

Marjorie E. Powell
Assistant General Counsel



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April 28, 2000

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

RE: Status of Useful Written Prescription Drug Information for Patients;
Docket No. 00N-0352; 65 Fed. Reg. 7022 (February 11, 2000)

Dear Sir/Madam:

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, happier, healthier and more productive lives. Investing \$26 billion in 2000 in discovering and developing new medicines, PhRMA companies are leading the way in the search for cures.

PhRMA is pleased to present these comments on the report of FDA's study, with the National Association of Boards of Pharmacy (NABP), of the usefulness of information provided to consumers with new prescriptions. FDA has asked several questions about the study methods and measurements, as well as questions about possible expansions of the study. PhRMA addresses some, but not all, of FDA's questions. The PhRMA comments focus largely on the role of actual users of the written patient information in an assessment of the readability, legibility, and usefulness of the documents collected in the already-conducted study and any future evaluations.

In considering these comments, it is important to note that PhRMA member companies provide a variety of patient information about prescription drugs. For many drugs, companies provide written information intended to accompany the product when dispensed to the patient. In addition, companies provide information on product or company web sites, in direct-to-consumer advertising, and in materials provided to prescribers to give to patients. All of these company-provided sources of information are separate from the written information addressed by the Action Plan and the subject of this FDA-NABP study.

Pharmaceutical Research and Manufacturers of America

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Minimum Usefulness Standard – FDA is asking what the minimum standard should be for determining that written patient information is useful. The study used the criteria developed during development of the “Action Plan for the Provision of Useful Prescription Medicine Information” (the Action Plan). It is important to remember that the Action Plan was developed with limited time and resources, and much of the available time was devoted to finding compromises among groups with differing perspectives on the role of prescription drugs within health care and the types of information that consumers wanted and would use. Therefore, the views of actual consumers could be used to confirm the appropriateness of the existing standards.

In response to a later question, PhRMA recommends that FDA involve a variety of consumers in the evaluation of written patient information already collected in the FDA-NABP study. In the context of that evaluation, FDA could also confirm that the current standards for minimum usefulness are consistent with consumers’ preferences. If the consumers identify other or additional standards, or report that some of the current standards are of lesser importance, then FDA could reconsider the minimum usefulness standards developed for the Action Plan. FDA might specifically ask the consumers to consider the types of information that influence their decisions to undertake an action, such as comply with a drug regimen. In addition, FDA might ask the consumers to consider the criteria they view as important when creators of written patient information determine what risks to include when the written information can’t, because of length constraints, include all possible but rare side effects.

Weighing of Criteria – FDA is asking whether some Action Plan criteria should be given more weight than other criteria in evaluating the usefulness of written information for patients. PhRMA recommends that FDA consider the weight assigned to the different criteria by the consumer panel that reviews the written patient information collected in the FDA-NABP study.

Assessment of Study’s Evaluation Forms – PhRMA has no comment on whether the study’s evaluation forms are an accurate translation of the Action Plan’s criteria.

Should FDA Use Additional Criteria to Evaluate Written Patient Information? – The criteria for evaluation of the written patient information were developed as part of the Action Plan, without the time for review or consideration of existing research into how to communicate complex written benefit-risk information to consumers, how adults learn, and what information consumers consider important when taking a new prescription drug. PhRMA recommends that FDA review that existing research literature in addition to the comments provided by consumers in the evaluation of written patient information.

Should FDA Conduct an Additional Assessment of Readability of Document? – PhRMA notes that readability differs from legibility, in terms of assessment of documents actually provided to consumers. Legibility depends, in part, on the quality and the maintenance of the printers available in retail pharmacies, and therefore may be beyond the control of third parties that provide the content of written patient information to pharmacies. That said, PhRMA recommends that FDA conduct a brief study of the legibility and readability of documents collected through the existing study, to decide whether to include an assessment of readability and legibility in subsequent studies of written patient information.

Consumers as Evaluators – PhRMA recommends that FDA include consumers, including consumers with varying educational backgrounds and from diverse ethnic groups, on panels to evaluate written patient information actually collected from pharmacies. The consumers should focus, briefly, on readability and legibility of documents, and then on the usefulness of the information included in the documents. It is important that FDA identify and work with a cross-section of actual consumers in the real world, not people whose jobs involve communicating with FDA or other government agencies. People who routinely interact with agencies concerning regulations, particularly as those regulations relate to any aspect of prescription drugs, may not adequately represent the universe of consumers of prescription drugs.

Studies of Non-retail Pharmacies – PhRMA recommends that FDA expand the study of written information provided to consumers to include mail-order and other non-retail pharmacies. This portion of the study might follow a protocol similar to the one used for the retail pharmacies, with modifications as developed through this comment process.

PhRMA would be pleased to discuss these comments further, if necessary.

Sincerely,

A handwritten signature in black ink, appearing to read "Marjorie E. Powell". The signature is fluid and cursive, written over a white background.

Marjorie E. Powell