blood chemistry which would lead to an increased tendency of the blood to clot (4).

Studies of women taking oral contraceptive agents have yielded relatively unimpressive data with respect to changes in their clotting mechanisms; i.e., changes in blood chemical constituents that have to do with clotting.

This point is my own view, and I should have pointed out prior to this that I am not expert in the field of clotting, though I do a great deal of general medicine, so I have some interest in this field. In referring back to the question of clotting mechanisms in the person with thrombophlebitis. This is also true of patients who have thrombophlebitis in clinical circumstances completely independent of oral contraceptive agents.

Studies of women taking oral contraceptive agents have led to the clear-cut finding of dilatation of the veins of the extremities—other veins as well perhaps but they have not been studied. These dilated veins carry the same amount of blood as before but since they are wider in diameter the blood flows more slowly.

The net effect of this series of events is a slowing of the blood flow during oral contraceptive therapy. This finding is distinctly abnormal and is not observed in any other circumstance in young women except during pregnancy or in the presence of varicose veins.

Further, apropos of the cause and effect question described above, the finding establishes a clear-cut relationship between oral contraceptive agents and changes in the veins which could lead to thrombophlebitis and ultimately pulmonary embolism(5, 6, 7).

I have listed a few conclusions which, of course, are those that I have reached on the basis of the kind of information just presented.

First, in the view of this witness, oral contraceptive agents have a clear-cut risk to the user. Present status of these agents is such that there is widespread public acceptance and in fact by this time, reliance on these agents so that withdrawal from the market would be difficult to accomplish, and probably unreasonable.

2. The benefits of these agents are primarily in the sphere of psychological benefits and the sphere of convenience to the patient, thus it seems unwarranted to this witness to suggest that "benefits outweigh risks."

3. Part of the problem as it presently exists, occurs as a result of public pressure; thus, education of the public should be an important aspect of the national response to the problem.

Regarding earlier questions, inserts should state in simple, nonwordy language, that leg soreness, redness of the leg, swelling or cramps of the leg, may mean the presence of phlebitis, and the patient should consult the physician at once. Again parenthetically, I think most of the inserts have so many words that even physicians tend not to read them. It is very difficult to separate the important aspect of it by simply scanning it.

Senator NELSON. You were referring, however, to the package insert?

Dr. WOOD. Yes, sir.

Senator NELSON. The package insert only goes to the pharmacist or, unless it is a sample, to the doctor. Are you saying that the same information should go directly to the patient?