ACTION PLAN
FOR
THE PROVISION OF USEFUL
PRESCRIPTION MEDICINE INFORMATION

Presented to
The Honorable Donna E. Shalala,
Secretary of the Department of Health and Human Services

by the
Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information

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PREFACE

This *Action Plan for the Provision of Useful Prescription Medicine Information* is the result of a collaborative process mandated by Congress. Public Law 104-180, which was passed on August 6, 1996, required the Secretary of Health and Human Services to organize a committee of diverse interests to develop a long-range, comprehensive action plan to improve oral and written communication to patients about their prescription medicines.[1] In response to that mandate, the Secretary published a notice in the *Federal Register* on August 23, 1996 outlining the process to be used in developing the action plan.[2] The Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information was subsequently formed. It first convened on September 18, 1996 and, by the terms of the statute, was given until December 4, 1996 to complete its work.

In accordance with the law, the Steering Committee included participants from health care professionals' organizations, consumer groups, voluntary health agencies, the pharmaceutical industry, drug wholesaling companies, patient drug information database companies, and other organizations.[3] The 34-person Steering Committee met 7 times in the Washington, DC area. Numerous smaller working group sessions and conference calls were also held. The Steering Committee was convened and facilitated by The Keystone Center, a nonprofit public policy mediation and education organization founded in 1975 and headquartered in Keystone, Colorado.

In accordance with P.L. 104-180, this Action Plan is hereby presented to the Secretary of Health and Human Services for consideration. The ideas and recommendations in this Action Plan were developed by the Steering Committee and represent the consensus of the Committee, unless otherwise noted in either the text or Appendix K.[4] *"Consensus" means that the members of the Committee agree to support the Plan* as a total package*, although individually they may not have an equal amount of enthusiasm for each idea or recommendation. In presenting this document, members of the Steering Committee commit to working toward the goals of this Action Plan and encourage their colleagues to do so as well.*

The Statutory Mandate

[1] Public Law 104-180 (August 6, 1996), *Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 1997*. See Appendix A for the relevant statutory language.
[2] Department of Health and Human Services (DHHS), "Prescription Drug Information for Patients: Notice of Request for Collaboration to Develop an Action Plan," *Federal Register* 61 (no. 166), 26 August 1996, 43769. See Appendix B for the *Federal Register* notice.
[3] See Appendix J for a complete list of Steering Committee members.
[4] Appendix K is comprised of letters from Steering Committee members that describe their particular perspectives about the Action Plan.

Public Law 104-180 required that the plan address six specific issues. The statutory language describing these six requirements is reproduced below. The page numbers in parentheses after each requirement refer to the pages within this document on which the issue is addressed*:*

"The plan...shall--

(1) identify the plan goals *[pp. 5-6];*
(2) assess the effectiveness of the current private-sector approaches used to provide oral and written prescription information to consumers *[pp. 10-14, 29, 44-49];*
(3) develop guidelines for providing effective oral and written prescription information consistent with the findings of any such assessment *[pp. 13,16-25];*
(4) contain elements necessary to ensure the transmittal of useful information to the consuming public, including being scientifically accurate, non-promotional in tone and content, sufficiently specific and comprehensive as to adequately inform consumers about the use of the product, and in an understandable, legible format that is readily comprehensible and not confusing to consumers expected to use the product *[pp. 16-25];*
(5) develop a mechanism to assess periodically the quality of the oral and written prescription information and the frequency with which the information is provided to consumers *[pp. 26-30];* and
(6) provide for compliance with relevant State board regulations *[p. 33]."*

CHAPTER 1

INTRODUCTION

Over the past three decades, consumer groups, health care providers, and others have shown an increasing interest in supplying consumers with more and better information about their prescription medicines. The hope is that consumers, armed with greater knowledge about the medicines they take, will be empowered to make better-informed decisions about their health and their health care. It is further hoped that the broader distribution of prescription medicine information will ultimately result in improved health outcomes and fewer medication-related problems. Today, consumers, manufacturers, health care providers, information vendors, the Food and Drug Administration (FDA), and public health policymakers have made the provision of useful information about prescription medicines a top health care agenda item. This chapter (1) sets forth the goals that this Action Plan seeks to achieve and (2) discusses the correlation between prescription medicines and public health.

GOALS OF THE ACTION PLAN

The purpose of this Action Plan is to improve the quality and availability of useful information that is voluntarily provided to consumers with their prescription medicines. The rationale for the Plan is that providing consumers with useful information about their prescription medicines can reduce the risk of preventable, medication-induced injury and improve health outcomes.

This Action Plan seeks to encourage health care providers, health care professionals' associations, consumer organizations, and other interested parties to voluntarily adopt a long-range strategy to improve the usefulness and availability of consumer-oriented information about prescription medicines.[5] Specifically, this Action Plan seeks to do the following:

- Encourage health care professionals to improve their communications with consumers about prescription medicines as a means of improving health outcomes and reducing preventable, medication-related injuries.
- Identify mechanisms and incentives to ensure that voluntary efforts to provide useful written information to consumers about prescription medicines meet the distribution targets set forth in P.L. 104-180; the law states that such information should reach 75 percent of individuals receiving new prescriptions by the year 2000 and 95 percent of individuals receiving new prescriptions by the year 2006.

[5] Please note that nothing in this Action Plan is meant to usurp the best judgment of the health care professional.

- Establish criteria for the development and distribution of written prescription medicine information for patients. The criteria will define the components that such information should contain, while allowing for some flexibility in content.
- Encourage activities to increase consumer understanding and awareness of the benefits and availability of written prescription medicine information and the importance of oral communication between health care professionals and patients.
- Develop mechanisms for the periodic, reliable evaluation of current and future voluntary efforts to provide useful written information about prescription medicines to consumers.
- Promote consistency with relevant State board regulations.

PRESCRIPTION MEDICINES AND THE PUBLIC HEALTH

Prescription medicines are potent substances that, when prescribed, dispensed, and used appropriately, have the potential to significantly improve a person's quality of life, relieve the symptoms of illness and disability, and achieve a cure. Prescription medicines are a major part of the medical armamentarium; in 1995, over 2.1 billion prescriptions were provided to consumers on an outpatient basis in the United States.[6] National studies of ambulatory care have consistently reported that almost two-thirds of office visits to physicians result in at least one prescription.[7] When prescribed, dispensed, or used inappropriately, however, prescription medicines can cause serious and sometimes fatal harm, induce new diseases, fail to relieve the symptoms or cure the disease, or otherwise adversely affect a person's quality of life. The increasing costs of prescription medicines, of treating preventable, medication-related injuries, and of problems related to the suboptimal use of prescription medicines are estimated to be in the tens of billions of dollars.

The following are examples of studies that document the benefits of prescription medicines and the problems that sometimes occur.

- The number of newborns infected with the AIDS virus declined 27 percent between 1992 and 1995, according to the Centers for Disease Control and Prevention. The decline was attributed to the fact that more pregnant women were being tested for HIV and, if found positive, began taking the drug AZT during pregnancy.[8]
- Anti-inflammatory therapies and bronchodilators reduced the number of deaths from emphysema by 31 percent between 1960 and 1990. Had no progress been made against this disease, roughly 335,000 more people would have died in 1990 alone.[9]

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[6] "U.S. Script Volume Up 7% in '95," *SCRIP World Pharmaceutical News*, 2 April 1996, 14.
[7] S.M. Schappert, "Advance Data from Vital and Health Statistics: Number 273," *National Ambulatory Medical Care Survey: 1994 Summary* (Hyattsville, MD: National Center for Health Statistics, 1996).
[8] "Number of Babies Being Born with HIV Infection Declining," *The Washington Post*, 22 November 1996.
[9] The Boston Consulting Group, *The Contribution of Pharmaceutical Companies: What's at Stake for America* (Boston: The Boston Consulting Group, 1993).

- Pharmaceutical products averted an estimated 456,000 deaths and between 2.6 to 6 million nonfatal strokes between 1970 and 1986. [10] In one study of heart failure patients, the drug enalapril reduced total mortality by 11 percent over a 3-year period.[11]
- Hormone replacement therapy has proved effective in reducing heart attacks in post-menopausal women. Also, a recent study indicates that the therapies may reduce the risk of Alzheimer's disease.[12]
- A U.S. General Accounting Office study published in July 1995 found that 17 percent of hospitalized older Americans had been admitted because of an adverse drug reaction.[13] FDA estimates that the cost of hospitalizations caused by inappropriate use of prescription medicines is about $20 billion annually.[14]
- A study published in the *Archives of Internal Medicine* estimated that drug-related morbidity and mortality in the ambulatory care setting in the United States cost almost $77 billion annually. The study also stated that the failure to take medications correctly results in the loss of 20 million work days and $1.5 billion in earnings annually in the United States for those patients with heart and circulatory diseases.[15]
- A study published in the *Annals of Internal Medicine* estimated that adverse drug reactions among elderly Americans living in the community may result in 2.2 million physician visits, 1.1 million laboratory tests, and 146,000 hospitalizations annually.[16]
- In August 1996, an article published in *U.S. News and World Report* stated that some pharmacists were filling prescriptions for combinations of certain prescription medicines whose simultaneous use was contraindicated. In addition, pharmacists failed to warn consumers of this potential to interact and cause harm.[17]

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[10] R.E. Brown and B.R. Luce, *The Value of Pharmaceuticals: A Study of Selected Conditions to Measure the Contribution of Pharmaceuticals to Health Status* (Washington, DC: Battelle Medical Technology and Policy Research Center, 1990).

