From PPI to PIL to PMI: Can the private sector do it better?[1]

During the second half of the last decade, the Food and Drug Administration (FDA), responding to some consumer activists, proposed the concept of the PPI (Patient Package Insert) to inform patients about the drugs that were prescribed for them.

During the same period some of the numerous drug reform bills introduced into the Congress provided for mandatory PPIs for *every* drug distributed by a pharmacist to *every* patient at the time the drug was dispensed.

Nobody questioned the right or the desirability of the patient to have information about the drugs that were prescribed. However, the American Medical Association (AMA) responded to these proposals on behalf of practicing physicians who had legitimate concerns about how PPIs would affect patient compliance and the physician-patient relationship, among other things.

At the 1977 Interim Session of the AMA House of Delegates, Report B of the Council on Scientific Affairs was adopted expressing preference for the term PIL (Patient Instructional Leaflet) instead of PPI and for discretionary rather than mandatory distribution to patients.

The report stated that PILs should not be required for all prescription drugs and that the PIL (or PPI) should not be considered the basic vehicle for drug information to the patient, but rather an adjunct to verbal instructions given by the physician. Consequently, it would be more conducive to the physician-patient interrelationship if physicians, not pharmacists, distributed the leaflets. They should not be a "package insert" in the true sense.

The Council's report expressed concern that if PILs were not appropriately written they could detract from patient compliance rather than enhance it. In fact, there were no well-designed studies to show that even sensitively written and well-balanced PILs would enhance compliance and the report called for such studies before undertaking a full-scale program to provide PILs for a large number of drugs.

The AMA position was expressed in numerous Congressional and FDA hearings on the subject. Notwithstanding, the FDA promulgated regulations in 1980 that would have required PPIs for 10 of the most commonly used drugs to be written by the agency and distributed by pharmacists unless the physician specifically instructed otherwise on the prescription.

Before these regulations were implemented, AMA offered to initiate a voluntary program to provide Patient Medication Instruction (PMI) sheets to physicians for distribution to their patients to reinforce verbal instructions and explanations about the drug being prescribed. FDA commissioner, Arthur H. Hayes, M.D., in keeping with the Reagan adminis-

Table. PMI (patient medication instruction) sheets available from the American Medical Association

Drug
1. Furosemide
2. Thiazide diuretics
3. Penicillins—oral
4. Beta-blockers
5. Digitalis preparations
6. Coumarin-type anticoagulants
7. Oral antidiabetics
8. Tetracyclines
9. Cephalosporins
10. Erythromycin
11. Nonsteroidal anti-inflammatory agents
12. Benzodiazepines
13. Nitroglycerin
14. Methyldopa
15. Insulin
16. Corticosteroids—oral
17. Cimetidine
18. Belladonna alkaloids and barbiturates
19. Phenytoin
20. Sulfonamides

[1] Reprinted from *Cleveland Physician*, **68**:6–7, Jan 1983 with permission from the Academy of Medicine of Cleveland.

tration's philosophy of minimizing regulations and permitting the private sector to respond to societal needs and concerns, recommended to Secretary Schweiker that the regulations requiring PPIs be withdrawn and the Secretary acted favorably to this recommendation.

PMIs for 20 of the most commonly used drugs are now available from the AMA (Table) and in 1983 PMIs for an additional 40 drugs will be ready for distribution. This effort is being supervised by John Ballin, Ph.D., director of the Division of Drugs at AMA. The PMIs have been written by the members of Dr. Ballin's talented staff who also write AMA-Drug Evaluations, the authoritative compendium on drug therapy. They have received invaluable help from the United States Pharmacopoeia convention from whose data base PMI drafts have been derived. Consultation on final wording was also sought from the pharmaceutical industry, the American Pharmaceutical Association, the FDA, and practicing physicians. The program has received the formal endorsement of Dr. Hayes.

Each PMI consists of a 5½″ x 8½″ sheet, printed front and back. They are bound into pads of 100. To defray the cost of postage and handling, a charge of 50 cents per pad has been established. Minimal order is 10 pads. They are available from: PMI Order Department, AMA P.O. Box 52, Rolling Meadows, Illinois 60008.

The PMI program is consistent with AMA policy established when the House of Delegates adopted Report B of the Council on Scientific Affairs in 1977.

It is the responsibility of the physician to inform patients about the drugs that are prescribed for them. We have been given the chance to do it without onerous federal regulations. If we fail, you can be sure that the regulations will be revived.

RAY W. GIFFORD, JR., M.D.
Department of Hypertension and Renal Disease, The Cleveland Clinic Foundation

President of the Academy of Medicine of Cleveland