

parently healthy young women reporting to a birth control clinic for contraceptive advice are quite a different population than young women reporting to a physician's office or an arthritis clinic at a major diagnostic center with rheumatic complaints.

Having reviewed the status of the several preliminary reports that are currently available in the medical literature, I would now like to present the results of our studies at the University of Michigan. In the spring of 1967, a 24-year-old housewife reported to our clinic with mild rheumatic complaints. She had been seen at another institution 6 weeks previously for evaluation of an abnormally low white blood cell count. She was found to have a positive LE cell test and antinuclear antibodies, these are the abnormal proteins that I referred to previously.

These three laboratory abnormalities are commonly associated with the serious rheumatic condition, systemic lupus erythematosus, one of the most serious diseases. She had been taking an oral contraceptive drug for 8 months. She was not taking any other medication. We confirmed these laboratory abnormalities and found that she had resolving thrombophlebitis in her leg. She was advised to discontinue her oral contraceptive therapy and within 6 weeks all of her laboratory abnormalities had disappeared.

This patient has been under our direct followup observation for the last 2½ years and she has no laboratory or clinical evidence of disease. She has no laboratory or clinical abnormality at the present time.

Subsequently, during 1967, seven other cases were identified at random from a total of 167 women aged 15 to 45 who were attending the arthritis clinics at our institution. The development of thrombophlebitis—inflammation in the veins of the legs—in five patients and a history of the development or exacerbation of rheumatic complaints in all of these patients led to the advice to discontinue oral contraceptive drugs.

These patients had been seen at intervals of 1 to 3 months in the arthritis clinics and blood specimens had been obtained from each individual during and after treatment with oral contraceptives. All of these women returned for special followup evaluation in the spring of 1968, 3 to 16 months after they stopped taking these drugs. This special followup evaluation was prompted by the preliminary report of Dr. Schleicher suggesting that abnormal LE cell tests had been induced in young women during therapy with oral contraceptive agents.

It is important to note that none of our patients were taking any other drugs except for aspirin. In tables 1–4 that I have submitted in my testimony, included at the end of this report, we have summarized the results of tests for antinuclear antibodies, LE cells and clinical findings in these patients during and after treatment with oral contraceptive agents. I will not detail that, but merely summarize it.

We found the laboratory tests reverted to normal in all but one, but this young woman had systemic lupus erythematosus. From this random and preliminary study we felt it was extremely important to initiate two additional studies from our patient population.

In this particular instance, the original data on the clinical and laboratory studies have been reported in the February 15, 1969, issue of the *Lancet*, pages 323 to 326.