[11] The SOLVD Investigators, "Effect of Enalapril on Survival in Patients with Reduced Left Ventricular Ejection Fractions and Congestive Heart Failure," *New England Journal of Medicine* 325, no. 5 (1991): 293-302.

[12] The Writing Group for the PEPI Trial, "Effects of Estrogen or Estrogen/Progestin Regimens on Heart Disease Risk Factors in Postmenopausal Women," *Journal of the American Medical Association* 273, no. 3 (1995): 199-208; M.J. Stampfer et al., "Postmenopausal Estrogen Therapy and Cardiovascular Disease: Ten-Year Follow-Up from the Nurses' Health Study," *New England Journal of Medicine* 325, no. 11 (1991): 756-762; M.X. Tang et al., "Effect of Estrogen During Menopause on Risk and Age at Onset of Alzheimer's Disease," *Lancet* 348 (1996): 429-432. Note: A Steering Committee member has requested that it be noted that they believe many studies on hormone replacement have been biased and/or flawed and that the complete body of literature on the topic does not support the conclusions stated in this bulleted paragraph.

[13] U.S. General Accounting Office (GAO), *Prescription Drugs and the Elderly*, Rpt. #HEHS-95-152 (Washington, DC: GAO, 1995).

[14] DHHS, Food and Drug Administration (FDA), "Prescription Drug Product Labeling; Medication Guide Requirements," *Federal Register* 60 (no. 164), 24 August 1995, 44232.

[15] J.A. Johnson and J.L. Bootman, "Drug-Related Morbidity and Mortality: A Cost of Illness Model," *Archives of Internal Medicine* 155 (1995): 1949-1956.

[16] J.F. Burnum, "Preventability of Adverse Drug Reactions," *Annals of Internal Medicine* 85 (1976): 80-81.

[17] S. Headden, "Danger at the Drugstore," *U.S. News & World Report*, 26 August 1996, 46-53.

- A number of studies reviewed by the National Pharmaceutical Council found that there are differences in the response to a number of medicines for specific racial and ethnic groups, indicating a need for increased monitoring and counseling.[18]

This list of studies illustrates both the benefits of prescription medicines and the potential for harm. One solution to the problems of the suboptimal use and misuse of prescription medicines (and the resulting potential for medication-related injury) is the education of consumers through the provision of useful information about their prescriptions. For example, providing patients with written information about how to take their medicine appropriately (i.e., at appropriate intervals, with or without food, in prescribed amounts) may enhance the therapeutic value of those medicines. This problem and its solutions are very important to public health and the economics of the health care system.

[18] R. Levy, *Ethnic and Racial Differences in Response to Medicines* (Reston, VA: National Pharmaceutical Council, 1993).

CHAPTER 2

BACKGROUND AND CURRENT STATUS

This chapter provides a short chronology of the key events that led to the development of this Plan. It then provides a brief assessment of current private-sector approaches to the provision of oral and written prescription medicine information to consumers.

BACKGROUND

The following is a brief chronology of events leading up to the development of this Plan.

1968: FDA began requiring warnings on isoproterenol inhalation products. This was the first prescription medication that required consumer-oriented written information. (Today, such information is required of more than 40 prescription drugs or drug classes. The information is written by pharmaceutical manufacturers and distributed by pharmacists, but requires FDA's review prior to distribution.)

1970: FDA responded to the concerns of women's health advocates and to new data on the potential for long-term side effects related to oral contraceptives and other hormone-based products by requiring that information written by manufacturers for consumers and reviewed by FDA be dispensed with these medications.

1979: FDA proposed a rule that would have required manufacturers to produce and distribute (after FDA review) written information known as patient package inserts (PPIs) for 10 drugs or drug classes (i.e., about 375 prescription medicines.)

1982: FDA withdrew the proposed PPI regulation. The same year, the National Council on Patient Information and Education (NCPIE) was formed, with support from FDA's Committee on Patient Education. NCPIE, with a membership of over 310 organizations, serves as a major coordinating body for private-sector initiatives working to improve communication about prescription medicines to consumers.

1993: Section 4401(g) of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), which required pharmacists to offer to counsel Medicaid recipients about their prescription medicines, took effect. Subsequently, more than 40 State boards of pharmacy required that the oral counseling provisions be applied for all consumers, not just Medicaid beneficiaries.[19]

[19] See Appendix C for the OBRA '90 language that applies to pharmacies, and see Appendix D for a list of state counseling requirements for pharmacists, prepared by the National Association of Boards of Pharmacy (NABP).

1995: FDA published a proposed rule in the *Federal Register* that aimed to increase the quality and quantity of written information about prescription medicines to consumers. This proposed rule, entitled "Prescription Drug Product Labeling: Medication Guide Requirements," is commonly referred to as the MedGuide proposal. In the proposal, FDA would have required manufacturers to produce "MedGuides" for certain medicines that pose a serious and significant public health concern. The proposal also encouraged written information leaflets to be produced and distributed for all drugs, and set targets for the distribution of these leaflets by pharmacists and physicians with new prescriptions. The MedGuide proposal also set criteria by which written information would be judged to determine if it was useful and should count toward achievement of the targets. In the MedGuide proposal, FDA stated that "inadequate access to appropriate patient information was a major cause of inappropriate use of prescription medicines, resulting in serious personal injury and costs to the health care system." FDA also indicated that while the rate of distribution of written information had increased, the quality of the information was variable.

1996: At an FDA-convened workshop on the MedGuide proposal in February, consumer- and patient-advocacy groups indicated strong support for the proposed rule. Health care professionals' organizations, information vendors, and associations representing the pharmaceutical industry supported the concept of providing better information about prescription medicines to consumers, but disagreed with some of the plan's assumptions and opposed some of the organizational details included in the proposal.

In August, Public Law 104-180 was passed. It included a provision that asked "interested parties" to meet and develop a plan that would achieve the goals in the MedGuide proposal but be implemented on a voluntary basis and without a regulatory mandate. If this Action Plan, which is submitted herewith, is satisfactory to the Secretary of Health and Human Services, then FDA will not have the authority to implement the MedGuide proposal.

BRIEF OVERVIEW OF CURRENT APPROACHES

Public Law 104-180 required that this Action Plan "assess the effectiveness of current private-sector approaches used to provide oral and written prescription information to consumers." The purpose of this provision was to help in developing future strategies to increase the delivery of useful prescription medicine information by assessing the best methods for providing such information. The short time frame provided to develop the Action Plan (120 days) precludes a comprehensive assessment of this topic. Because it believes the results of a more comprehensive study would be valuable, however, the Steering Committee recommends that a process be put in place to undertake such an evaluation, with a 12-month deadline and proceeding concurrently with the other implementation activities described in the Plan. This comprehensive evaluation is described in Chapter 4 and Appendix E. [20]

[20] In addition, see Appendix F for a selected bibliography of literature about private-sector approaches.

The remainder of this section (1) describes briefly the types of written information that are currently being disseminated with prescription medicines and (2) describes in some detail the Steering Committee's recommendations regarding oral counseling. Although the discussion of oral counseling is more detailed in this chapter than the discussion of written information, it is one of the few places in the document where oral information is discussed explicitly; the remainder of the Plan focuses almost exclusively on written information.

Written Information About Prescription Medicines

Many types of written information are currently being distributed with some prescription medicines. The FDA requires that more than 40 prescription medicines, such as metered-dose inhalers and oral contraceptives, be accompanied by consumer-oriented written information. This information is written and produced by product manufacturers and reviewed by FDA. Drug manufacturers and pharmacies have developed their own programs to increase the quantity and quality of written information being provided to consumers.

FDA surveys indicate that the proportion of patients reporting that they received written medicine information from pharmacists increased from 16 percent in 1982 to 55 percent in 1994.[21] Also in 1994, the National Association of Boards of Pharmacy (NABP) found that 64 percent of consumers reported receiving written medicine information. Of those who received such information, 92 percent said that they read the information. Of these respondents, 97 percent said that they felt the written information was clear and easy to understand.[22] In July 1996, the American Pharmaceutical Association found that 81 percent of consumers surveyed reported always receiving written information when having a new prescription filled. Of those receiving such information, 69 percent read all or most of the information, and 75 percent of those respondents found the written information "very useful."[23] FDA surveys report that the percent of physicians providing written information to consumers increased from 5 percent in 1992 to 14 percent in 1994.[24]

The computerization of pharmacies over the past decade has enabled many pharmacists to more readily provide written information to consumers about their prescription medicines. Computerization has also spurred the development of innovative information software by private-sector information vendors. This software enables pharmacists and other professionals to produce customized written information for each individual who has a prescription filled.

Oral Information About Prescription Medicines

[21] DHHS, FDA, *A National Survey of Prescription Drug Information Provided to Patients* (Rockville, MD: FDA, 1994).
[22] NABP, *Consumer Patient Counseling Survey: Summary Report* (Park Ridge, IL: NABP, 1994).
[23] American Pharmaceutical Association (APhA), *1996 National Pharmacy Consumers Survey* (Washington, DC: APhA, 1996).
[24] DHHS, FDA, "Prescription Drug Product Labeling," 44191.

The Steering Committee believes that oral counseling is a critical component of the successful prescribing, dispensing, and ultimate use of prescription medicines. At the time of prescribing, the physician, nurse, or other prescriber knows the specific indication for which the medicine has been prescribed. The prescriber is best able to openly and thoroughly discuss with the patient the diagnosis, the specific indication for use of the medicine prescribed, the appropriate dosing, and possible side effects. At the time of dispensing, pharmacists or other authorized dispensers of prescription medicines can provide complementary information, as well as directions on how to take the medicine.

