Senator NELSON. Are any long-term studies under way at the present time that you are aware of?

Dr. KANE. I really do not know. I have heard Dr. Hertz speak when he was at the NIH of studies with the Kayser group. I do not know whether they are looking into behavior very systematically. They were monitoring for cancer mostly. Whether there are systematic studies of this sort behaviorially, I do not know. I am not aware of any, but that does not prove anything. The National Institutes of Mental Health could probably furnish you this information.

Senator NELSON. Would you know whether all, none, or part of these studies were underwritten by NIH?

Dr. KANE. I do not think any of them were.

Senator NELSON. You do not think any of them were?

Dr. KANE. No. The two Swedish ones were not, mine was not, and neither was the British study.

Senator NELSON. Do you consider it important that such studies be conducted, sponsored by NIH and——

Dr. KANE. I do not think there is any question about it. I think it should have been done when the pills came out. At some point, we ought to do a prospective study with some of the new drugs, at least now, much in the model of the Swedish study, and compare these with other contraceptive agents, because this is the only meaningful comparison we can have.

Senator NELSON. Thank you very much.

Senator Dole, do you have questions?

Senator DOLE. Do I understand perhaps in summary that there has been no real valid conclusion reached. Do I interpret correctly, that there are certain areas where there is considerable evidence of mild neurotic psychiatric morbidity associated with the oral contraceptive? But are there any other areas in which you have reached a valid conclusion? These seem to be very inconclusive.

Dr. KANE. I think the clinical studies are in very good agreement. I think where I would be very hesitant is to look, say, at the metabolic studies we have been doing, because these are based only on 10 patients. I think the fact that all four of the other clinical studies pretty much agree that about half the women feel poorly——

Senator DOLE. You are referring to mental depression?

Dr. KANE. Right. I am referring only to behavioral effects. There is fairly good agreement that somewhere between 20 and 50 percent of the women are adversely affected and that 10 to 15 percent of the group are going to discontinue medication because of it, I think this can be agreed upon. Whether this will change with other medications, we do not know, because there is simply no information. The information we have clearly indicates that the combination agents, as specified in these studies, and they were specified, do provoke this.

There is some evidence suggesting that lower levels of progestin in the pill will give you less trouble. I think again, that remains to be seen. I think more study has to be done. As these pills come along, they must be evaluated for this. I am prepared to be convinced that this will change.

For instance, when the steroid hormones came out originally, they had a great deal of trouble because excessively large doses were used.