SUPPLEMENTARY STATEMENT OF
MERCK & CO., INC.
IN
RESPONSE TO PORTIONS OF TESTIMONY BY
JOHN JENNINGS, M.D., ACTING DIRECTOR,
OFFICE OF MARKETED DRUGS, BUREAU OF MEDICINE
FOOD AND DRUG ADMINISTRATION,
GIVEN ON
WEDNESDAY, MAY 1, 1968
BEFORE
THE MONOPOLY SUBCOMMITTEE
SENATE SELECT COMMITTEE ON SMALL BUSINESS

This statement is filed pursuant to permission granted Merck by the Chairman of the Subcommittee to comment on testimony by witnesses who appeared before the Subcommittee on April 23 and 24 and May 1 and 2 during hearings inquiring into this Company's performance in the development and marketing of its product "Indocin".

On May 1, Dr. Jennings, testifying for the Food and Drug Administration, described the negotiations between the Agency and the Company that led to two package circular revisions in the fall of 1966. (Pages 4690–4704) The general impression we receive from Dr. Jennings' testimony is that the Food and Drug Administration tried from July 15 forward to get the Company to add additional warnings, contraindications, and adverse reactions to the package circulars on "Indocin", but that the Company was reluctant, even recalcitrant, in doing so. It is implied that the Company should have voluntarily made the requested changes long before it did so. Thus, "By regulation, these changes could and should have been put into effect by the firm at the earliest possible times, without awaiting approval from the FDA." (Page 4690)

On the other hand, there is in the same testimony an implied criticism of the Company for proceeding voluntarily without FDA approval when it did change the package circular. "Rather than wait for all the recommended labeling changes to be worked out with us, interim revisions of the labeling were put into effect by the company without our advance approval." (Page 4694)

Dr. Jennings concludes that our letter to doctors transmitting the volunteered package insert changes was "promotional literature" in which the original intent to war physicians of additional hazards was "completely lost." (Page 4695)

His concluding testimony on this subject could leave the impression that the Agency was struggling with the massive problem of a recalcitrant firm unwilling to convey to the doctor important new information on hazards of its drug.

This impression is not justified by the actual facts. We submit below a brief review of our communications with the Food and Drug Administration during the spring and summer of 1966 on revisions in the package insert for "Indocin." These are summarized from our internal memos and records of correspondence with the Agency.

1. *April 6, 1966.* Telephone call to our Dr. Shaffer from Dr. O'Grady, FDA investigational Drug Branch. This call dealt with the Company's IND on "Indocin" covering studies in indications not in the then-approved NDA. Dr. O'Grady reported that the Adverse Reaction Bureau, FDA Bureau of Medicine, thought there was an increasing number of side effects associated with the use of "Indocin". Dr. Shaffer told Dr. O'Grady that from our review of reported adverse reactions, the incidence of such reactions was not increasing but decreasing with more widespread use of the drug. A request was made to discuss the entire investigational program with Dr. O'Grady.

2. *April 7, 1966.* Dr. Shaffer telephoned Dr. O'Grady for a date for conference. This was tentatively set for April 15, but later in the day changed to April 18. FDA was asked whether it had adverse reaction data from sources independent of Merck.

3. *April 19, 1966.* Conference between FDA and Company medical representatives. Although the conference related primarily to the investigational studies for added claims, the FDA representatives reported their opinion that the current package insert should be revised to reflect current adverse information reports, including some data they had that we did not have. The Company medical representatives felt Merck should make a complete review of the labeling and