The statute requires the Steering Committee to address various issues relating to the provision of oral information to consumers by health care professionals. There was significant discussion by Committee members about the extent to which the Plan should address this topic, given that, as a professional practice issue, the evaluation of oral counseling has traditionally been the purview of the State boards of pharmacy, medicine, and nursing and the relevant professional associations. The Steering Committee has thus attempted to craft a series of steps designed to meet the statutory provisions while respecting and supporting the roles of the State boards and professional organizations in overseeing the nature and content of the practice of their respective disciplines (including oral counseling).

The provisions in the statute, which are in quotes and bold type below, and the steps recommended by the Steering Committee to address them, are as follows:

"Assess the effectiveness of the current private-sector approaches used to provide oral... information to consumers"

The Steering Committee recommends that State boards of pharmacy continue their efforts to assess the quality of oral counseling provided by pharmacists in all settings in which prescription medicines are provided to ambulatory patients. This assessment should include the nature and effectiveness of the "offer to counsel" made to the consumer. Current State pharmacy practice act guidelines, which are most often based on the prospective drug use review provisions of Section 1927(g) of OBRA '90, should be used as the baseline for determining the effectiveness of current oral counseling.

Pharmacists have been required since 1993 to offer to counsel Medicaid recipients on how to use their prescription medicines. Most states have extended this requirement to non-Medicaid recipients, and many states have allowed offers to counsel to be in writing on a poster or sticker. Although this law has been in effect for almost four years, there is concern that an insufficient number of consumers are receiving meaningful offers from pharmacists to orally counsel them on their medications. For example, a July 1994 survey conducted by NABP found that consumers reported offers for counseling only 38 percent of the time.[25] A survey released in September 1996 by the New York City Office of the Public Advocate found that, although a law exists that requires pharmacists to offer counseling to all

[25] NABP, *Consumer Patient Counseling Survey*.

consumers, only 42 percent of independent community pharmacies and 27 percent of chain community pharmacies provided consumers with some offer to counsel about their prescription medications.[26]

The Committee also recommends that FDA, as part of its consumer telephone survey of the provision of written prescription information to consumers (discussed on p. 28), continue to assess the extent to which consumers indicate that they receive useful oral information from health care providers about their prescription medicines. This assessment would include counseling provided by all health care professionals, including physicians, pharmacists, and nurses. In addition, these surveys should include all settings in which prescription medicines are provided on an ambulatory basis, including retail, mail-service, hospital, and outpatient pharmacies and physicians' offices where prescription medicines are dispensed.

Finally, the Committee recommends that the literature review described on p. 29 and in Appendix E include a review of the effectiveness of oral counseling provided by all health professionals, including their "best practices" and typical practices. The Committee suggests that these assessments be reviewed by the implementation entity established under this Plan for potential further referral. Furthermore, the assessment should accurately capture the racial and ethnic differences of those patients receiving the information.

"Develop guidelines for providing effective oral...information consistent with the findings of any such assessment"

The Committee recommends that a National Symposium on Oral Counseling by Pharmacists about Prescription Medicines be convened in 1997 by pharmacists' groups, including NABP. The Symposium would include representatives of consumer groups, health care professionals, public and private third-party payors, information technology companies, and other interested parties. The purpose of this conference would be to assess the effectiveness of current oral counseling guidelines based upon the data collected and the assessments made in the above section of the Plan, and to assist State boards of pharmacy and NABP in enforcing existing guidelines and developing new guidelines, if necessary, for oral counseling. It would recognize that multiple factors are responsible for the provision of effective oral counseling by health care professionals to consumers. In this regard, the symposium would provide a neutral forum for interested parties to discuss the following issues, specific to pharmacists:

- the effectiveness of current oral counseling guidelines relating to prescription medicines
- identification of "best practices" for oral counseling
- suggestions for refinement to current guidelines, if needed, with referral to State boards of pharmacy
- strategies to reduce the economic, practice, and social barriers relating to providing useful oral information about prescription medicines

[26] New York City Office of the Public Advocate, *Prescription for Danger: Drugstore Counseling Routinely Ignored* (New York: NYC Office of the Public Advocate, 1996).

"Develop a mechanism to assess periodically the quality of the oral...information and the frequency with which such information is provided to consumers"

As discussed on p.21, the Steering Committee believes that FDA should continue to conduct periodic consumer surveys to determine whether consumers are receiving oral counseling when they obtain their prescription medications. The results of these surveys should be shared with all stakeholders, including the organizations representing and evaluating the health care professions.

The Steering Committee believes that the appropriate mechanism to assess the quality of the information being provided to consumers by pharmacists, as well as the offer to counsel, should be developed by individual State boards of pharmacy, consistent with State pharmacy practice acts and regulations, or any modifications made to such practice acts as a result of any new guidelines developed. The State boards of pharmacy, colleges of pharmacy, and pharmacy practice associations are called on to continue to educate pharmacists about the importance of oral counseling in prescription medication and use.

The Steering Committee also recommends that other health care professionals--specifically, physicians and nurses--be encouraged to continue and expand their efforts to improve the frequency and quality of oral counseling at the time a prescription is given to the patient. As discussed above, this is the optimal time for conveying patient-specific information. The development of mechanisms, such as best practice guidelines, to encourage more frequent and better quality oral counseling, fall to the organizations representing those professions, and this recommendation is not intended to supplement or replace these groups with new Federal or State regulations.

The Steering Committee encourages the organizations representing nursing and medicine to establish fora, such as symposia, to evaluate the status of oral counseling by members of their respective professions. These symposia would allow the nursing and medical professions to receive feedback from a broad group of stakeholders and to use that feedback in their efforts to develop and/or refine guidelines for effective oral counseling.

In addition, the Steering Committee suggests that it would be appropriate to organize a broad-based symposium on oral counseling involving all relevant parties. NCPIE has suggested that its next annual meeting could serve as a venue for such a discussion.

Finally, all organizations representing health care professionals are encouraged to establish educational programs that will do the following:

1. Incorporate the basic principles of effective oral counseling by their respective professionals in the curriculum of relevant undergraduate and graduate schools.
2. Provide their practicing professionals with specific prescription medicine information that should be conveyed to the consumer.
3. Teach the techniques of counseling to their respective professionals that will lead to desirable changes in attitudes and behavior on the part of consumers and result in better clinical outcomes.

Summary

As a result of public and private initiatives, advances have been made to date in providing useful information to consumers about prescription medicines. However, the Steering Committee recognizes the need for additional steps if the goals of the statute are to be achieved; those goals call for useful written information to be provided to 75 percent of individuals receiving new prescriptions by the year 2000 and 95 percent by the year 2006. The Committee also recognizes that information provided to consumers should include specific elements that are considered to be useful and that some standardization of the format through which this information is provided would be beneficial. There is a recognition that the quantity and quality of oral counseling provided to consumers by health care professionals need to be substantially improved, and a number of activities are recommended to help foster that improvement. Finally, the Committee recognizes the need to develop efforts that increase the cultural competency of oral and written communication as well as efforts to reach underserved populations in order to meet the goals of this Plan.

CHAPTER 3

GUIDELINES FOR USEFUL PRESCRIPTION MEDICINE INFORMATION

The guidelines described in this chapter are meant to encourage the development of written prescription medicine information that is useful to consumers. Useful written information is that which is sufficiently comprehensive and communicated such that consumers can make informed decisions about how to receive the most benefit from medicines and protect themselves from harm. Both the substance and presentation of the information are important.

The following guidelines are intended to provide direction for the developers of written prescription medicine information, but are not meant to be overly prescriptive. The guidelines for both the content and the format represent the best judgment of the Steering Committee members as to the essential elements and characteristics of useful information and the preferred methods of presenting such information. It is expected that, as the Plan is implemented and additional information is gained concerning what constitutes "useful" information, these guidelines will be subject to periodic review, evaluation, and refinement. (This review process is discussed in Chapter 4.) The written information that meets these guidelines--i.e., adheres to the criteria, includes the suggested components, and substantially conforms with the formatting suggestions here and in Appendix G--will be deemed "useful" information and will "count" toward the quantitative goals of the Plan.

As discussed in the previous chapter, the Steering Committee recognizes the critical role of oral counseling in the effective communication of information about prescription medicine; however, this chapter does not provide guidelines for the provision of oral information about prescription medicine. Laws and guidelines relating to oral counseling by pharmacists already exist, including OBRA '90, a number of State statutes, and professional association guidelines. Nothing in this Action Plan is intended to intrude upon this existing legal, regulatory, and professional practice structure. The Steering Committee encourages all health care professional groups to continue to strengthen their efforts to ensure the improved quality and increased frequency of oral counseling.

CRITERIA

Written prescription medicine information should be (1) scientifically accurate, (2) unbiased in content and tone, (3) sufficiently specific and comprehensive, (4) presented in an understandable and legible format that is readily comprehensible to consumers, (5) timely and up-to-date, and (6) useful. These criteria are described in detail in this section.

In the following discussion, distinctions are sometimes made between "generalized" prescription medicine information and "customized" information. "Generalized" information is that which is intended for all consumers for whom medication is prescribed. "Customized" information is that which includes information designed specifically for an individual consumer. Both generalized and customized information should count toward the quantitative goals, if they meet the guidelines set forth in this chapter.

