promptly. Early reports from the Puerto Rican study were highly favorable, but again the evaluation of long-term results from this study is in question.

There exist almost no other clinical studies which purport to deal in a serious way with the cancer risk. The study in Chicago in which I participated was initiated as a supplement to a cytology screening program. No appreciable demographic information was recorded and there was considerable uncertainty about the validity of some of the data. No attempt has been made to randomize or otherwise control the choice of contraceptive methods and, as indicated earlier, it was judged that no useful results could be obtained from the material at hand. A study initiated in New York City is liable to some of the same difficulties and it has not so far contributed information on incidence among patients under continuing observation. Finally, a prospective study has been initiated at Kaiser-Permanente, but this has just begun to get underway. At the present time, then, we appear to have very little useful evidence on the question of possible carcinogenic effects.

The main point I have been trying to make is that, in the area of low incidence-high fatality diseases which might be related to use of the pill, we are deplorably ignorant. Why should that be so?

It is easy to lay the blame on the manufacturers, and they certainly deserve their share. It is in my view a major responsibility for the manufacturer and distributor of any product to investigate and to inform the public about the consequences of its use. At the same time, I take it for granted that manufacturers in general—whatever their line of effort, and whatever their rhetoric—are primarily concerned with making money, and that they will undertake to fulfill such responsibilities only to the extent that custom, pressure, or regulation require.

Of far greater concern to me is the failure of our governmental agencies to exercise their responsibilities in seeing to it that appropriate studies were carried out. It seems to me that the reasons are complex, but I think it is worth our while to consider some of them and to consider how the defect may be repaired. I spoke on this point at a conference a year ago, and my next remarks are a paraphrase of what I said then.

I think what has happened is that we have been overcome by a lack of appropriate organizational structure. It is only recently that we have begun to take responsibility for monitoring such effects as these, and we are not very experienced in this role. After all, which agency really had the responsibility? The Food and Drug Administration, even in those periods when it has enjoyed some fraction of the administrative and political support that I think it merits, does not ordinarily take on-going responsibility for long-range studies of a drug or food additive, once it has been judged that the product is reasonably safe. Certainly it has never had the staff or the budgetary support to justify such ventures. The National Institutes of Health, while budgetarily better equipped, has not seen this kind of activity as coming within its scope.

One might have expected the NIH research grant mechanism to fill the gap. It has not, and I think there are obvious reasons why it