Although we did not agree with this medical judgment, we did include these statements because of the FDA's insistence.

In the judgment of our medical staff, the total prohibition of 'Indocin' in juveniles suffering from acute rheumatoid arthritis is not warranted. Acute juvenile rheumatoid arthritis is a serious and often hopeless disease. If treated with corticosteroids, very serious effects—including loss of calcium in the bones and the disturbance of the endocrine system—can frequently result. In those children who do not respond to aspirin or cannot tolerate it, we believe it is medically preferable to treat them with 'Indocin' than to risk corticosteroids or to leave them untreated. The FDA does not agree with us, and for that reason we have always contraindicated 'Indocin' for this purpose in the United States. But many doctors do administer the drug successfully to children in Europe. The matter presents a question of refined medical judgment, but it is one on which you will find much responsible opinion on our side.

It must be accepted as a truism that the FDA is at all times in a position to bring great pressure on us to adopt every detail of what they want. For our part, we wish to cooperate as much as possible with the Agency. Good relations with it are essential for us.

Subsequently, when at Dr. Goddard's request we met on November 11, 1966, with him and his staff to discuss our labeling and advertising of 'Indochin', we reviewed the differences of opinion about the controversial points and the transmittal letter to doctors. As a result of the meeting, even though our respective medical staffs continued to be in disagreement on a number of issues, we chose to abide by FDA's wishes and sent out a further revised circular containing all the changes FDA requested, including the different typographical and position treatment of the contraindications in children. This revised circular was transmitted to doctors in December, 1966, with a letter which made reference to nothing but the changes in the insert. Both the circular and the letter were worked out with the FDA.

Neither in these meetings nor subsequently was there any recalcitrance on our part. In our opinion, sincere disagreements in medical opinion cannot be equated with recalcitrance. We were deeply concerned at the time at what seemed to be imputations to us of bad motives and lack of integrity. We argued against such imputations most vehemently. But we worked out this particular problem on the basis of a full and frank discussion of where we and they stood on the matter.

Perhaps it is fair to say that the Company and the FDA must share the responsibility for the time it took to issue the first revised circular. The job could have been done faster if we and the FDA officials concerned had been able to arrange more frequent meetings and to obtain prompt decisions. With respect to the wording of the first transmittal letter to doctors, we must and do accept sole responsibility.

SUPPLEMENTARY STATEMENT OF MERCK & CO., INC. IN RESPONSE TO PORTIONS OF TESTIMONY BY ROBERT S. McCLEERY, M.D., ACTING DIRECTOR DIVISION OF MEDICAL ADVERTISING, BUREAU OF MEDICINE FOOD AND DRUG ADMINISTRATION GIVEN ON THURSDAY, MAY 2, 1968 BEFORE THE MONOPOLY SUBCOMMITTEE SENATE SELECT COMMITTEE ON SMALL BUSINESS

This statement is field 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'. This supplementary statement covers portions of the testimony of Dr. McCleery on May 2.