Exhibit I

Reprinted From the Journal of the American Medical Association
December 20, 1965, Vol. 194, page 1311

To Label or Not to Label

In a less sophisticated era, when the art of medical practice outweighed scientific knowledge, physicians did not tell their patients the identity of the medications they prescribed. Today, this practice is being gradually abandoned, and increasing numbers of physicians ask pharmacists to indicate on the label the names and strengths of the drugs they prescribe. The Council on Drugs believes that all physicians should adopt this policy, and make an exception only when such disclosure would be detrimental to the welfare of the patient. In a prior discussion of this subject,[1] the Council made a number of the following points:

The patient has the right to be informed about his illness and the medications prescribed.

In emergency situations, such as accidental poisoning, overdosage, or attempted suicide, immediate identification of a prescription drug from the label may be lifesaving.

The information is invaluable when the patient changes physicians, moves to another locality, or contacts the prescribing physician at a time when his records are not readily available.

The information on the label is of value in group practices in which the patient may not always have the same attending physician.

It is advisable that patients with allergies know what is being prescribed.

This specific information on the label helps to prevent mix-ups between two or more drugs being taken concurrently, or between medications being taken by different members of the family.

Should it become necessary to issue a warning against the use of a particular drug, the name on the label serves as a danger signal to those who have been given prescriptions for the product.

In its earlier consideration of this subject, the Council on Drugs passed the following resolution[1]:

> The Council resolves that it favors labeling of prescriptions as a general practice, and furthermore, it is recommended that prescription pads contain boxes for a "yes" or "no" on whether to label; if these boxes are not filled in by the physician, the prescription will be labeled.

That resolution was received favorably by many. However, pharmacy organizations and several state medical societies have opposed the method that the Council suggested for implementing its recommendation. The Professional Relations Committee of the American Pharmaceutical Association agreed with the position expressed by Apple and Abrams,[2] who concluded that unless a prescriber specifically requests labeling, ". . . a pharmacist should not by himself, or upon request by a patient, disclose the ingredients in the prescribed medication by labeling." This reflects the feeling of the pharmacist that he needs a directive to label from the physician, who alone has the authority to make such a decision.

Physicians and pharmacists who are opposed to labeling as a routine measure and feel that it may create or accentuate various problems have the following objections:

The practice may lead to self-medication and to "patient-prescribing" for others.

A patient who knows the drug name may compare prices at different pharmacies, and thus tempt pharmacists to bid for business on a price basis rather than on a basis of professional service.

The information may only confuse and trouble the patient.

The practice reduces the stature of the physician and lowers the status of the prescription to practically that of an over-the-counter item.

Patients may put other drugs into bottles labeled with the previous contents, which may then lead to charges that a pharmacist dispensed the wrong medication.

Labeling could make it easier to channel drugs into illegal markets.

The Council believes that the advantages of labeling outweigh these objections in almost every instance; the Council always has recognized that there are occasions when such labeling is inadvisable for psychological or other reasons, and that the physician is the one who must decide.

However, only in exceptional circumstances is it desirable not to reveal the identity of prescribed drugs under today's conditions. Moreover, the physician's explanation to his patient regarding the purpose of a prescribed drug and what may be expected from it, together with the public's growing awareness of the effects of drugs—both beneficial and harmful—will help to minimize problems that may occur occasionally.

After consultation with officers of the national pharmacy organizations and after further deliberation, the Council on Drugs strongly reaffirms its position that in the best interest of the patient the prescription container should, as a rule, be labeled with the name and strength of the drug. To implement this recommendation, the Council suggests that the physician use two sets of prescription blanks, one of which is for routine use and is imprinted with an order to label. This procedure is consonant with the ethics of medicine and pharmacy, and with the physician's responsibility to decide whether the prescription label should or should not identify the drug.

The Council further urges that the physician always designate the number of refills he wishes the patient to have, and that he prescribe only the number of doses usually required in any specific condition, since adjustments in dosage are often necessary to obtain the desired result in individual cases. The Council also recommends that any prescription that does not indicate the number of refills, or that is labeled "p.r.n." or "ad lib," not be refilled.

The Drug Abuse Control Amendments that were recently passed by the Congress regulate the refilling of prescriptions for stimulant and depressant drugs. No prescription for drugs in these classes can be renewed more than five times, or more than six months after the date of issue unless the physician gives additional authorization for refilling.

The physician's responsibility for the medication regimen of his patient is clear, and he should therefore heed the pharmacist's requests for specific instructions on renewals.

The Council hopes that this statement will clarify its position on the question of labeling and refilling of prescription drugs, and earnestly solicits the cooperation of physicians, pharmacists, and other health personnel in implementing these important public health recommendations.

References

1. Labeling of Prescription Drugs, editorial, *JAMA* 185:316 (July 27) 1963.

2. Apple, W.S., and Abrams, R.E.: Problems in Prescription Order Communications, *JAMA* 185:291-293 (July 27) 1963.

Printed in U.S.A.