Senator McINTYRE. Do you think that in view of the state of our knowledge in this particular area that the labeling you have just discussed is sufficient at the present time?

Dr. BOLE. It would be my own opinion that it would be useful to all physicians to point out the single statement that I feel I can stand on; namely, that some of the tests useful in making rheumatic diagnoses may be modified, and I think that could justifiably be included.

Mr. GORDON. I have one question.

Actually it is a few questions that I would like to group together. In the cases you have studied where women had some evidence of rheumatoid arthritis or systemic lupus, were there any with concomitant impaired kidney function? Was there any correlation between rheumatic disease functions and a finding of abnormalities in blood coagulation or blood sugar or—in other words, were any of these women or any other things studied comprehensively as to possible combinations of disorders?

Dr. BOLE. We did not investigate all of the things that you have spoken about. We did do some of these tests, and we did do many other studies. It is known that these abnormal proteins, so-called antinuclear antibodies, segregate to some degree with abnormalities in the normal antibodies, and so an antibody profile of the three major classes of these compounds were looked at.

We did not do coagulation studies in this particular group of patients. They were accomplished in some of the patients in the laboratory of one of my colleagues, but I cannot give you the results of these tests at the present moment.

I am not sure they have been completed. The blood sugar was observed in two patients to be modestly elevated, but not very much.

Mr. Gordon, I would say in the constellation of previously reported laboratory abnormalities, elevated erythrocyle sedimentation tests, have been found, those are very simple tests. It is done in patients with a variety of inflammatory problems and reports that the pill produces elevations have already appeared in medical literature. There was no consistent elevation in our patients.

We did sedimentation tests in patients with comparable disease, along with C-reactive protein, another abnormal laboratory test, that has been reported to be produced by oral contraceptive agents; it was studied in some of the patients, it was elevated, but these patients should have a highly significant frequency of positive reactions to this particular test.

So I am merely trying to report the spectrum of laboratory tests that we did; we were trying to look for what I would call bad soil—I think this is what my own personal feeling is at the time, that there are some women in whom this is inappropriate therapy. But I have no knowledge that this means every person in the United States should be taken off these drugs, and we continue our study looking at this particular question.

Are there any indicators that would suggest a specific genetic marker of protein systhesis that could predict adverse reactions? As to blood groups, we did not find, for instance, as noted in earlier testimony about blood groups, high frequency of one the major types in our small groups; there was no cross-correlation with the other