

Mr. DUFFY. Perhaps, you can—maybe I am not using the proper terms—you may be able to clarify this for me, if you experience similar results in pregnant women as a result of the natural introduction of these hormones into their system, and it remits after pregnancy terminates, which I understand is your experience, can you say that since it is also your experience that many of the symptoms disappear after termination of pill use and have been absent for 2½ years, would that be substantial evidence to you that this may be just a normal body function that occurs whenever these hormones are used?

Dr. BOLE. The patients I have stated that remitted had very early, almost undiagnosed disease, there were physical findings. We cannot meet the accepted criteria to classify them as a patient, say, with rheumatoid arthritis or with lupus, and there are different form of rheumatic disease. There were objective physical findings, and they had abnormal laboratory tests.

The oral contraceptive drug was stopped, and the longest followup we had was 2½ years, and in the index patient that I cited, that was cited in some detail. In that particular patient, both symptoms and laboratory tests reverted to normal, as has been reported by others, in about 6 weeks and have remained normal until the present time. That is not universally true because in the second series that I cited for you we intentionally took patients with established clear-cut rheumatoid arthritis, these tests were abnormal, and the oral contraceptive did not reverse abnormal tests, and it did not uniformly influence their findings.

So my point is merely I have to infer that the ones that remained abnormal differed from those that returned to normal and have remained so, whether they are truly “normal” depends on additional followup of the patient because we know in all of the rheumatic diseases that they are subject to spontaneous fluctuation.

I would stand at the moment on the fact that because three of the young women who went back on the pill on their own volition and in every instance when they went back on the pill, while their laboratory tests were completely normal, and their physical findings were normal, their tests became abnormal again and that it was related to the use of the pill.

We have had one young lady who accommodated us, not because we asked her to but because she wants to be on the pill, go on and off the pill three times, and these laboratory tests have become positive and negative each time.

Now, what that implies in terms of the future, I think, has to await the future. I would not generalize further because I think it is unjustified, but I am saying that there may be an important small group of patients with rhematic disease about whom we don't know all the answers and that doctor should know that their tests may be rendered abnormal during use of the pill, as is listed for other laboratory tests.

It is important in the interpretation of tests in a particularly serious disease, SLE, that we not jump to the conclusion that the patient has lupus. The patient can read the Encyclopedia Britannica and find she may die of this disease—we all recognize that patients want to be informed about their disease whether by a doctor or on her own volition, and this particular patient may arrive at the wrong conclusions. So I think it is important to recognize that bad tests do not always mean bad disease and contrawise.