Now, in terms of your studies and your concern about the importance of the metabolic changes, how frequently and what kind of examinations do you believe users of the oral contraceptives should have, and how often?

Dr. WYNN. Well, I think that this does pose considerable difficulties. As far as a physical examination is concerned, one has to be practical. There are economic factors and other social factors involved. I would think a physical examination every 6 months would be a minimum. If a woman is thoroughly examined every 6 months, that would be at least a reasonable minimum of clinical medical care.

Now, unfortunately, so far as the metabolic side is concerned, I personally think that nothing significant can be done or recommended. If you were to recommend that every woman have an oral glucose tolerance test with the measurement of serum lipid estimations every 6 months or every year, the cost of this medication would put it out of reach of everybody except those who are extremely wealthy. It is just not practical.

I might add that every time we carry out such an investigation on one of our patients, we are spending a considerable sum of money, some of it belonging originally to the American taxpayer.

So it is not practical to do metabolic investigations on a field sort of survey basis. It is only practical for these investigations to be carried out in specialized departments set up for the purpose, and I hope very much that far more of these departments will be set up in this country and in Great Britain than already exist.

But there should be a high index of suspicion. Certain patients should arouse the suspicion of the physician. A patient with a bad family history of diabetes, a patient with a bad personal history suggesting the possibility of subclinical diabetes, such as large babies or frequent unexplained abortion or malformation in the birth of the child, that sort of thing should arouse suspicion in the mind of the physician.

Now if a woman is given the oral contraceptive and gains weight rapidly, say 6 or 7 pounds in 3 or 4 weeks, and it continues to rise, that she has gained 10 or 14 pounds in a month or so, in my view that patient—either the necessary metabolic investigation should be carried out in her or the medication should be discontinued.

Another cause for suspicion that untoward metabolic changes are occurring would be the development of obvious water and salt retention, the swelling that women get in the hands and feet and around the face when they take the medication, if it persists, and if it is obvious, then those women—the reason for it is because of an untoward metabolic change, and either you investigate that patient or stop medication, depending upon the availability of facilities.

Senator NELSON. Thank you very much, Doctor.

Senator McIntyre?

Senator MCINTYRE. Dr. Wynn, the statement has been made here several times that the British findings regarding increased risk of thromboembolic disease with use of the pill cannot be applied directly to women in other countries including the United States. In fact, a statement to this effect was allowed in the official labeling of the oral contraceptives by FDA in 1968.