

TABLE VII.—*Miscellaneous*

Complication:	Cases
Chloasma-----	2
(Enovid, 5 mg., for 6 months)-----	1
(C-Quens for 9 months)-----	1
Peptic ulcer, radiologically clear 2 months after pills omitted (Enovid for 3½ years)-----	1
Vitreous bodies in posterior chamber of the eyes beginning 6 days after onset of pills (eyes still not clear 6 months after pills omitted) (C-Quens for 2 months)-----	1
Attempted criminal abortion twice when 3 months amenorrhea occurred after pills omitted (Enovid for 6 months)-----	1
Total-----	5

TABLE VIII.—*Major complications associated with the oral contraceptive pills*

Type:	Cases
Emotional or psychiatric problems-----	7
Central nervous system symptoms-----	4
Vascular accidents-----	3
Ophthalmologic changes-----	1
Attempted criminal abortion-----	1
Total-----	16

Senator NELSON. Thank you, Doctor.

What's your view of the question of informed consent?

Dr. McCAIN. This, I think, is almost impossible to give in a satisfactory manner. If one were to take virtually any medical therapy and were to go down the list of all of the possible complications that can be involved, from even as we mentioned in the first of the paper, even such a simple thing as aspirin, we cannot fairly say a patient carries no risk. I can give what in my opinion would be a generally satisfactory explanation to the patient of the risks involved. However, I think that virtually any such statement can be challenged, and perhaps successfully, as not being satisfactory informed consent in the various courts of the country.

Senator NELSON. Would you agree that the situation is somewhat different in the case of a patient suffering from serious disease of some kind or other which would indicate the use of some potent drug in which the doctor has to make a judgment whether a patient is better off taking the risk of some side effect or not take any drug at all? In other words, this is a medical judgment about a situation involving a disease. Does that not differ from the situation in which, for the first time in history in this country, 8½ million healthy people, with some exceptions—a small percentage—are receiving a very potent drug? Are not those two situations quite different?

Dr. McCAIN. I think you are right. I think there is a difference. I was giving what I would consider an overall opinion of informed consent. Variations are certainly quite in order. I think, in giving a statement to a patient; and I will be frank in my statements here, that when I am speaking with doctors, I will give a little different interpretation of my opinion regarding the risks of contraceptive