How can we insure that the information the physician receives on drugs via word of mouth conforms with the FDA's requirements on package inserts and printed advertisements of these same drugs?

These are some of the questions we hope to consider over the next several days.

Today, we shall direct our attention to the drug Indocin. On May 3, Mr. Henry W. Gadsden, president of Merck, testified as follows:

(Merck) seeks to make sure that the marketing profile of a drug corresponds in every respect to its medical profile. * * * It is Merck's policy to avoid the possibility of including any questionable statement or theme in any of our advertising or promotion. * * * Our internal procedures require that every piece of advertising and promotion must have the approval of a physician and a lawyer, who are responsible for its medical accuracy and conformity with the law. * * *

Testimony by the FDA indicated that these statements by the President of Merck were not in accord with reality. In fact, the FDA's Bureau of Medicine recommended prosecution of Merck for false and misleading advertising.

It was obvious that Merck's journal advertisement, submitted by the FDA as exhibits, made claims beyond those authorized in the package inserts.

In addition, the Merck Co., according to FDA's testimony on May 2, turned a "Dear Doctor" remedial letter into a promotional piece. FDA then directed Merck to send a second letter to correct the first. This kind of activity on the part of any drug company should not be tolerated by the FDA, and it is difficult, indeed, to conclude that Indocin's marketing profile, as Mr. Gadsden put it, corresponded in every respect with its medical profile.

What have the detail men been telling doctors about Indocin? I suspect that neither the FDA nor any of us here know. We do know, however, that Merck's promotional instructions to their detail men suggested uses not approved by the FDA and this is the subject of today's hearing.

On May 20, 1968, I sent the following letter to the Commissioner of the Food and Drug Administration:

I am enclosing a number of instruction bulletins on Indocin sent to Merck and Company's detail men, apparently by the district supervisor in one of the firm's sales regions.

Without attempting to interpret the law, it appears that these instructions seek to promote use of Indocin which you have not authorized.

It would be greatly appreciated if the relevant officials in your agency would examine these bulletins and send me their comments on the accuracy of the claims made and the effect on medical practice of the selling techniques recommended.

Your cooperation is greatly appreciated.

On June 17 I received an answer from the FDA, which I shall put into the record in its entirety at this point.

(The information referred to follows:)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
FOOD AND DRUG ADMINISTRATION,
*Washington, D.C., June 17, 1968.*

Hon. GAYLORD NELSON,
*Chairman, Subcommittee on Monopoly, Select Committee on Small Business, U.S. Senate, Washington, D.C.*

DEAR SENATOR NELSON: This is in reply to your letter of May 20, 1968, enclosing a number of bulletins addressed to Western District Sales Associates of Merck Sharp and Dohme, Division of Merck and Company, Inc.