

just mentioned, and to evaluate the drugs and, hopefully, to require the drug houses to establish proper standards.

I think that they are doing the best they can with a very difficult problem, and if we could take the data which we have one step further in terms of knowing the implications of all the findings, then one could know who was right and who was wrong in such situations. But there is an element of judgment involved, and I think their judgment has been a middle-of-the-road course insofar as their knowledge is concerned. I think now they might do some evaluations.

Senator DOLE. Yesterday, there were a series of questions propounded to Dr. Wynn, and I wonder if I might ask you to comment on two or three of these.

First, is there clinical data to suggest that the alterations in metabolism which are frequently attributed to the use of the pill are in any way related to the inevitable production of damage, permanent or otherwise?

Dr. SALHANICK. Well, I am not sure what kind of alterations you are referring to.

As I have indicated, the step between the abnormal findings and the disease is difficult to establish. Now, persons with those diseases, let us say diabetes, for example, have abnormal glucose-tolerance tests. Persons who take the pills have, to a lesser degree, abnormal glucose-tolerance tests.

Now, the next step as to whether persons with the pill have diabetes is a somewhat difficult one, and philosophical one, depending on the definitions of abnormality and definitions of diabetes, and that kind of difficulty, so I do not think that can be answered in a simple fashion.

Senator DOLE. Is it true that during pregnancy certain hormones are elevated but are biologically inactive? Would that be a true statement?

Dr. SALHANICK. Well, it is true that during pregnancy certain hormones are elevated. How one determines that a particular steroid is biologically inactive I do not know. Historically we used to think that the metabolic products of some of the steroids were inactive, and recent work has indicated that they do have biological activities which were not suspected.

Senator DOLE. Then the second part of that question which was propounded to Dr. Wynn, as I understand, you have the same results that some hormones are activated with the use of the pill. Is there any certainty that these may not be biologically inactive?

Dr. SALHANICK. I am sorry I do not understand your question.

Senator DOLE. I am not certain I do either. That is why I was asking you. [Laughter.]

Is there any link in the selection of patients from which alteration of metabolism data are derived which might prejudice the development of metabolic abnormality, such as overweight, large babies, abnormal glucose tolerance?

Dr. SALHANICK. Yes. I think this is part of what I meant by the statement, which I am beginning to think is a bad statement, the metabolic reserve. I think people who have had large babies, which is indicative of diabetes, at least the diabetic state in pregnancy, who have had previous histories of abnormal glucose tolerance tests, and so on, should be carefully considered as candidates for the pill.