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MEDICAL ECONOMICS™
THOMSON HEALTHCARE

March 21, 2001

Dockets Management Branch HFA-305
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20857

Re: Docket No. 00N-1269
RIN 0910-AA94

Dear Sir/Madam:

The following comments are submitted by Medical Economics Company, the publisher of *Physicians' Desk Reference (PDR)*. As the nation's leading compendium of approved product labeling for the past 55 years, *PDR* figures prominently in any discussion of the distribution and utilization of FDA-approved prescribing information. It has more extensive experience in the delivery of such information, through a variety of formats and media, than any other independent organization in the United States.

The consistent goal of *Physicians' Desk Reference*—in fact, its reason for being—is to provide health care practitioners with ready access to all FDA-approved information needed for safe and effective use of pharmaceuticals, biologicals, and related products. We therefore fully support any proposal that promises to enhance the practitioner's ability to locate and employ needed prescribing data in the most convenient and expeditious manner possible. We commend the FDA's efforts to improve the utility of professional product labeling.

We believe that the proposed new format for prescription drug labeling represents a significant improvement over the format currently in use, and support the proposed changes subject to the following provisos and considerations.

1. Since practitioners are most likely to refer to approved product labeling when faced with unusual complicating factors or members of special patient populations, it is mandatory that complete product labeling be readily available at the moment of decision. A "Highlight" section of bulleted prescribing information is, by itself, insufficient to meet all of the practitioner's reference requirements.
2. In addition, distribution to practitioners of anything less than complete prescribing information will not satisfy pharmaceutical manufacturers' obligations under the learned intermediary doctrine. In the absence of legal reform, it is incumbent upon the manufacturers to provide, along with the proposed "Highlight" section, full

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information on all benefits and disadvantages of their products. A "Highlight" section alone, by its nature, cannot fulfil this requirement.

3. On the other hand, the proposed "Highlight" section does serve as an excellent vehicle for drawing the practitioner's attention to the most important facts and precautions associated with a prescription drug product. As long as full prescribing information is also available to support more intensive research, this section could become a useful and convenient source for quick reminder information in routine situations.
4. The proposal would apply the new format only to labeling of new and recently approved products. We recommend that this format be made standard for all prescription drug products, including those approved 5 or more years prior to the effective date of the final rule. We strongly believe that a standardized format for all approved products is needed to facilitate electronic retrieval and permit comparison of similar products for safe and effective use.
5. The proposed reorganization of the product labeling is a positive step that better reflects the manner in which the information is actually employed at the point of care. Again, however, we would recommend that the new organization be standardized across all approved products, not just those most recently introduced.

Medical Economics Company and the staff of *Physicians' Desk Reference* will be pleased to cooperate in the implementation of the proposed new format for prescription drug labeling in any way that may prove helpful. We stand ready to work with the agency and all parties involved to make these improvements a reality in a timely and orderly manner.

Sincerely,

Mukesh Mehta, RPh
Vice President, Clinical Communications &
New Business Development

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