Senator NELSON. What is your view about the question of informed consent? I will raise a couple of questions: What should the user of the pill be told and what, if any, literature should she receive? I note that Dr. Ley recently said that he thought that there ought to be an insert in the package that goes to the user. What is your view about that whole question of informed consent?

Dr. HERTZ. In the first place, Senator Nelson, my view would be that the application of these medications in their present state of knowledge constitutes a highly experimental undertaking. That the individual called upon to take these materials, particularly for prolonged period of time, should be regarded as, in effect, a volunteer for an experimental undertaking. I think she should be so informed.

I think that the various aspects of our knowledge and ignorance in these matters should be made clear to her and in as explicit language as can be done, and that on that basis she should be expected to either accept or not accept this form of medication.

I feel that to approach the universal application of this material without such proper information to the individual is very ill-advised, and a presumption on her personal rights and privileges.

Senator NELSON. Doesn't it also raise the question of the competence of a user of any drug to make a judgment of their own as to whether or not they ought to use it?

Dr. HERTZ. In entering into a doctor-patient relationship the patient does surrender a degree of her own voluntary commitment to what she will or will not accept. As long as she sustains this confidence in this physician or as in this case the health officials involved, in the conduct of these widespread programs, she may agree to what is recommended.

On the other hand she is completely entitled to full information in every instance.

Senator NELSON. Let me read something that puzzles me a little bit. In the second report on oral contraceptives—and you were a member of the committee—is that not correct, you were a member of the committee in the second report.

Dr. HERTZ. Yes, sir; in both reports.

Senator NELSON. The concluding sentence on page 9 says:

> Specific risks as well as requisite practices for follow up of patients have been detailed in the labeling of oral contraceptives. When these potential hazards and the value of the drugs are balanced the committee finds the ratio of benefit to risk sufficiently high to justify the designation "safe" within the intent of the legislation.

The chairman of the task force was Dr. Hellman.

Dr. HERTZ. The chairman of the committee.

Senator NELSON. Of the committee, yes.

Dr. HERTZ. Which broke down into several task forces, cancer, thrombophlebitis and so on; yes, sir.

Senator NELSON. Now, Obstetrics and Gynecological News of August 1, 1967, quotes Dr. Hellman as saying—well, from the article it says:

> Finally, we are ignorant of the pill's long range effect particularly as a contributing cause of cancer. This latter concern has led Dr. Hellman, Chairman of the most recent FDA Advisory Committee on Oral Contraceptives to state "If I were a young lady these days and had any fear of cancer I probably would use an intrauterine device."