

STATEMENT OF THE
AMERICAN SOCIETY OF INTERNAL MEDICINE
ON
PATIENT PACKAGE INSERTS
TO
THE INSTITUTE OF MEDICINE

FEBRUARY 13, 1979



american society of internal medicine

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STATEMENT OF
THE AMERICAN SOCIETY OF INTERNAL MEDICINE
TO THE INSTITUTE OF MEDICINE .
TUESDAY, FEBRUARY 13, 1979
WASHINGTON, D. C.

Mr. Chairman, I am James M. Moss, M.D., representing the American Society of Internal Medicine. I am a member of its Task Force on Pharmaceuticals.

ASIM appreciates the opportunity to offer testimony today before the Institute of Medicine concerning patient package inserts (PPIs).

ASIM's purpose is the continued improvement of patient care. We endorse patients' rights to know about the drugs that are prescribed for them. We will withhold judgment and comment, however, on PPIs pending the findings and recommendations of your study. It is our purpose here today to comment on the various aspects of the study, and recommend how it should be conducted.

ASIM has advocated controlled studies of the effects of PPIs since 1975. Our suggestions and comments reflect our concerns as practicing internists.

We commend the IOM for calling this hearing, as it affords the opportunity to address important questions we believe have not been answered, and issues which have not been sufficiently resolved.

TYPE OF STUDY

ASIM believes a more scientific and less subjective study than those carried out in the past would provide more reliable information about the usefulness of PPIs.

In lieu of previous consumer interview studies, we suggest double blind controlled studies that would be conducted in the following manner. Test subjects

would be divided into three groups. Group One patients would not receive PPIs (or "placebo" PPIs). Group Two would receive relatively brief PPIs designed by physicians to increase compliance. Group Three would be given a more lengthy and detailed PPI, similar to present package inserts.

Neither physicians nor pharmacists would know which PPI is given to patients. Both physicians and patients would be questioned by trained interviewers at appropriate intervals to permit comparisons between the three groups. Interviews should be supplemented by pill counts and other objective methods.

SPECIFICS TO BE STUDIED

A variety of drugs, diseases, practice situations, and patient populations should be studied. Acute or self-limited clinical problems are less likely to provide the needed information than are the chronic conditions which require prolonged therapy. Two clinical situations which would be of high priority for research are: I) patients with asymptomatic, chronic diseases requiring prolonged therapy, and II) patients with symptomatic, chronic diseases. A study of patients with more serious life threatening illnesses and those with acute symptomatic problems should be deferred until these first two types have been evaluated.

Suggestions for study in type I include evaluation of PPIs on patients taking antihypertensive drugs for the treatment of essential hypertension and patients on oral hypoglycemic drugs for treatment of adult onset stable diabetes mellitus.

Both of these conditions have the interest and attention of the public as well as the medical profession. Hypertension is perhaps the largest and most treatable health problem today with a variety of effective therapeutic agents available. Hypertension may require a variety of drugs, and its effective management requires patient compliance, cooperation, information, and understanding. The recent controversy regarding the use of oral hypoglycemic drugs helps to emphasize

the potential usefulness of PPIs in those instances where these drugs are used in the management of diabetes mellitus.

Those patients who have both hypertension and 'diabetes mellitus requiring oral drug therapy would offer a unique opportunity to evaluate PPIs in the common clinical situation of patients with multiple health problems.

Hyperuricemia, hyperlipidemia, and osteoporosis are other conditions that might be studied.

A study of type II would add different information on compliance, side effects, complications, and even self-medication and drug abuse. The treatment of depression with different classes of antidepressants and the use of diuretics in a variety of clinical situations are examples where PPI research would be helpful. The need for continued, regular daily therapy for depression and the sometimes variable and intermittent use of oral diuretics suggest that different information might result from PPI studies in these instances.

Mr. Chairman, ASIM believes that these PPI studies should include the full spectrum of the population, with all sexes, ages, socioeconomic, and educational levels represented. This will permit a better evaluation of the relative benefits and different problems for different segments of the population. Such information is necessary to evaluate socioeconomic factors, education, and age in relationship to such groups as the elderly, the poor, and the mentally and educationally disadvantaged.

EFFECTS TO BE STUDIED

The effects of PPIs on patient compliance deserves the highest priority for continued investigation. We strongly recommend your examination of the following areas:

-- Design of Inserted Brochure

Should it be developed by a physician with emphasis on improved compliance or written to maximize patient choice?

-- Compliance

Use of objective methods of patient surveillance, such as pill counts and/or drug concentration of excretion studies. Such methods would help provide compliance information which is usually difficult to monitor.

-- Incidence and Detection of Side Effects

- A. Will patients increase their recognition of side effects that otherwise might have gone unnoticed or unreported to their physician?
- B. Will patient anxiety be increased by the inclusion of detailed descriptions of potential side effects?
- C. Will PPIs make it more difficult to separate real from psychologically induced drug related side effects?
- D. Will unnecessary anxiety result in decreased compliance with prescribed therapy?

-- Physician/Patient Relationships

- A. Will patients who read about potential side effects doubt the judgments of their prescribing physician?
- B. Will the necessary trust between a physician and his patient be undermined.

-- Patient Behavior

- A. Will detailed drug information encourage patients to engage in improper self-medication or medicine swapping?
- B. Will patients be more likely to give their medicine to friends with similar symptoms?
- C. Will patients take medication prescribed for a friend or relative without consulting a physician?

-- Cost

- A. What will be the costs of developing, printing, and distributing PPIs?
- B. Who will bear the costs?
- C. What are the cost/benefit ratios?
- D. How much physician time will be needed to respond to patient inquiries?

Mr. Chairman, I have outlined today ASIM's thoughts, concerns, and recommendations about the PPI study, based upon our own training, knowledge, and experience as internists.

ASIM applauds the IOM for undertaking this study, and stands ready and willing to offer its advice and expertise should the need or occasion arise.