Scientifically Accurate

For the purposes of this Action Plan, the term "scientifically accurate" refers to one criterion that can be used to determine whether or not written information about prescription medicine is useful and counts toward the goals. This section does not purport to define "scientifically accurate" in any other context. The Steering Committee recognizes that there is considerable information that may be considered scientifically accurate in other contexts and that the determination of what is "scientifically accurate" is an ongoing process within the practices of medicine and pharmacy. The narrow definition of "scientifically accurate" that follows does not preclude the conveyance of information that falls outside of the definition, either by oral communication between health care providers and consumers (which the Steering Committee strongly encourages), or by means of written information that is "customized" for a specific consumer at a specific time.

The Steering Committee agreed on several points concerning the interpretation of "scientifically accurate" as it pertains to the implementation of this Plan, including many scenarios involving various sources of information (e.g., FDA-approved labeling, legislatively recognized compendia, peer-reviewed literature) provided in different contexts (e.g., generalized or customized information). Specifically, the Steering Committee agreed on the following:

- Information consistent with or derived from FDA-approved labeling should be included in both generalized and customized prescription medicine information.
- Information from scientific literature about indications or uses not approved by FDA is appropriate only in customized prescription medicine information. For other details about the medicine, such as potential adverse effects, information from scientific literature is appropriate when consistent with the process of making changes to the product's labeling.
- Written information should contain a statement that specifically points out that the medicine may be prescribed for a use or indication that is not listed and that communication with the prescriber and/or dispenser is encouraged. For example: "This information is a summary. It does not include all actions, precautions, adverse reactions, side effects, or interactions. In addition, your doctor may have prescribed this medicine for a use not listed above. You should ask your health care provider about any additional information you would like to have, such as the professional package insert, and any concerns you may have."
- Customized written information may include information specific to the prescription, such as information that is provided by the prescriber and/or the dispenser about a use or indication for use that is off-label, and should be counted toward the goals of this Action Plan if it meets the criteria in this chapter. A prescriber may opt to prepare customized information in advance for distribution to

his or her patients for whom the diagnosis matches the off-label use. This may also apply to dispensers who have appropriate information for these off-label indications for use for the specific patient.

- Manufacturer-produced "patient package inserts" (PPIs), which are reviewed by FDA and do not include off-label use information, should be counted toward the goals of this Action Plan if they meet the criteria in this chapter.

The issue that remains unresolved relates to the appearance of off-label information, specific to uses of or indications for the use of medicines, that is derived from compendia. The Steering Committee agrees that off-label information concerning uses or indications can appear in customized information. There is disagreement among Steering Committee members, however, regarding the appearance of off-label uses in generalized information. Many options were discussed concerning how off-label use information could be addressed. No consensus could be reached on any one option. The two options most discussed by the Steering Committee are summarized below.[27]

Option 1

- In generalized information materials, information about the use of or indication for use of the medicine will be considered "scientifically accurate" only if it is consistent with FDA-approved product labeling or is otherwise permitted by FDA. (In other words, generalized information that meets the criteria in this chapter can be counted toward the goals only if the information about the use of or indication for use of the medicine is consistent with FDA-approved product labeling or is otherwise permitted by FDA.)

Option 2

- In generalized information materials, information about the use of or indications for use of the medicine will be considered "scientifically accurate" only if it is consistent with the FDA-approved product labeling, is otherwise permitted by FDA, and/or appears in federally recognized drug compendia.[28] (In other words, generalized information that meets the criteria in this chapter can be counted toward the goals only if the information about use of or indication for use of the medicine is consistent with the FDA-approved product labeling, is otherwise permitted by FDA, and/or appears in federally recognized drug compendia.)

The Steering Committee acknowledges that the current FDA policy regarding off-label use information is under discussion. If this policy is modified by the agency or by Congress, then it may be appropriate to also modify this Plan with respect to off-label use information.

[27] See Appendix K, which contains letters from Steering Committee members, for information about which organizations support which option.

[28] The term "federally recognized drug compendia" in this Plan is distinct from "federally recognized drug compendia and peer-reviewed literature" as discussed in Medicaid reimbursement legislative language. Option 2 includes only the compendia that are listed in that legislation, not the peer-reviewed literature that is listed.

Unbiased in Content and Tone

Presentation and content of written prescription medicine information should be unbiased in tone and should meet the accepted standards of scientific literature (i.e., explanatory; neutral; without comparative adjectives, untruthful claims about the benefit of a product, or hyperbole; and distinguished from any promotional or other information provided to the patient). Written information should promote compliance with the specified dosage and appropriate use, but should not promote a specific brand, manufacturer, or distributor for the purpose of economic gain. In addition, the information should represent a fair balance between descriptions of the benefits and descriptions of the risks.

Sufficiently Specific and Comprehensive

Prescription medicine information should be specific enough and comprehensive enough to enable patients to use the medication correctly, receive the maximum benefit from it, and avoid harm. It should include directions for taking the medication and information about avoiding negative consequences. Information should be included regarding proper monitoring of the impact of the therapy by correctly interpreting physical reactions to the medicine. This would include, for example, informing consumers about when to call their health care provider if they do not notice signs of improvement. Also, risk information should include enough detail for the consumer to understand the significance of the hazard described; for example, the information should allow consumers to distinguish between a warning about an improper use that could be life-threatening and one that could result in minor discomfort. Information that explains specific directions or cautions is important in order to inform the consumer about the benefits of the medicine and how to protect themselves from preventable harm. Consumers also should be able to recognize that the information materials are summaries and are not exhaustive, and consumers should be encouraged to ask for additional information, such as the professional package insert.

The components of useful information, discussed on p. 20, are meant to set a "floor" for defining written prescription medicine information as sufficiently specific and comprehensive. Certain medicines or certain uses of medicines, however, may require additional information to meet this criterion.

In an Understandable and Legible Format that is Readily Comprehensible to Consumers

Written prescription medicine information should be presented in an understandable and legible format that is readily comprehensible to consumers. A standardized format should make it easier for consumers to locate particular information and would provide an opportunity to reinforce important aspects of that information (e.g., adverse effects) and the importance of oral counseling. At the same time, allowing for flexibility and variation in the content and format of prescription medicine information will be the best way to identify those formats that are truly understandable and readily comprehensible. (For further discussion, see Language and Format section on p. 23.)

The Steering Committee recognizes the importance of providing written information in the language a consumer feels most comfortable reading and at a reading level appropriate for the greatest number of consumers. Accordingly, the Steering Committee encourages written prescription medicine information to be available in both English and Spanish, and recommends that other major language adaptations be available in regions where those languages are spoken by a significant proportion of the population and through special request. Non-English information should be developed as an adaptation rather than a direct translation, in order to ensure the accuracy of the information, and information should be available at the sixth- to eighth-grade reading levels.

Timely and Up-to-Date

Written prescription medicine information is expected to be distributed in a variety of ways. With computerized distribution to most pharmacies, it is expected that information will be updated based on scientifically accurate sources and distributed to the consumer in a timely fashion. Assessment of this Plan's implementation will enable a better understanding of whether new scientifically accurate information is being included in information materials in a timely manner.

Useful

Prescription medicine information shall be useful to consumers. "Useful" is defined as enabling the patient to use the medicine properly and appropriately, receive the maximum benefit, and avoid harm. This Plan suggests criteria, components, and formats that, combined, provide guidance for developing and presenting "useful" information. The Plan also identifies steps for assessing, evaluating, and revising these criteria, component, and format suggestions as additional information is gathered through consumer testing and other appropriate means.

COMPONENTS OF USEFUL INFORMATION

The components of useful information that are outlined in this section are based upon the preceding criteria. As a total package, they are meant to be scientifically accurate, unbiased in content and tone, sufficiently specific and comprehensive, understandable and in a legible format that is readily comprehensible to consumers, timely and up-to-date, and useful. The examples given below are not all necessary for information to be deemed useful, but are meant to provide ideas of what may be appropriate in some, but not all, situations.

The order in which these components are listed is the suggested order for a standardized format. Steering Committee members especially want to encourage publishers to list items A-D (names of the medication, "black box" warnings if required, indications for use, and contraindications) first in the written prescription medicine information and in this order. Items E-K also should be included, but not necessarily in this order. The Steering Committee does not mean to imply by this list that each of these items must be listed separately under a separate heading. Some could be combined together under a

single heading, for example. (See p. 24 for more on headings.) If alternative formats are developed (i.e., changing the order of components A-D), they should be tested to demonstrate their usefulness according to the criteria.

