

Statement of the Pharmaceutical Research and Manufacturers of America
Before the Food and Drug Administration's
Public Meeting on the Current Status of Useful Written Prescription Drug Information for
Consumers

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The Pharmaceutical Research and Manufacturers of America (PhRMA) welcomes the opportunity to present its views on the current status of useful consumer prescription drug information. PhRMA is an active stakeholder in this issue as our member companies are actively engaged in the research and development of important new medicines that allow patients to lead longer, happier, healthier, and more productive lives. In 2002, our members invested over \$32 billion in the discovery and development of new medicines.

PhRMA is a strong believer in empowering patients with information about their prescription drugs. Useful information improves patient compliance, helps to avoid preventable errors, and results in superior health outcomes. As we consider the issues raised at this meeting today, it is important that there be a demonstrated linkage between disseminated information and patient benefit. Furthermore, all parties need to consider how and where quality information is being generated and how we collectively can maximize the dissemination of such information to the patient.

PhRMA member companies are but one link in the information chain. Both the physician who prescribes and the pharmacist who dispenses the drug are central players, along with the manufacturer, in ensuring that patient questions are adequately addressed. In order to receive maximum benefit from a drug, patients must be aware of issues related to the drug's administration. For example, patients should know whether the drug need be taken with food or on an empty stomach and if there are specific foods, beverages and/or even other drugs that should be avoided when taking their medicines. It is also important for the patient to understand that drugs may pose certain risks. It is in everybody's interest, the health care provider, pharmacist, and pharmaceutical manufacturer, to ensure that patients are well-educated about the drugs prescribed to treat their medical conditions, since this will maximize the possibility of a positive health outcome.

In 1996, PhRMA along with representatives from the medical community, pharmacy, consumer organizations, and voluntary health agencies participated in the Keystone dialogue that resulted in the Action Plan on Useful Consumer Information. PhRMA supported the Keystone initiative in its desire to produce useful information, language, format and layout. However, as PhRMA commented at the time, the Plan suffered from some serious deficiencies. First, PhRMA noted that that the drug sponsor and the FDA are ultimately the best sources of scientifically accurate information about medicines for patients. In failing to recognize this, the Plan could potentially lead to an erosion of the standards for scientific accuracy. Proper safeguards must be installed to ensure that

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patients receive accurate and medically sound information. By focusing on the risks inherent in the use of prescription drugs, the overwhelming benefits of pharmaceuticals were neglected. Finally, the Plan failed to properly acknowledge the role of physicians and other health care providers who also disseminate useful information to patients. Focusing only on pharmacist distributed leaflets would impose financial burdens on pharmacies without identifying the incentives that would ensure that pharmacists could fulfill the responsibility set forth in the Plan.

Since the publication of the Keystone recommendations, PhRMA has partnered with a number of organizations to improve patient outcome. The goal of all these partnerships has been to improve the usefulness of pharmaceutical product information. Some of these activities are detailed below:

- PhRMA is one of the original members of the National Coordinating Committee for Medication Error Reporting and Prevention (NCC-MERP). Consisting of leading national health care organizations, NCC-MERP meets to collaborate and cooperate to address the interdisciplinary causes of errors and to promote the safe use of medications. In 2000, the organization sponsored a workshop on bar coding of pharmaceutical packaging that resulted in a FDA-proposed rule this past spring that will lead to the adoption of new IT approaches to reduce hospital-based medication errors.
- PhRMA partnered with the National Patient Safety Foundation, pharmacy associations and the FDA in developing a public service guide to managing the benefits and risks of medicines.
- PhRMA partnered with the Centers for Education and Research on Therapeutics (CERTs) and the FDA on a series of workshops exploring how benefit and risk are assessed, communicated and managed.
- PhRMA, working with representatives from the pharmacy and health care provider communities, is working with two vendors on approaches to deliver prescription drug prescribing information (the drug label) to pharmacies in an easy to use electronic format. A proof of concept test last year was highly successful and a larger test is planned for this year. One of the features of this approach is that the pharmacist will always have the most current prescribing information on hand. PhRMA believes that IT solutions such as this one should be more readily employed by all stakeholders.

