

Until recently, the metabolic effects of the contraceptive steroids have been inadequately investigated or ignored. These accumulated data and other suggest that no tissue or organ system is *** a biological function and/or more *** effect of contraceptive steroids. Many of these changes appear to be reversible after short periods of treatment. But it is impossible to form judgments on the reversibility of some of the changes resulting from prolonged administration. This question becomes more important daily for the many patients who already had long-term contraceptive steroid treatment.

It seems to me this raises a very serious question, since we really do not know what the consequences of these metabolic changes are over a long period of time.

My question is: Are you satisfied that we are doing enough research on this aspect of the problem, and if not, do you have some view about what we ought to be doing?

Dr. EDWARDS. By "this aspect of the problem," you are referring to the time period over which the oral contraceptive is given a particular patient; right?

Senator NELSON. And the metabolic effects of it.

Dr. EDWARDS. And the permanent effects this might have on the patient's metabolic system, et cetera.

I share with you concern about this, and certainly I think this is an area that we have to look at very seriously, along with groups at the National Institute. I have personal reservations about allowing the oral contraceptive to be given over indefinite periods of time. I have no knowledge of scientific evidence at the moment that would substantiate this view, but I think that some of the retrospective and prospective studies we are proposing or actually have in progress at the moment will help answer some of these questions. But it is a very serious subject of concern and I think it is one I hope our advisory group will address themselves to this next week.

Senator NELSON. That is the question of extended administration without interruption?

Dr. EDWARDS. Right, and what kind of studies would best allow us to make some scientific judgment on the advisability of this, or what is the ideal length of time over which one of the oral contraceptives can be given.

Senator NELSON. As you know, we have had a number of witnesses who have expressed their opinion, again without having the proof, as you said, who had reservations such as you have indicated you have.

One of the witnesses said that he would not want to have it used more than 2 or 3 years continuously without interruption.

Others expressed a similar viewpoint about long-term usage, simply because we do not have the studies that would indicate whether or not the metabolic changes that are effectuated on account of the administration of the pill have any long-term damaging effects.

Do I understand you to say that the new committee being constituted now on obstetrics and gynecology will address itself to the question of length of time the drug should be administered?

Dr. EDWARDS. I think there are a number of areas that we would like to have them address their attention to, but this certainly is one of the areas that should receive a high priority on the agenda of the committee.