The components of useful information are as follows:

A. The established **name** and brand name (e.g., the trademark or proprietary name), if any. The phonetic spelling of the established name, or of the brand name if an established name does not exist. If no established or brand name of the product exists, a list of the active ingredients.
B. If applicable, a prominently displayed statement that is consistent with or derived from any "black box" **warnings** (as required by FDA on the professional labeling) that are relevant to the consumer.
C. A section that identifies a medicine's **indication for use**, including pediatric indications, if any. (See discussion of "scientifically accurate" on pp. 17-18 for the uses that may be included.)
D. Information on the circumstances under which the medicine should not be used for its labeled indication (i.e., its **contraindications**). Directions regarding what to do if any of the contraindications apply to a consumer, such as contacting the licensed professional or discontinuing use of the medicine. A general statement, such as, "Talk to your health care professional before taking this medication if any of these apply to you," as well as a statement of precaution regarding any circumstances in which the use of the medicine could lead to serious injury or death.
E. If applicable, a statement or statements of **precautions** the consumer should take to ensure proper use of the medicine. (These statements are encouraged in serious situations.) The following list is not meant to be exhaustive:
    1. A statement that identifies activities (such as driving or sunbathing) and drugs, food, or other substances (such as tobacco or alcohol) that the patient should avoid.
    2. A statement of the risks to the mother and the fetus or infant from the use of the medicine during pregnancy, labor, and breast-feeding (or, if the risks are unknown, a statement such as, "When taken during pregnancy, labor, and breast-feeding, the effects of this medicine on the development of the exposed offspring are unknown").
    3. If the medicine has specific hazards associated with its use in pediatric populations, a statement of the risks.
    4. When the use is not contraindicated, additional precautions that apply to the safe and effective use of the medicine in identifiable patient populations.
F. A statement of the symptoms that indicate **possible adverse reactions** from the use of the medicine that are serious or occur frequently. Guidance for the definition of "adverse reactions" can be found in 21 CFR § 201.57(g) as, "an undesirable effect, reasonably associated with the use of the drug, that may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence." Organizing and explaining adverse reactions may vary by drug product; for example, information may be organized by organ system, severity, or frequency. A combination of these approaches, or other appropriate means, is suggested for providing information adequate to explain possible adverse reactions.
G. A statement of the risks, if any, to the patient of developing a **tolerance to** or **dependence on** the drug product. "Drug dependence" may be defined as a pattern of behavior in which drug use is given a much higher priority than other behaviors that once had a higher value. It is not absolute, but

exists in degrees, and its intensity is measured by the behaviors that are associated with the use of the drug. Drug "tolerance" has developed when a given dose of a medicine produces a decreased effect or when increasingly larger doses must be taken to obtain the same effect as when the original dose was taken.[29] An example of a statement about tolerance could include the following: "When sleep medicines are used every night for more than a few weeks, they may lose their effectiveness to help you sleep. This is known as "tolerance." Sleep medicines should, in most cases, be used only for short periods of time, such as a few days and generally no longer than one or two weeks. If your sleep problems continue, consult your doctor, who will determine whether other measures are needed to overcome your sleep problems." An example of a statement concerning dependence is the following: "Sleep medicines can cause dependence, especially when these medicines are used regularly, or for longer than a few weeks, or at high doses. Some people develop a need to continue taking their medicines. This is known as dependence or 'addiction.' [It continues with a discussion of physical signs of addiction and withdrawal.]"

H. Information on the **proper use** of the medicine, including the usual dosing instructions and the following:
    1. A statement stressing the importance of adhering to the dosing instructions prescribed by your health care provider.
    2. A statement of what the patient should do if he or she misses taking scheduled doses of the medicine.
    3. A statement describing any special instructions on how to administer the medicine (e.g., route of administration, with food or water, at specific times of day).
    4. A statement about what the patient should do in case of overdose of the medicine. If overdose information is determined to be important for a particular medicine, signs of overdose should be included so that patients may recognize the symptom(s). In all cases in which symptoms of overdose are listed, overdose information should be directly followed by instructions for what to do, such as call a poison control center or other emergency number, should symptoms occur.

I. Proper **storage instructions**.

J. **General information**, including:
    1. A statement encouraging discussion with a health care professional about the prescription medicine.
    2. A statement that the medicine should only be used by the patient for whom it is prescribed and is not to be given to other persons.
    3. The name of the publisher of the information.
    4. The date of publication or most recent revision or review for adequacy and accuracy of content.

K. **A disclaimer** statement containing the following concepts:[30]
    1. The materials are summaries and do not contain all possible information about the medicine.
    2. The health care professional who has prescribed the medicine has more information.

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[29] J.H. Jaffe, "Drug Addiction and Drug Abuse," in *The Pharmacological Basis of Therapeutics*, 8th edition, eds. A.G. Gilman et al. (New York: Pergamon Press, 1990).

[30] See Appendix H for examples of currently used disclaimers and sample disclaimers suggested by some Steering Committee member organizations.

3. The health care professional's information addresses both the medicine and the patient's specific health needs.
4. The health care professional can provide and answer questions about the information in the professional labeling.

A summary section (containing the medicine's approved indications, critical aspects of proper use, significant warnings, precautions, contraindications, serious adverse reactions, and potential safety hazards) should be considered for inclusion, but is not essential for the written information to be considered "useful." Another optional item is a 1-800 number; such a number could encourage the use or creation of a service that would provide information to consumers with impaired vision, marginal or no literacy, or whose first language is not English. In addition, pharmacists and other dispensers are encouraged to provide prescription medicine information in the language a consumer prefers to use. It is currently estimated that 8 percent of the U.S. population prefers speaking Spanish and an additional 6 percent prefers speaking a language other than English or Spanish.[31] Information provided in languages other than English should not be simply translated from the English, but rather should be carefully edited and adapted to provide the same sense of the information that is found in the English version.

LANGUAGE AND FORMAT

In developing written prescription medicine information that is presented in an understandable and legible format and is readily comprehensible, publishers must find the optimal balance between standardization and flexibility. A format that presents information in a set order makes it easier for consumers to locate particular information and would provide an opportunity to reinforce important aspects of prescription medicine use (e.g., potential side effects) each time a consumer refers to this information. At the same time, allowing for flexibility and variation in the content and format of prescription medicine information will be the best way to identify those formats that are truly understandable and readily comprehensible. As evaluation and assessment of these format suggestions occur, through consumer testing or other recognized means, modifications may be appropriate to improve the usefulness of the information to consumers.

While acknowledging that prescription medicine information can and will be provided through numerous different media (e.g., computer and video), the following guidelines are suggested for printed prescription medicine information. These are general guidelines; designers and publishers of written information know that readability and legibility depend on a combination of factors, including type size, style, letter and word spacing, line length, and contrast between ink and paper color. A specific discussion of these factors, providing more precise guidance, is included in Appendix G.

- Design of written prescription medicine information should ensure that information is readable and legible and that important information is prominent and conspicuous. Formats should also help distinguish between the degree of seriousness of cautions or warnings.
- Prescription medicine information should be written, preferably, at the sixth- through eighth-grade reading levels. The same information could also be available at higher reading levels. When possible, information should be written clearly and concisely, and complex terms should be avoided. Polysyllabic words could be replaced by shorter, simpler words (e.g., "harmful" rather than "detrimental"), even if it takes several words to get across a concept that can be expressed in a single, more complex term.

[31] M.R. Reddy, ed., *Statistical Record of Hispanic Americans* (Detroit: Gale Research, Inc., 1995).

- Use of pictograms is encouraged. Pictograms can help consumers with low literacy skills understand important information about prescription medicines. Pictograms should never be used alone, but should accompany written information. Universal symbols (e.g., the circle with slash, which connotes "no") should be used where appropriate. Any new symbols should be consumer-tested before and after they appear in written information.
- Written prescription medicine information should be widely available in both English and Spanish. Other major language adaptations should be available by special request.

Written prescription medicine information that is generally consistent with the language and format guidelines set out here and in Appendix G will be presumed to be understandable and readily comprehensible, and will satisfy this criterion for useful information absent evidence to the contrary. It may be established, through consumer testing or other acceptable means, that information that is not consistent with these guidelines is, nonetheless, understandable and readily comprehensible. Such consumer testing would likely result in revision to the guidelines. These revised guidelines should then be followed in subsequent assessments of written prescription medicine information.

Layout

Information should be included according to the recommendations in the Components of Useful Information section on p. 20. As stated in that section, however, all of the components listed need not come under their own heading; they can be combined as needed. The headings listed below are intended as concepts for such headings; they are not meant to propose exact wording. Writers of prescription medicine information are encouraged to use standardized phrases for headings reflecting these concepts so that, in the interest of promoting usefulness, consumers will be familiar with the layout of information rather than confused by different formats. The suggested order of general headings is as follows:

1. Personalized information in a box
2. Established name and brand name
3. "This medicine is used for..."
4. "Do not take this medicine if you are..."
5. "How to take this medicine..."
6. "Side effects include..."
7. General information

Samples of written prescription medicine information that are consistent with the guidelines in this chapter are included in Appendix G. The headings used in the examples reflect the concepts in this chapter and are in no way intended to be considered the only acceptable headings.

CHAPTER 4

ASSESSMENT AND IMPLEMENTATION

The Steering Committee understands that the opportunity to design and implement this Plan on a voluntary basis brings to those organizations supporting the Plan a responsibility to apply the resources and energy necessary to carry it out. The statute makes clear that if the Secretary determines that the voluntary effort is not successful by 2000 or 2006, she has the authority to institute a regulation. The Steering Committee further recognizes that the Secretary must make a decision within 30 days of submission of this Plan as to the likelihood of it being successfully implemented with its quantitative and qualitative goals being reached. Therefore, the implementation activities called for by the Steering Committee in this chapter are intended to convey to the Secretary that the Committee intends for this voluntary Plan to succeed.

The collaborative, voluntary nature of this Plan, as called for by the statute, provides unique opportunities and poses unique challenges. In order to ensure effective and successful implementation using this new model, the Steering Committee believes that:

1. there must be structured, periodic communication between the Secretary and the various organizations involved in developing and implementing this Plan;
2. the process must take advantage of the strengths of existing entities *and* recognize that communication and coordination among these entities is critical; and
3. the collaborative nature of the partnership that developed this Plan must continue in some form, at least temporarily, in order to oversee those implementation tasks that do not logically fall to any existing entity.

