3. Although I understand that the 1962 Puerto Rican study has been given up as a lost cause by its foundation supporters, I am not at all convinced that the case is hopeless. In view of the uniqueness in design and duration of this study, a federally supported review of the history and present circumstances should be undertaken with a view to possible renewed effort on it.

4. A committee including experts from Government, the academic community, and industry should be convened to consider the design of suitable short-term and long-term studies and to recommend ways in which they might be funded and carried out. It may be that the National Academy of Sciences could contribute to the process of naming a suitable committee. A commitment is needed both from the Congress and from the administration to full support for such a committee's recommendations. Without such assurances, the proposed committee would be simply one more in a long list of advisory groups which have operated in the knowledge that their advice in support of further studies was most unlikely to be acted upon.

5. A final recommendation of broader scope concerns the role of the Food and Drug Administration. It must develop the capacity to deal effectively with problems of the type before us. As it is organized at present, this is an unrealistic expectation. This agency, which has so critical a role in the public interest, needs a great expansion of Federal support, both in terms of budget and in commitment to its role.

That completes my statement.

(Attachments to Dr. Meier's prepared statement follow:)

THE UNIVERSITY OF CHICAGO,
DEPARTMENT OF STATISTICS,
Chicago, Ill., November 18, 1969.

Dr. EDWIN ORTIZ,
Director, Division of Marketed Drugs, Bureau of Medicine, Food and Drug Administration, HEW, Washington, D.C.

DEAR DR. ORTIZ: I write in response to your invitation at the time of our meeting on November 4. As you recall, I discussed with you and your colleagues some of the limitations which, I feel, are inherent in the interpretation of the findings in retrospective studies—in particular as these apply to the Sartwell report on the possible relationship between the use of oral contraceptives and the occurrence of thrombo-embolic phenomena.

As you know, my professional work brings me into close contact with a number of public health problems, such as the evaluation of the Diet-Heart Feasibility Study Report, and, more particularly, the study of undesirable effects following from the use of oral contraceptives in the studies undertaken by Professor George Wied of the University of Chicago. I read the British studies which provided the early evidence of the possibility of a relationship between oral contraceptives use and thrombo-embolic phenomena with great interest and with concern that the suggestive evidence provided there be followed up with more convincing studies—particularly large scale prospective studies.

I came to see you at the request of Dr. William Govier of Mead Johnson. I knew Dr. Govier when he was employed at Warner-Lambert pharmaceutical Co. where I was (and am) a statistical consultant. Late in the previous week Dr. Govier called to ask if I would be willing to read the Sartwell report and send him my comments. On Friday he asked if I would be willing to be present at the Tuesday meeting. The report had been in my hands only since Saturday. I should add that although Dr. Govier and his colleagues evidently feel that my view is helpful to their case, I have no connection other than the one I have described with Mead Johnson and I have no special interest in their