

The 1969 FDA report is available, but not easily accessible to the average physician. It is going on 5 months since the last FDA report and the profession has received no official statement of the findings. Now, new information comes from Great Britain. Physicians in Great Britain have been warned against pills with high estrogen levels. FDA is unwilling to issue such a warning here to date, although their own data points in the same direction. An advisory can be withdrawn—but high dose pill injuries that may occur in the meantime cannot.

Press releases state that the British results will take 2 to 3 months to make the raw data available for release, thus thwarting FDA attempts to examine the data, as far as the United States is concerned. When the British released their first preliminary data we refused to act for over 1 year, and then when we did, we neutralized the warning.

Finally, "full disclosure" to the patient is desirable and morally necessary as the pill represents a mass experiment. Full disclosure should not become an escape device, placing final responsibility for using the pill upon the patient. Many women are unequipped by experience or temperament to make this difficult assessment.

While the experiment continues, it would be prudent to acknowledge both the known and unknown risks by reducing total exposure to these steroids. This can be done, in large part, without interfering with private or public population problems. Simply stated, the pill should not be recommended for women who have not completed their families.

This is the one group where the contraceptive risk cannot be substituted for a pregnancy risk but must be added to it.

Senator McINTYRE. Doctor, if I may make a reference to the fact this morning a difference arose between the task force report headed, I believe, by Dr. Hertz and the Chairman's overall summary. It seemed to some of us there was an inconsistency in the fact that, as a task force chairman he, at least, approved the summary of Dr. Hellman.

This has caused us, the Chairman here, the Senator from Wisconsin, has indicated that he really does not know what is meant by the word "safe" within the intent of the legislation, which was the term used in the Chairman's overall summarizing of the report.

I am informed that Dr. Hellman will eventually be a witness before the committee, so I think we will all get a chance to find out what is meant by "safe" as opposed to "safe within the intent of the legislation," if there is any difference.

So I can appreciate Mr. Duffy's and your difficulty in trying to get straight on that.

Doctor, you seem to be taking the position that if the pill remains on the market it should be reserved for women who had completed their families. Is that a correct interpretation and, if so, why did you think it should be reserved for this group of women?

Dr. KASSOFF. That is in general. That will not solve everybody's need for the pill. I think it is evident now from what we have heard, so far it would be wiser to reduce the experiment rather than to enlarge it. There seems to be a big cloud hanging over the pill in the form of cancer and in the form of metabolic disorders. The experts have told us it is going to be many years before we have an indication if it is so or not.

I think it would be prudent for those who do not have a real need, and overriding need, to use one of the more conventional methods.