

Women usually begin to have normal cycles within 4 to 8 weeks after they cease medication but a few fail to institute normal menstruation for 6 months or longer. Such women become pregnant but for most women, cycles eventually resume with or without special treatment. It is not yet known if oral contraceptives actually cause this condition and it will be difficult to settle this issue since periods are known to cease spontaneously and without certain cause in about 3 percent of young women.

An important and certain effect of oral contraceptives on reproductive function is inhibition of lactation after delivery. This effect has particular importance for developing countries where children depend on breast milk for nutrition. We know that oral contraceptives in high doses will decrease or stop lactation within the first or second month of use but it appears that smaller doses have little or no significant effect, although this question has not been fully resolved.

Apparently minor changes in liver function tests have been observed in many women on oral contraceptives. The liver is one of the most complex organs in the body and has a multitude of functions, one being changing certain chemicals so that they may be eliminated from the body. A good way to test liver function and its efficiency is to measure how quickly it can help eliminate such chemicals. We know that oral contraceptives decrease the liver's ability to change one such chemical (sulfobromophathalein) in about 40 percent of women. The degree of this effect appears dependent on the amount of oral contraceptives used. It is also probably related to the fact that oral contraceptives, as well as other steroid chemicals, decrease the ability of the liver to excrete bile.

Senator NELSON. What studies have been done to evaluate the significance of the change in the liver's capacity to eliminate certain chemicals?

Dr. CORFMAN. This is the crux of the issue so far as I am concerned, Senator Nelson: to ascertain the significance of the many changes we have observed. This is why people with statistical and epidemiological skills are so important to this kind of undertaking. Many observations have been made, but we still do not know if changes in liver function indicate harm to the woman's health.

We need carefully designed epidemiological studies over a period of years to decide if these effects have any significance. The same thing applies to the changes in sugar and fat metabolism that were discussed yesterday.

Senator NELSON. Are you going to discuss at a subsequent point what studies are now underway to evaluate the significance of the effect on various organs' capacity, such as the liver?

Dr. CORFMAN. Yes, sir. I shall review our own studies in a later part of my testimony.

Another commonly observed change in liver function is an alteration in certain enzymes, chemicals normally present in small amounts which control vital body processes. An example of such alteration is the elevation in transaminase levels which occur in about 20 percent of women on medication.

Jaundice occurs in about one woman in 10,000. Such patients also show altered liver function tests. The jaundice subsides and the liver