It is of interest that a 3.5-percent incidence of positive antinuclear antibody tests was observed prior to oral contraceptive therapy. This increased to 5.7 percent during therapy, if we combine the two groups. But by so doing, this is not a statistically valid difference.

To date, positive LE cell tests have failed to develop during the use of oral contraceptive drugs in this "normal" population. Our studies contrasting patients with rheumatic symptoms evaluated in an arthritis clinic population with women reporting to a birth control clinic confirm the observations reported by other investigators. In other words, results obtained in these two different population groups reflect an inherent difference in the individuals studied in these two settings.

We would conclude from our present studies that the decision to use oral contraceptives in patients with early or established rheumatic disease should be individualized. It is important for physicians to recognize that abnormal tests for antinuclear antibodies, LE cells, and rheumatoid factor—the latter reported by McKenna, Weimer, and Shulman—can be associated with the administration of oral contraceptive drugs.

Since these tests are important in the differential diagnosis of rheumatic disease, the physician should inquire regarding use of these agents before attempting to interpret the significance of these tests in individual patients. We do not feel that it is justified at this time to generalize further on our preliminary findings.

Needless to say, additional studies are warranted, and we hope to continue to accumulate additional information bearing upon the effect of these agents on patients with both undiagnosed and established rheumatic disease. The long established clinical observation that natural pregnancy may ameliorate rheumatoid arthritis and may flare symptoms in patients with SLE must be considered when entertaining the use of these drugs in patients with rheumatic disease.

Not all patients with systemic lupus erythematosus experience an exacerbation of their clinical symptoms during administration of oral contraceptive drugs, but as has been reported by Pimstone some patients may experience worsening of their disease during treatment with these agents. Since natural pregnancy can worsen this disease, as noted previously, it is extremely important to use the most effective contraceptive regimen in such patients in order to avoid unwanted pregnancy. The medical dilemma in this particular situation is clearly apparent to all.

Lastly, I would like to point out that large prospective studies of the 20,000 or 30,000 cases are both extremely expensive and sometimes impossible to accomplish, and in a sense, as an investigator sitting and testifying before this commttee, I think that it is clear to all that if we are going to resolve these problems we cannot at the present time make support for health research the prime candidate for reduction in the face of fighting our problem of inflation.

I interject this, Senator, with some additional comments that I have made in my submitted testimony. I think this is an extremely important problem that has to go, in my view as a citizen, hand in glove with the expressed concern for adverse effects from any source for any group of people in any situation, and I am sure there are