It is difficult to present objective evidence in rebuttal of these subjective imputations. We would remind the Subcommittee, however, that there is a common sense and essential logic in our position that any such motivation would inevitably damage our reputation with the doctor and the patient, and would be detrimental to our business interests in the long run. Since our business is uniquely dependent on what the health professions think of or character and reputation, it would make little sense for us to engage in this kind of conduct—and we do not do so.

As I said in my direct testimony, it is not the Food and Drug Administration that is ultimately responsible for the safety and effectiveness of our products, including the information we give to the doctor about them. It is we who must bear that responsibility and who must suffer the consequences of failure. This is the way it should be, and this is the way the Food and Drug Administration should want it to be.

We would appreciate your placing these materials in the record at the end of the testimony of Dr. O'Brien, Dr. Jennings, and Dr. McCleery respectively, and request that this letter be placed at the end of the Merck testimony on May 3.

Sincerely,

H. W. GADSDEN, *President.*

SUPPLEMENTARY STATEMENT OF
MERCK & CO., INC.
IN
RESPONSE TO PORTIONS OF TESTIMONY BY
WILLIAM M. O'BRIEN, M.D.,
ASSOCIATE PROFESSOR OF PREVENTIVE AND
INTERNAL MEDICINE, UNIVERSITY OF
VIRGINIA SCHOOL OF MEDICINE
TUESDAY, APRIL 23, 1968
BEFORE
THE MONOPOLY SUBCOMMITTEE
SENATE SELECT COMMITTEE ON SMALL BUSINESS

This statement is filed pursuant to permission granted 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 with regard to this Company's performance in the development and marketing of its product 'Indocin'. This supplementary statement covers two points.

(a) Dr. O'Brien was permitted, at the Committee's request, to review Merck's indomethacin New Drug Application file at the Food and Drug Administration, including FDA's internal memoranda relating to the application. Dr. O'Brien quoted extensively from a January 25, 1967, memorandum of David Hurwitz, M.D., of the Food and Drug Administration. (Pages 4538–40) Dr. O'Brien failed to mention that the document quoted from was primarily concerned with a review by Dr. Hurwitz of a supplement to the original New Drug Application, filed in May 1966 to cover additional indications. Dr. O'Brien quotes the document as if it dealt only with the approval of the original New Drug Application.

As Dr. Hodges pointed out in his testimony (pp. 4668–70), Dr. O'Brien also appears to have overlooked a subsequent memorandum of Dr. Hurwitz dated August 1967, in which he, after further review of the data, substantially revised the opinions expressed in his memorandum of January 25, 1967. We have appended to this statement a copy of Dr. Hurwitz's August 1967 memorandum, and request that it be placed in the record at this point.

(b) In his testimony on April 23, Dr. O'Brien appeared to cast doubt on the integrity and reliability of clinical investigators selected by Merck and other pharmaceutical companies, and on the method of their selection.

To complete your record, we are setting forth below Merck's policy and procedure in the selection of investigators. (Copies of this statement were, at the request of the Subcommittee staff, submitted prior to Merck's appearance on May 3, 1968, but were not made a part of the record.)

MERCK'S POLICY AND PROCEDURE IN THE SELECTION OF INVESTIGATORS

After careful review of preclinical evidence of safety and pharmacological activity of a new therapeutic compound, it may be cleared for clinical study. The Company's medical and scientific staff then must decide whether they wish to carry the compound into the clinical investigative process. If they do, a plan for