The Commissioner of FDA said last night on television "There is no reason at this time for women to stop taking the pill," that the emotionalism centered around these hearings will soon fade away and people will not worry about it so much. And if this is not promotion of the pill I do not know what it is.

I think it is not only incorrect medically. I think it is contrary to the facts. I think it is unethical.

The balance of my paper has to do with my analysis of the report submitted by the advisory committee, and I would like to read the last two pages and that will be my summary. This begins at the top of page 14:

The Chairman in his summary states:

Specific risks as well as requisite practices for followup of patients have been detailed in the labeling of all hormonal contraceptives.

Specific risks have not been detailed fully. The labeling still contains serious and misleading ambiguities, such a relationship has been neither confirmed nor refuted for the following serious adverse reactions: neuro-ocular lesions, e.g. retinal thrombosis and optic neuritis.

And:

Although the following adverse reactions have been reported in users of oral contraceptives, an association has been neither confirmed nor refuted: an ovulation post-treatment . . .

This kind of language gives the people who are prescribing the pill something to hide behind if in fact they do not want to believe the facts that have been coming out of these hearings and that are available elsewhere.

As to the "requisite practices for followup" it is interesting to note in the labeling what this includes:

(1) CARCINOGENICITY

Close clinical surveillance of all women taking oral contraceptives must be continued.

If this is not a word of caution and warning I do not know what it is. But the followup finds the cancer after it has occurred and followup does not prevent it. It may prevent its extension but it does not prevent its initial appearance.

(2) THROMBOTIC DISORDERS (INCOMPLETELY LISTED LIMITED TO THROMBOPHLEBITIS, PULMONARY EMBOLISM, CEREBROVASCULAR DISORDERS, AND RETINAL THROMBOSIS)

Should any of these occur or be suspected the drug should be discontinued immediately.

In other words, the followup here relates to the fact after it has happened, and followup does not prevent those things from happening in most instances. It only enables the doctor to find them if and when they do develop.

(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.

Again followup consists of recognizing it after it happens and does not have anything to do with preventing it from happening.