Each organization listed in Appendix J is committed to supporting this Plan's implementation in a manner consistent with its organizational scope and goals. It is acknowledged that, given the diversity of the Steering Committee, this commitment will entail a range of activities, but the Steering Committee believes that such a commitment by its diverse membership will be critical to the success of this Plan.

ASSESSMENT OF PROGRESS

In order to be deemed successful, implementation of this Action Plan must result in "the distribution of useful written information to 75 percent of individuals receiving new prescriptions by the year 2000 and to 95 percent by the year 2006." This section discusses the assessment of progress toward these goals.

What Should Be Measured

Measurement of the distribution of written prescription medicine information to consumers requires (1) a definition of the total number of all prescription medicines that progress will be measured against (i.e., the "denominator") and (2) a definition of "what counts" toward meeting the goals (i.e., the "numerator").

For the purposes of measuring performance, the total (or "denominator") will include all new prescriptions that are filled for medicines that are dispensed at community pharmacies, mail-service pharmacies, hospital-based outpatient pharmacies, physicians' offices (see below for discussion about excluding samples), and medical clinics. The total will also include new prescriptions that are filled in any other situation or setting in which the medicine is intended to be self-administered by the patient or administered by a care-giver, such as a family member or home health aide. (The total does not, thus, include in-hospital situations or other circumstances where the drug is administered by a health care professional.) A "new" prescription is any prescription that is not a refill. In the case of a chronic condition for which medication is taken repeatedly, the prescription will be considered new every time the physician physically writes out, transmits electronically, or makes a telephone order to a dispenser for another prescription for the same medication.

For the purposes of measurement toward the goals, drug samples will not be included as a part of the total of prescription medicines. However, if a physician provides a drug sample that is not accompanied by a prescription order, the Steering Committee strongly encourages those physicians to include written information about the drug with the sample. The Committee anticipates that this may occur in situations, for example, in which only a small amount of the drug is needed and the physician has enough samples on hand to fulfill the needs of the patient, or in a clinic in a low-income community where the physician knows that the patient is not financially able to have the prescription filled. Any such clinic providing medications free of charge is encouraged to distribute the relevant written information. (In every situation in which drug samples are given to a patient, oral communication about the drug and its proper use is also strongly encouraged.)

Compounded prescription drugs should also be excluded from the total number of prescription medicines against which progress will be measured. A physician may prescribe a unique compounded formulation for a patient when a commercial pharmaceutical product is not available or when some special circumstances prevent the patient from using a commercially available product (e.g., different dose, sensitivity (allergy) to a component of the commercial product, or (rarely) consumer preference issues such as flavor). Some prescription medicines are compounded based upon standard formulae, and written information is often available based on that formulae. In these circumstances, written information should be provided. The Steering Committee urges all dispensers of compounded prescriptions to provide written information whenever possible.

The "numerator" should then be determined as follows: every written information product that (1) accompanies a prescription medicine that falls within the total described above and (2) adheres to the

criteria, includes the suggested components, and substantially conforms to the guidelines in Chapter 3, will count toward meeting the goals of the Action Plan.

Who Should Do the Measuring

The Steering Committee recognizes and supports the statutory language that gives the Secretary of the Department of Health and Human Services the authority to measure the distribution of useful written information. Accordingly, the Steering Committee recommends that the Department:

1. continue its biannual consumer survey in 1997 and 1999;
2. expand and refine its survey methodologies in order to measure in 1997 and 1999 the amount of written prescription medicine information that is "useful";
3. adopt the Steering Committee's definition of "useful," which is described in Chapter 3;
4. use the guidance on pp. 27-28 regarding the measurement of performance in conducting its surveys; and
5. solicit expert advice on both the best methodologies with which to conduct the above assessments and ways to refine the definition of "useful written information" after 2000. This might include convening an advisory panel subject to the Federal Advisory Committee Act, convening a symposium of experts in the field, and/or working closely with the various stakeholders involved in the development and implementation of the Action Plan.

IMPLEMENTATION ACTIVITIES

As discussed in the introduction to this chapter, implementation will require effort on the part of all Steering Committee member organizations. The 120 days allotted by law to the Steering Committee did not allow enough time to agree upon the exact entity best suited to do every activity. Thus, a "Transition Group" is proposed as a way to further develop an implementation strategy for the Plan and to serve as the decisionmaking body for any issues that were either left unresolved in the Plan or were not addressed or contemplated at all. The structure and governance of the Transition Group would mirror the Steering Committee, but would include only about 15 members, in order to allow a more efficient management process. The Steering Committee has agreed to finalize a process for selecting the membership and to schedule the first meeting of this Transition Group within 30 days after meeting with the Secretary (or her designee) to initiate implementation activities.

Among the tasks the Transition Group would expect to assume are:

- the coordination, prioritization, and focusing of the activities of the various parties involved in the provision of useful written information about prescription medicines in order to maximize the likelihood of achieving the goals of the voluntary Action Plan;

- the development of ways in which to provide feedback, available at the request of those involved in developing and providing the written information, on whether or not their products are meeting the guidelines and criteria called for in this Action Plan;
- the exploration of ways in which to work closely with FDA in order to ensure that all parties are in agreement with the definition of useful written information after 2000; and
- the management of a process to study the costs and savings resulting from implementation of this Plan.

The Steering Committee has agreed that two additional tasks are central to an effective Action Plan, but they were not able to reach consensus on who should oversee these tasks. The first task is to provide "real-time" feedback to all participants involved in the implementation of the Action Plan on whether or not their products and efforts meet the criteria called for in the Plan.

The second task is to develop and test written information prototypes, in order to better evaluate current private-sector approaches to the distribution of written information and to produce sound data on which to base decisionmaking regarding the refinement, if necessary, of the guidelines described in Chapter 3. The Committee believes that such an assessment would take no more than 12 months to accomplish and should occur concurrently with the other implementation activities set forth in this chapter. The sound data that will result and the methodology used to obtain the data add to the overall credibility of the Plan, which will, in turn, help to encourage pharmacists and physicians and their suppliers and vendors to undertake this voluntary Plan. Also, it fulfills the provision of the statute that requires such an assessment. A detailed methodology for conducting this assessment is set forth in Appendix E. In brief, the assessment includes the following steps:

1. Review of selected published and unpublished literature, in order to ascertain what has been found to contribute to effective oral and written communication about prescription medicine.
2. Development of written information prototypes (based upon the guidelines in Chapter 3) for three commonly prescribed medications.
3. Testing of the prototypes with consumers, pharmacists, physicians, and nurses.
4. Refinement of the prototypes to reflect the findings of the literature review and the results of the surveys about the initial prototypes.
5. Testing of the final prototypes in pharmacies and possibly other settings in which the medicines are dispensed.

The two options for managing these two tasks--the "real-time feedback" and the prototype development and testing--that were discussed by the Steering Committee are as follows:

Option 1

- FDA should coordinate both tasks using the advisory panel called for in #5 of the assessment effort on p. 28. The mechanism by which the feedback would be provided was not explicitly discussed, but the limited discussion implied that it would either by done by the advisory panel itself or by an entity established and funded by the advisory panel.

Option 2

- The Transition Group should assume the responsibility for both tasks and would subcontract to a reputable third party the field testing of the guidelines. The mechanism by which the feedback would be provided was not explicitly discussed, but the limited discussion implied that it would either by done by the Transition Group itself or by an entity established and funded by the Transition Group.

Education

Another key element of the implementation of this Action Plan is education. Two kinds of education efforts must occur. The first is narrowly defined as education *about the Action Plan* and its implementation. The second is a much broader effort to raise the awareness of all health care professionals about the importance of properly prescribing and dispensing medicine *and* to raise the awareness of the public about the importance of complying with prescription directions.

Education About the Action Plan

All Steering Committee members and the organizations they represent share the responsibility for educating individuals and organizations about the Action Plan. They will begin by educating their own constituencies about the details of the Action Plan, including its voluntary nature, the guidelines for prescription medicine information, the quantitative goals, and the consequences of not meeting those goals. Because manufacturers, information vendors, and pharmacists have, perhaps, the greatest responsibility for ensuring that accurate and useful information is generated and distributed, the greatest efforts should be made to educate these groups of individuals. To a lesser degree, but equally important, other health care professionals involved in prescribing and dispensing medication (i.e., physicians and nurses) will need to be informed about the Plan's details. Finally, efforts must focus on consumer groups and regulators.

Large-Scale, Awareness-Raising Effort

Ultimately, it is hoped that the implementation of this Action Plan will result in consumers and health care professionals becoming better partners with each other. Toward that end, a long-term, awareness-raising effort should:

1. educate health care professionals about the need to effectively communicate with their patients about prescription medicines;
2. educate consumers about the appropriate use of prescription medicines and how to ask their health care professionals effective questions about them; and
3. reach out to the underserved segments of the population who, for reasons of age, language, education, the health system, or other barriers, need targeted communications and education efforts on the effective use of prescription medicines.

ADDITIONAL ISSUES

This section discusses other implementation issues of importance, including details on the production and distribution of information; incentives and disincentives; and compliance with State board regulations.

Production and Distribution of Useful Information

The Committee anticipates that written information will likely be produced and distributed in the form of a point-of-sale computer printout. Other possibilities exist, of course, from pre-printed leaflets to World Wide Web sites and other high-technology methods. Access to these various media will depend on the availability of appropriate computer technology, which may differ significantly depending on the setting in which the information is distributed. The Committee thus encourages the publishers of such information to make it available in a variety of forms that are accessible to and efficient for dispensers, and enable it to reach the greatest number of individuals.

