women taking oral contraceptives must be continued." (2) Thrombotic disorders (incompletely listed as thrombophlebitis, pulmonary embolism, cerebrovascular disorders, and retinal thrombosis): "Should any of these occur or be suspected the drug should be discontinued immediately." (3) Vision: "Discontinue medication pending examination if there is sudden partial or complete loss of vision, or if there is a sudden onset of proptosis, diplopia or migraine." (4) Cancer again: "The pretreatment and periodic physical examinations should include special reference to the breasts and pelvic organs, including a Papanicolaou smear since estrogens have been known to produce tumors, some of them malignant, in five species of subprimate animals." (5) Endocrine and liver function tests: "If such tests are abnormal in a patient taking The Pill, it is recommended that they be repeated after the drug has been withdrawn for 2 months." (6) Fluid retention: " * * * conditions which might be influenced by this factor, such as epilepsy, migraine, asthma, cardiac or renal dysfunction, require careful observation." (7) Vaginal bleeding: "In undiagnosed bleeding per vaginam adequate diagnostic measures are indicated." (8) Mental repression: "Patients with a history of psychic depression should be carefully observed and the drug discontinued if the depression recurs to a serious degree." (9) Diabetes: "* * * diabetic patients should be carefully observed while receiving The Pill." (10) Tissue specimens: "The pathologist should be advised of The Pill therapy when relevant specimens are submitted. "(11) Blood pressure: "Susceptible women may experience an increase in blood pressure following administration of contraceptive steroids."

What is not included in the "requisite practices for followup" is most interesting. The doctor is not told that strokes occurring in women on The Pill have almost always been preceded by a headache (not necessarily a "migraine" headache), or that fainting spells may be the signal. He is not reminded that thrombotic disease also includes mesenteric thrombosis (intestines), hepatic vein thrombosis (liver), arterial thrombosis, coronary thrombosis, and others. He is not reminded that when changes in vision occur, or first sign of stroke appear, it may be too late already. The labeling implies that these catastrophes are generally reversible with cessation of medication.

The Chairman goes on:

> When these potential hazards and the value of the drugs are balanced, the Committee finds the ratio of benefits to risk sufficiently high to justify the designation safe within the intent of the legislation.

These "potential" hazards are *real* hazards, presenting themselves constantly in millions of women whose physiologic margins of safety have been narrowed in a multitude of ways.

The Chairman, perhaps with the concurrence of some of the Committee, has arbitrarily presumed to decide what is "safe" for millions of women. He has done so knowing that his information is woefully incomplete, that documentation of dangers of The Pill has been growing steadily and cumulatively for 10 years, that the most serious problems may be emerging only now. In making that declaration of safe, he has known that his language would be utilized to the fullest extent in further promotion of the oral contraceptive drugs. For, regardless of all else in the report, the word "safe" is all the drug companies needed out of it.

Senator NELSON. Thank you very much. I am sorry we had to interrupt your testimony by the recess and we appreciate your patience in waiting and your taking the time to come here to testify.

Dr. WILLIAMS. Thank you, Senator.

Senator NELSON. Senator Dole?

Senator DOLE. I had an opportunity to question Dr. Williams earlier.

As I understand it, you probably would not prescribe the pill. Is that a correct conclusion?

Dr. WILLIAMS. That is absolutely correct, sir.

Senator DOLE. I think again—and I do not quarrel with what you have said because you apparently have a great amount of experience from the legal standpoint—have you concluded any of these lawsuits before you withdrew as counsel?

Dr. WILLIAMS. No, sir; I did not.