



U.S. Pharmacopeia  
The Standard of Quality<sup>SM</sup>

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Ln, Rm 1061  
Rockville MD 20852  
April 26, 2000

Re: Docket No. 00N-0352—Status of Useful Written Prescription  
Drug Information for Patients

Gentlemen:

Thank you for the opportunity to comment on the study regarding the current status of useful written prescription drug information for patients. Some of the findings by Svarstad and Bultman in their 8-state study of written prescription information provided in community pharmacies are encouraging. The study shows that the penetration of written information for patients is high; overall, about 87% of "patients" in the study received written information. The written patient information provided by community pharmacies in the study was generally accurate and unbiased. For two of the drugs in the study, amoxicillin and paroxetine, the quality of most of the information provided was judged by study panelists to partially or fully meet over 80% of the sub-criteria in the study.

Although the study found high adherence to Criterion 9 (legible and comprehensible), we do not believe the study was designed to evaluate comprehension. Comprehension is the *sine qua non*, thus the most important criterion for evaluation. Fulfilling criteria 1-8 and 10 below does not automatically make a leaflet useful; criteria for comprehension must be met. It is not possible to evaluate comprehension without cognitive studies among consumers. Research performed in a cognitive laboratory (under a contract awarded by USP to the University of North Carolina at Chapel Hill and Duke University) demonstrated that adherence to cognitive principles (e.g., information load, order of information, spacing, format, chunking, and coding) was critical to comprehension of written patient medication information. Standards for achieving and testing comprehension are needed. USP is currently drafting such standards and will subject them to its open process of consensus development. In light of the fact that the principal investigator of the FDA study stated in her closing remarks that FDA should consider using USP guidelines for developing useful patient information, we would welcome a dialogue on this issue with the Agency.

In relation to the design and implementation of the study, we feel that the lack of involvement of true "consumers" in the review and evaluation of leaflet content could possibly have had an impact on the results. Although the experts selected to serve on the review panel are certainly knowledgeable and respected, their views may not necessarily reflect what the average consumer would judge as acceptable content.

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Additionally, we believe more information is needed to interpret the study. The ratings done by the expert panel are not interpretable without the following information:

1. Percentage of leaflets that were identical in both content and format, and
2. Percentage of leaflets that were identical in content but not in format.

It is conceivable that half or more of the leaflets have the same vendor source and identical content. Thus for these, all the ratings 1-8,10 below should be the same. It would be useful to know if they are the same and how much format alone influenced the ratings. For further interpretation, the number of leaflets per vendor and the number of leaflets representing the same vendor but having different content should be known.

Definitions are needed for the terms “consumer,” “useful,” “comprehension,” and ADR (side effect?). When measuring how frequently written and oral information is provided, consumer should be defined as “A person who has independent responsibility for any aspect of medicine use or for giving medicine to others.” Useful should mean that recipients receive, understand, and can apply written information about their medicines to achieve maximum benefit and avoid harm. Comprehension is measured in terms of consumer readability, memory, and behavioral intention (note: behavior, the ultimate measure of usefulness is optimal but measurement is rarely feasible). ADR is often distinguished from side effect as follows: if expected the unwanted consequence of medicine use is a side effect; if unexpected it is an ADR.

Finally, it is of considerable concern that readability is set at grade 6-8 in view of the fact that 40% of the American public read at 6<sup>th</sup> grade or below. We suspect that when comprehension is measured by the criteria above, it will become clear that the reading levels should be set at 6<sup>th</sup> grade or below.

Despite the concerns we have about the study, we are pleased with its positive findings. We are especially pleased that vendors met a substantial portion of the Keystone criteria although the criteria, and expert guidance about the criteria, were absent as the vendors developed patient information. This may be attributable to the use of USP DI patient information as a model for vendors. We encourage the Agency to adopt a continuous quality improvement model to evaluate the progress that vendors make in providing useful patient information. We believe that if guidance is provided regarding the comprehension of patient information, vendors will use the guidance to improve the patient information provided.

Sincerely,



Keith W. Johnson  
Vice President and Director  
New and Off-Label Uses Division

cc: Nancy M. Ostrove, Ph.D.

List of Keystone criteria used by panel to rate written information

1. Scientifically accurate
2. Unbiased in content and tone
3. Identifies drug and its benefit
4. Identifies contraindications and what to do if applicable
5. Includes specific directions about how to take medication, receive maximum benefit, and interpret results
6. Includes specific precautions while using medicine, their significance and how to avoid harm
7. Includes enough detail for proper monitoring, interpretation, and action regarding adverse reactions that are serious or occur frequently
8. Includes proper storage instructions and general information
9. Information is legible and readily comprehensible to most consumers
10. Information is up-to-date and timely



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