The content of "package insert" type of labeling is initially approved by FDA during the new drug clearance procedure and is constantly reviewed by our medical staff to insure that the labeling is consistent with current knowledge. Often the "package insert" is the only source of such necessary data on medicines which are prescribed daily.

Unfortunately this information seldom reaches the physician—it remains on the local pharmacist's shelves. Proper utilization of this information is further hampered by the present format of the "package inserts." They are printed in fine type and are extremely lengthy. Adidtionally, it is impossible to determine whether a particular insert is the most up-to-date version, thus the physician may prescribe a drug without full knowledge of recent discoveries that are important to proper use of the product.

Although this full disclosure labeling provides an excellent library of drug information for each pharmacy which might be used to advantage by the prescribing physician, it is essential in our view to develop a mechanism that makes it more available to and more useable by the practicing physician.

The "package insert" only has to accompany the drug package from which the prescription drug is dispensed. The drug labeling would hardly be meaningful to the patient and, indeed, could be detrimental.

The legal basis for an insert is founded in regulations promulgated pursuant to Section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act which requires the labeling of all drugs to bear "adequate directions for use."

These regulations provide that the prescription drug *label* must bear: the statement "Caution: Federal Law prohibits dispensing without prescription"; the recommended or usual dosage; the route of administration if not for oral use; the name of all inactive ingredients (with some exceptions) if not for oral use; and an identifying code number from which it is possible to determine the complete manufacturing history of the drug. These *label* requirements are obviously most essential for proper usage and in order to monitor recalls. The concept of a compendium should in no way abrogate such *label* information.

Additionally, the regulations require:

> "Labeling on or within the package from which the drug is to be dispensed bears adequate information for its use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented; and
>
> "If the article is subject to (the new drug, antibiotic and insulin provisions) of the act, the labeling bearing such information is the labeling authorized by the approved new-drug application or required as a condition for the certification or the exemption from certification requirements applicable to preparations of insulin or antibiotic drugs: *Provided, however*, That the information required by (the above paragraph) may be omitted from the dispensing package if, but only if, the article is a drug for which directions, hazards, warnings, and use information are commonly known to practitioners licensed by law to administer the drug.

The information required by this regulation is appropriate and useful. I do not believe that anyone would say that the physician is not entitled to such labeling. Instead, the busy physician relies on promotional literature in medical journals and publications such as the Physician's Desk Reference (PDR). As you know, we have instituted several regulatory actions against drugs because of their advertisements, and we are presently requesting four drug firms to issue "Dear Doctor" remedial letters in order to correct PDR monographs. We are also engaged in revising our advertising regulations issued pursuant to the Kefauver-Harris Amendments.

This type of surveillance of advertising coupled with our administrative action will, I believe, substantially increase the quality of such promotions. Nevertheless, advertising will remain advertising.

The information contained in package inserts is essential to counter-balance the claims made in many drug promotions. Unfortunately, the inserts are not accomplishing this function. Primarily, this is because it is not directed to the physician himself. Further, it is not in an easily readable form because of its length, and, of course, there is no index to package inserts or coordination with other drugs. Obviously, the "package stuffer" is just not an available reference