At present, prescription medicine information is published by a variety of entities. The FDA, in its MedGuide proposal, identified eight commercial vendors that currently supply the majority of written information about prescription medicines. Manufacturers also produce written information, not only for the approximately 40 medicines for which the FDA has required them to do so, but for others as well. A number of patient-advocacy groups produce written information of interest to their constituents that is available in many forms, including pamphlets and sites on the World Wide Web and other computer services.

This Action Plan assumes that this variety of producers of written information will continue, and even expand. In other words, the Steering Committee anticipates that the majority of written prescription medicine information will be supplied by commercial vendors, but that their work will be augmented by information produced by manufacturers and patient-advocacy groups. Written prescription medicine information from any source that meets the Plan's guidelines for "useful" information will be counted toward the Plan's goals, as discussed further below.

The Action Plan assumes that the information will be distributed any time a prescription medicine is dispensed. The dispensing activities that will "count" toward the goals are discussed in detail on pp. 27-28.

Confidentiality of Patient Information

Protection of the confidential nature of patients' medical information, which is always a concern for all health care professionals, becomes a greater concern with the expanded distribution of written prescription medicine information. When pharmacies dispense a prescription medicine to someone other than the person for whom the prescription was written, a question arises about how to distribute

the written information. Perhaps more important, the preparation and distribution of customized written information presents numerous opportunities for unintended release of confidential medical information. All health care professionals are urged to devote attention to the need to protect confidential medical information. The Steering Committee recommends that the methods for creating and distributing patient-specific written information be monitored and, if release of confidential medical information increases, that steps be taken to prevent such release.

Access to Health Care Providers

The Steering Committee recognizes that the best environment for effective communication about prescription information is between the consumer and his or her regular provider of health services. However, 11 percent of adult women under the age of 65 do not have a regular provider of care and 18 percent of all consumers are uninsured.[32] In addition, difficulty in finding a provider who can communicate in the language preferred by the consumer and in a culturally competent manner, or who is accessible in the community in which consumers live, also act as a barrier to using a regular provider of care. This lack of a regular provider of care creates a need to develop innovative approaches to reach these consumers. Such approaches would include consumer education materials on how to take medications; culturally competent consumer education campaigns; technology options for medication tracking at the dispensing source; and community-based campaigns to educate consumers about how to talk to their health care providers about prescription medicines. The Transition Group should review and recommend options for supporting the above and other approaches to effectively communicate with consumers who do not have a regular provider of care.

Incentives and Disincentives for Implementation

The Steering Committee recognizes that implementing all of the steps called for in this voluntary Action Plan will result in additional costs for some entities (e.g., pharmacies) and savings for others (e.g., third-party payors, employers). For example, pharmacies and other prescribing and dispensing entities will likely assume a large proportion of the burden for distributing written and oral information. Expenses relating to computer hardware and software changes and the purchasing of monthly updates are just two of the many direct costs required. Unfortunately, today's health care marketplace is structured such that providers are often compensated for the volume of patients served and not for the amount of time spent with those patients. In fact, physicians, nurses, and pharmacists have found their time with patients increasingly limited as the result of the cost-containment policies of third-party health care payors. Furthermore, most third-party payors and private-pay consumers cover only the cost of dispensing the prescription medicine and do not cover the expenses of providing extended consumer counseling.

Thus, the Steering Committee recommends that a study be conducted to analyze the costs and savings involved in implementing this Action Plan. The Transition Group would manage a request-for-proposal

[32] DHHS, National Center for Health Statistics, *Health, United States, 1995* (Hyattsville, MD: Public Health Service, 1996). The report also states that 33 percent of Hispanic consumers and 21 percent of non-Hispanic black consumers are uninsured.

process in order to retain an objective, independent, and credible entity to conduct this study. The results of this study would be shared with all relevant stakeholders. If the study shows that implementation of this Action Plan has added more costs to those providing the information called for in the Plan, the Transition Group would be authorized to recommend appropriate payment to offset such costs by all payors, including governments. Even before that study is undertaken, however, third-party payors (including government agencies) should consider the health care and economic benefits they will likely receive due to improved oral and written communication and are strongly encouraged to provide payment to health care professionals for providing these services.

Several members of the Steering Committee expressed concern that the increased distribution of written information may result in litigation against health care providers, manufacturers, and the producers of written information alleging that they failed to warn of specific risks or that they used the "wrong" language to describe the risks. The Steering Committee does not wish to have this issue become a disincentive to the production and distribution of useful written information. Others on the Committee believe that the distribution of useful information should, in fact, reduce litigation. The Committee believes that the criteria in this Plan are an acceptable standard of care for the type of written information described in this Plan and provided with prescription medicines. Also, the Steering Committee recommends that the potential for inconsistent State requirements be monitored and, if such inconsistent requirements are created by State legislatures or courts, that the Transition Group consider ways to address the difficulties that may result.

Compliance with State Board Regulations

Public Law 104-180 states that this Action Plan "shall...provide for compliance with State board regulations." Because this Action Plan sets forth a voluntary program for improving the quality of oral and written prescription information to consumers, it must *by definition* comply with all existing State board regulations and guidelines. Therefore, all actions and steps proposed by this Action Plan assume compliance with State board regulations and appropriate health professional groups' practice acts. It is also assumed that the onus for ensuring continued compliance rests with the various stakeholders and entities involved in implementing this voluntary Plan. Furthermore, nothing in the development or implementation of this Plan is intended to change the existing regulatory boundaries between the FDA and the States with regard to regulating and monitoring the practice of medicine or the dispensing of prescription drugs.

SUMMARY

The members of the Steering Committee are committed to making this collaborative, voluntary Plan succeed. They recognize that the key elements to successful implementation include keeping the lines of communication open (both with the Secretary and amongst themselves); supporting the transition process set forth above; and harnessing the strengths of their own organizations when needed.

APPENDIX A

PUBLIC LAW 104-180:
RELEVANT STATUTORY LANGUAGE

Please contact scheval@keystone.org, or 970-513-5800 for hard copies of this report, including appendices,
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APPENDIX B

FEDERAL REGISTER NOTICE

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APPENDIX C

OBRA '90:
RELEVANT STATUTORY LANGUAGE

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APPENDIX D

ORAL COUNSELING REQUIREMENTS BY STATE

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APPENDIX E

PLAN FOR EVALUATING CURRENT PRIVATE-SECTOR APPROACHES

A number of steps are suggested in this appendix for completing an assessment of current approaches to providing oral and written prescription information to consumers, as well as refining the guidelines and criteria submitted in the Action Plan in a timely basis. The steps called for in this assessment process have been culled from more lengthy and detailed market-survey processes often undertaken by companies prior to their bringing a product to market. The Steering Committee believes that the data collected in this assessment should, wherever possible, be reported for major racial and ethnic groups, and the protocols should be tested for cultural competency.

While these steps represent the best thinking of the Steering Committee at this time, it is recognized that further refinements to the assessment process are likely needed. The Steering Committee supports such refinements as long as the following goals are still met: (1) the assessment will enable an evaluation of the likely usefulness of the guidelines in Chapter 3 and allow for iterative modifications to improve those guidelines, and (2) it will add to the overall credibility of the Plan by engaging in a logical, market-based review of the guidelines before asking pharmacists and physicians, and their suppliers and vendors, to undertake this voluntary Plan.

REVIEW OF SELECTED PUBLISHED AND UNPUBLISHED LITERATURE

The purpose of a review of literature about written and oral prescription medicine information and education is to determine what contributes to the highest level of effectiveness in the provision of such information to consumers and to identify and discuss current approaches that seek to provide this information to consumers in the United States and in other countries. The analysis will utilize (1) a

computer-assisted literature search of appropriate databases and (2) a call for important unpublished data. The literature review will identify peer-reviewed and other journal articles; well-conducted, scientifically and statistically valid studies; and published and unpublished policy positions and reports that:

1. assess the effectiveness of past initiatives and experiments aimed at providing prescription medicine information;
2. document patient and health care provider preferences;
3. document past and current states of affairs with respect to the provision of prescription medicine education by health care providers (e.g., physicians, pharmacists, nurses);
4. document the positions of various stakeholders;
5. summarize recommendations for improvements to current written prescription medicine information and education practices and products;
6. identify best practices and products; and
7. identify parameters for further research.

The literature review of the materials collected will give priority attention to reporting:

1. what elements are needed to ensure the transmittal of useful written information to the consuming public;
2. how to achieve the highest possible level of scientific accuracy in written information;
3. how to present written information that is nonpromotional in tone and content, but sufficiently specific and comprehensive to adequately inform consumers about the use of the product;
4. how to develop an understandable, legibly written information format that is comprehensible and not confusing to the variety of consumers expected to use the product; and
5. how to design and implement the most effective mechanism for periodically assessing the quality of oral and written prescription information and the frequency with which it is provided to consumers.

DRAFT PROTOTYPES

Based on the guidelines in Chapter 3 and the results of the literature review, prototype prescription medicine information might be drafted for:

- a broad-spectrum antibiotic;
- an anti-hypertensive medication; and
- an analgesic.

