

Moreover, the Sartwell study did come up with a different finding regarding the magnitude of the increased risk in the United States as opposed to Great Britain.

Do you know, Doctor, of any reasons why the British and the American female population should be any different with respect to the increased risk of thromboembolic disease resulting from use of oral contraceptives?

Dr. WYNN. Taking the women by and large, I think the answer to that question is no. I would not expect there would be substantial differences between British and American women so far as risk of thromboembolism is concerned.

What the data reveal is the very great difficulty of carrying out epidemiological studies. You see, you take the Sartwell study. It was not identical to the British study.

They identified over 2,500 cases—I am speaking from memory—2,500 cases of thromboembolism, but they excluded all but a small fraction, 176, for one reason or another. Now some of the reasons for exclusion were in my view unreasonable.

They excluded women with varicose veins and family histories of diabetes, and so on. Now in conversation with Dr. Sartwell, he has agreed with me that some of the reasons for exclusion were not really those which he would advocate at the present time. Be that as it may, it merely gives some indication of the great difficulties in this type of study.

You see, doctors sit around a table, and they ask themselves this question: Are women taking oral contraceptive medication at risk from thromboembolism? How do we know and how do we find out?

Well, the thing is to go into the hospital and find all the women who have had thromboembolism, and find out how many of them are taking the medication, but it is not as simple as that by a long means.

One has to take into account the spontaneous occurrence of the disease. One has to match the women that are found in the hospital with women who are not in the hospital, or if they are, are in there for some other condition.

All this poses tremendous and even profound epidemiological problems, and I do not think that we have the answer. I do not think that we have the solution to the epidemiological problem, and it is this which worries me more than anything else.

We can sit here and talk about the risks of atherosclerosis or hardening of the arteries. We can sit here and talk about the risks of the development of cancer.

We can sit here and talk about thromboembolism and its risks, and the risks of stroke, but the difficulties of proving with precision what is in fact happening are fantastic, and if I may just refer very briefly to the testimony of Dr. Goldzieher, he has taken out of Dr. Sartwell's study a table showing the great variability between the incidence of thromboembolism as it has been found in New York and Baltimore, compared to that found in another American city, and he says that this disproves the validity of the Sartwell study.

It does nothing of the sort. It is merely a statistical chance that those data came up the way they did, and all I can say is that is a very, very difficult problem. It must be left to the experts, and even when the