It is critical that FDA see the provision of useful information to patients as a continuum. The landscape of information providers has changed markedly since the Keystone dialogue of 1996. Companies have traditionally provided physicians with brochures outlining the use of particular medicines that can be handed out to patients. The rise of the Internet now provides consumers with direct access to significant amounts of information. Many PhRMA member companies have interactive web sites that provide consumers with not only the full prescribing information (i.e., the drug label) but also patient-friendly information on diseases and their treatments. Other medical information providers such as WebMD, RxList, and Medscape, as well as the myriad of disease societies also provide significant information on prescription drugs. Finally, the FDA

web site has a very useful “Consumer Drug Information” page that describes new drugs approved since January of 1998.

Direct to consumer (DTC) print advertising of select prescription drugs provides yet another avenue for the transmission of useful patient information. A “brief summary” of the advertised pharmaceutical must accompany such advertising. Over the past year there has been a move to make the “brief summary” in print advertising friendlier to patients. When companies first began to employ direct to consumer advertising it was common to summarize the drug label so that the specific points that FDA required would be covered.. Because of the increasing amount of direct to consumer advertising, there is a far greater amount of FDA-approved patient labeling than was the case at the time of the Keystone discussions. According to the draft guidance that was issued by the Division of Drug Marketing, Advertising, and Communication, FDA “...believes that approved patient labeling that comprehensively addresses the product’s most serious and most common risks is a suitable means of communicating risk information to patients.” FDA currently is working to finalize a guidance on using FDA-approved patient labeling in consumer-directed print advertisements.

In the Federal Register notice announcing this meeting, FDA poses four questions regarding the current status of useful information.

1. *What steps is the private sector taking to improve the usefulness of the written information patients receive with prescription drugs and to meet the Year 2006 goal.*

Pharmaceutical companies are submitting and receiving approval for a great many patient package inserts (PPIs). Many of these are included in products that are packaged “unit of use.” However, consumers often do not receive PPIs due to flaws in the distribution system. The pharmaceutical industry can work to make these PPIs compatible with current pharmacy distribution systems and can support efforts to make PPIs available to consumers via alternate alternative distribution pathways (e.g., web-based solutions). Also, some innovative packaging designs which integrate useful consumer information into the design itself have recently come onto the marketplace.

2. *What barriers exist for the private sector to meet the Year 2006 goal, and what plans exist to overcome these barriers?*

There are a number of third party vendors who supply pharmacies with hardware, software, and content that generate leaflets to patients as they receive their prescriptions. PhRMA believes that these vendors should work with pharmaceutical companies to ensure that the information in the vendor systems accurately reflects the current approved product information. Further, third party vendors should use FDA approved patient package inserts whenever they exist. If possible, end-point pharmacies should not edit, abbreviate, or alter these vendor- and FDA-approved labels. Finally, if not already in use, IT systems should be developed that will facilitate easily updatable materials to ensure so that patients can be certain to receive up-to-date and accurate information.

PhRMA has demonstrated that the electronic delivery of full prescribing information to pharmacies and other dispensing sites is achievable. We are moving towards a wider test of this approach this year and believe that full implementation of this approach can be achieved in the near term.

3. *What should the role of FDA be in assuring full implementation of the Action Plan to meet the Year 2006 goal?*

More patients, particularly those on medication for chronic medical conditions, are receiving prescriptions from mail order pharmacies. The recent survey that FDA conducted to evaluate the level of useful information received by consumers did not look at this distribution pathway. It would be useful for FDA to study mail order pharmacy, as it may play an increased role in the future, particularly when a Medicare drug benefit is passed by Congress. Such a survey could lead to markedly different results than those reported by FDA in 2001.

As PhRMA has already noted, there is a multiplicity of sources that provide useful consumer information on pharmaceuticals. FDA should examine third party surveys that take into account the many different means of useful information transmission currently available to consumers. Only by considering the totality of the useful information to which patients are exposed will FDA be able to place in proper context the written pharmacy information, and in turn fairly assess the full extent of useful information received by patients. Finally, FDA should work to better establish and understand a direct linkage to benefit from any useful patient information. In so doing, FDA should survey patients and healthcare providers to best determine what information is critical to safe medication practice.

4. *What other initiatives should FDA consider for providing patients with useful written information about prescription drugs as endorsed by Public Law 104-180? Such initiatives could include the possibility of FDA requiring manufacturers to provide authorized dispensers with the means to distribute useful written information approved by FDA.*

FDA could issue a Guidance for Industry on the Preparation of Useful Consumer Information. PhRMA uses the term "industry" in the above sentence broadly, referring to both pharmaceutical companies and other providers of pharmaceutical product information destined for consumers. Such a Guidance would outline the broad Agency expectations of the content of documents containing useful consumer information.