

their high degree of effectiveness as contraceptive agents. Two, that they introduce an increased risk of thromboembolic phenomena. After that we are in the area in which I think from the standpoint of legal consideration we would have to say that we have not reached a standard of definitive establishment of any of these considerations to warrant their legal consideration. That is not to say that we have not reached the point where their medical consideration must be very seriously undertaken.

Mr. DUFFY. Do I understand your answer to be then that there have been some studies conducted as to each one of these items but that the quality of these studies may be considerably lacking—the sampling involved, is far too small to reach a conclusion for an example?

Dr. HERTZ. No, I think the effects have been substantiated. What has not been substantiated is the significance of this wide variety of effects for the health of the individual, and the welfare of the individual.

Take, for example, the diabetes mellitus effect. At this point we know patients taking oral contraceptives have a very disturbed carbohydrate metabolic effect. We do not know what this implies in terms of their health status and so on.

Mr. DUFFY. May I interrupt you at this point?

Dr. HERTZ. It was that aspect about which the uncertainty in the discussion continues.

Mr. DUFFY. Now, is this effect that you are talking about now something that one may usually observe in a normal pregnancy?

Dr. HERTZ. You mean the diabetes effect? Sometimes.

Mr. DUFFY. You say sometimes?

Dr. HERTZ. Sometimes and sometimes to the same degree. But certainly not universally, and not universally seen in women taking oral contraceptives, but very frequently.

Mr. DUFFY. Let's take this specific item for a moment. Are you aware of any studies which explore this question?

Dr. HERTZ. With respect to, with respect to whether this occurs or not.

Mr. DUFFY. The risk of diabetes and what this means to the pill user.

Dr. HERTZ. At this point I don't think anybody could give you a definitive answer.

Mr. DUFFY. Have there been studies made?

Dr. HERTZ. There have been numerous efforts made by a wide variety of individuals with somewhat differing end results due to differing conditions of study, different criteria applied, and I would say that this is still in the area of medical discussion and controversy.

Mr. DUFFY. I note that Doctor——

Dr. HERTZ. Just as ——

Mr. DUFFY. I note Dr. Corfman and Dr. Seigel are here with us today. Are you familiar with their paper which was published in JAMA in 1968 which set forth a basis for determining the patient population size which is necessary to document some of these things?

Dr. HERTZ. Very familiar with it.

Mr. DUFFY. To your knowledge have any of the studies you just mentioned been conducted involving patient populations as determined in accordance with the Corfman-Seigel paper?

Dr. HERTZ. The numbers that I quoted were based on these obser-