisdiction and its proposed "MedGuide" regulation.

Some pharmacy organizations have taken advantage of this situation to promote an agenda that they call "pharmaceutical care." These organizations have attempted to use the Action Plan as a mechanism to legitimize the role of the pharmacist as a primary counselor of patients about prescription medicines. It is the unwavering view of the physician organizations that this is inappropriate as it distorts the reality of actual practice. While pharmacists can help improve medication use by reinforcing to the patient the instructions of the prescribing physician, they clearly are not the primary counselors.

The convening of a national symposium to discuss oral counseling by pharmacists with the expressed purpose of developing consensus for new legislation, regulation or guidelines is an Action Plan proposal we greet with great concern. Organizations representing the parties in interest clearly have met and will continue to meet in their ongoing efforts to improve patient information and education. However, a national meeting under the auspices of the Action Plan and sanctioned by the Secretary of Health and Human Services by way of her acceptance of the Action Plan, creates a clear impression of agenda setting.

6. Ongoing Assessment of the Quality and Distribution of Prescription Information

Members of the Steering Committee have called for the establishment of an independent, quasi-regulatory body, most likely an Advisory Committee to the FDA, to provide ongoing assessment of Action Plan implementation, including some form of "accreditation" of written information. Our physician organizations vigorously oppose the creation of any new entity or mechanism that implies regulation for a program that is supposedly voluntary.

The Action Plan also calls for the establishment of a "Transition Group" that would assist in implementation. The composition and governance of this new 15-member entity would mirror that of the full Steering Committee. This raises substantial concerns for physician organizations. As with the Steering Committee, physicians again would be given so limited a voice as to render them impotent on the very issues (e.g., oral counseling of patients about their medicines) where they have the greatest responsibility.

The National Council on Patient Information and Education (NCPIE) is nationally recognized as an organization with a long and positive track record in promoting improved compliance and better communication between health care providers and patients about prescription medicines. NCPIE could easily provide the private sector "umbrella" to see that this voluntary program is moving forward, and it is our view that it should be so designated. Furthermore, consumers will be adequately protected because the statute requires that FDA assess the voluntary program's success in meeting the goals of the Action Plan prior to January 1, 2001. If the goals are not achieved, the Secretary has the authority to seek public comment on other initiatives to achieve the goals.

We appreciate the opportunity to comment on the critical issue of written and oral information for our patients. We urge you to reject the Action Plan.

Sincerely,

American Academy of Family Physicians
American Academy of Orthopaedic Surgeons
American Academy of Otolaryngology - Head and Neck Surgery
American College of Cardiology
American College of Emergency Physicians
American College of Obstetricians and Gynecologists
American College of Physicians
American Medical Association
American Osteopathic Association
American Psychiatric Association
American Society of General Surgeons
American Society for Gastrointestinal Endoscopy
American Society of Internal Medicine
Society of Cardiovascular and Interventional Radiology
The Society for Vascular Surgery