These three drug types were selected because they represent the top three therapeutic classifications of all prescription drug mentions, according to a federal survey.[33] These products would also be selected

[33] Schappert, "Advance Data."

to represent acute versus chronic therapy, different levels of disease severity, as well as different measurements of utility to patients. For each of the three medications indicated above, three versions of written information would be produced. One version would represent a currently available type of written information; a second version would be derived from the proposed criteria developed by the Steering Committee; and a third version would be based on knowledge gained from the literature review. It is noted that these prototypes will represent only three versions of information for three medications, and knowledge and information gained from field testing (described below) may not be directly transferable to all medications.

The Steering Committee recognizes that prototype testing is the most costly step in determining if the information is meaningful to the consumer and is delivered appropriately by the health care provider. Testing must be focused and specific to the product and its intended use, in order to provide results that will validate its utility.

CONSUMER TELEPHONE SURVEYS

A series of national, random-sample telephone surveys using the broadest possible range of qualifying patient populations will be conducted to assess consumers' responses to the prototype materials described above. This survey would be designed with the input of experts and could be designed along the lines proposed below.

The three versions of information for each medicine would be sent to groups of 100 patients suffering from relevant conditions. For example, three groups of 100 hypertensive patients would each receive one of three versions of written information about the hypertensive medication under study. The three versions would be delivered in sealed envelopes to be opened during a subsequent telephone interview. During the telephone interviews, the respondents would evaluate each version separately in terms of the following:

- Comprehension of message
- Amount of new information content
- Most/least valuable or useful information
- Likelihood of reading
- General likes/dislikes regarding the information
- General likes/dislikes regarding physical characteristics (e.g., size, shape)

As a part of these surveys, there must be an affirmative outreach to underserved populations, including the poor who may not have telephones, those who speak or read languages other than English, and those who are unskilled readers.

TESTING OF PROTOTYPES WITH PHARMACISTS, PHYSICIANS, AND NURSES

To assess the prototypes of written information with pharmacists, physicians, and nurses, personal interviews would be conducted in different ambulatory care practice settings. The sample size of physicians and nurses would be limited because the information materials under investigation would be primarily designed for use by pharmacists and, therefore, physicians and nurses would be secondary audiences. Feedback from all respondents would be sought on the following topics:

- Perceived value/accuracy of content
- Areas likely to cause patient confusion
- Perceived appropriateness for use by pharmacists
- Likelihood of using the same or similar documents in their practice
- Description of how materials would be used
- General likes/dislikes
- Evaluation of physical characteristics: size shape, print, etc.
- Perceived impact of the written information materials on provider-patient relations
- Perceived impact of the written information materials on the safe and effective use of the product prescribed
- Perceived impact of the written information materials on therapy compliance and clinical outcomes
- Recommendations for improvements

REVISION OF PROPOSED GUIDELINES

Consistent with the findings of the literature review, consumer surveys, the assessments from the health care providers, and the recommendations made by the Steering Committee regarding guidelines for useful written information, prototype materials will be revised and prepared for final testing.

FINAL PROTOTYPE TESTING OF WRITTEN MATERIALS

The Steering Committee recommends that the effectiveness of information for use by consumers be validated through a recall study of patients' responses to randomly received final prototype materials, which the patient receives in various pharmacy settings. Some examples include the following:

- A nationally distributed sample of pharmacies would be recruited, representing a mix of urban, suburban, and rural settings; chain versus independent ownership; and low-, middle-, and high-socioeconomic-level clientele.
- Pharmacists would distribute one of the three types of information with the appropriate products. Patients would be recruited for participation in the study at the time they receive the prescription, or they could be contacted "blindly" afterward and asked to participate in a study about their receipt of written information.

Emphasis will be placed on distinguishing between readability and comprehension of the information being presented.

Final prototype testing in pharmacy settings would proceed in the following stages:

1. Participating pharmacies will distribute prototype materials to consumers receiving a particular prescription product.
2. Participating consumers will be contacted after a period of time and asked to participate in a telephone interview about their receipt of written information about their prescription medicines. Those who participate will be asked about:
   - Whether they remember receiving the information
   - Did they read it, keep it, learn anything, or do anything differently as a result of the information
   - Usage and perceived value of the information
   - Comprehension and retention of information in the written information materials
   - The role that the written information played in achieving the desired health outcome, current health status, and compliance with the medication therapy
3. Participating pharmacists will also be surveyed for their opinions and reactions to using the prototype materials. Relevant topics for consideration would include:
   - Feedback on patients' interest in materials
   - Ease/difficulty of using the materials (e.g., degree of fit with other activities or responsibilities)
   - Additional information requested by patients
   - Time required to read
   - General likes/dislikes
   - Recommendations for improvement
4. The evaluation of the study will provide:
   - If possible, a statistical analysis of the results, including findings as to the most effective information materials for consumers of prescription medicines
   - Suggestions for guidelines concerning minimal content, format, and design of printed information
   - Conclusions as to how to prepare a final prototype that will be recommended for distribution by dispensers to 75 percent of patients receiving a new prescription by the year 2000

APPENDIX F

CURRENT PRIVATE-SECTOR APPROACHES: A BIBLIOGRAPHY

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APPENDIX G

SPECIFIC LANGUAGE AND FORMAT GUIDELINES, WITH SAMPLES

The following guidelines reflect widely recognized standards used by designers and publishers of written information to ensure that the materials are legible and readable.[34] Legibility and readability cannot be reduced to a precise formula; rather, they depend on a combination of factors. The pages that follow are examples of information materials that adhere to these guidelines.

- **Prescription medicine information should be printed in no smaller than 10-point type**. Type size is very important to readability. Newspapers are usually printed in 8-point type, while 12 point is generally recommended as the smallest type size to use for materials intended specifically for older persons, who are significant consumers of prescription drugs.

- **Ornate typefaces and italics, which are hard to read, should not be used**. Too much curve or detail obscures the letters and slows reading. A bolder type should be chosen over a thin version of the same style. Opinions vary on whether a "serif" font (as is used in this document) or a "sans serif" font (like this one) is more readable. Many experts recommend that sans serif should be used for headings, while serif style should be used for text.

- **Upper and lower case lettering should be used**. Upper and lower case letters have more variation in shape and are easier to identify than all upper case lettering.

[34] M.R. Boyce, *Guidelines for Printed Materials for Older Adults* (Lansing, MI: Michigan Health Council, 1981); Association for the Advancement of Retired Persons (AARP), *Truth About Aging: Guidelines for Accurate Communications* (Washington, DC: AARP, 1986); C. Baker, *Just Say It!: How to Write for Readers Who Don't Read Well* (Washington, DC: Plan Incorporated, 1992).

- **Use bold-face type or a box to call attention to important information**. Highlighting or underlining for this purpose can impede readability.

- **Adequate space between letters, lines, and paragraphs enhances readability**. If the lines of text are too close together, the material will be difficult to read. Generally, text should have no more than -3 "kerning" (i.e. space between letters). With 10-point type, 12-point "leading" (i.e., space between lines) is generally recommended. Adequate space between paragraphs and space above and below headings can also facilitate reading.

- **Line length should not be too long**. Optimal line length is approximately 40 letters long (in 10-point or 12-point type).

- **There should be good contrast between the ink and paper colors**. Good contrast will facilitate reading. Black, dark blue, or brown ink on pale yellow or white paper provides the best contrast. Combinations that provide insufficient contrast should be avoided (e.g., brown on gold, blue on green, red on pink). Also, material should be printed on uncoated paper.

- **Short paragraphs and bullets should be used where possible**. This increases the readability of prescription medicine information.

APPENDIX H

SAMPLE DISCLAIMER STATEMENTS

The following are disclaimer statements either recommended for use on written prescription medicine information or currently used on other, similar, information.

The **U.S. Pharmacopoeia** currently uses the following statement in its leaflets:

The information in this leaflet has been selectively abstracted from USP DI for use as an educational aid and does not cover all possible uses, actions, precautions, side effects, or interactions of this medicine. It is not intended as medical advice for individual problems.

The **Association for the Advancement of Retired Persons** uses the following statement in its leaflets:

If you want more information about this medicine, ask your doctor for a more technical leaflet, the professional package insert.

Medi-Span, Inc. uses the following statement in its information materials:

The information in this monograph is not intended to cover all possible uses, directions, precautions, drug interactions, or adverse effects. This information is generalized and is not intended as specific medical advice. If you have questions about the drugs you are taking, check with your doctor, nurse, or pharmacist.

The **AIDS Treatment Data Network** uses the following language in information that it provides on the Access Project page on the World Wide Web:

The medicine descriptions on these pages are intended for information purposes only. The Network does not promote or endorse the use of any specific treatment for any health-related

condition. The medications described here can only be dispensed by a licensed health care professional. The information may have changed since these pages were updated, though every effort is made to keep these pages current. Please contact The Network at (800) 734-7104 to make sure you have the most up-to-date information.

The **Pharmaceutical Research and Manufacturers of America** suggests the following language:

This "patient leaflet" is a summary and is not intended to take the place of discussions with your doctor. It does not list all benefits and risks of [specific product name or "this medicine"]. Your licensed health care professional has prescribed this medicine and has information about your own medical condition and more information about the medicine, including how to take it, what to expect, and potential side effects.

The **AIDS Treatment Data Network** suggests the following language:

This medicine information page is a summary and intended for information purposes only. If you would like more information, ask your doctor or pharmacist for the complete insert. The medication described here can only be dispensed by a licensed health care professional.

APPENDIX J

LIST OF STEERING COMMITTEE MEMBERS

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APPENDIX K

LETTERS FROM STEERING COMMITTEE MEMBERS

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