lute certainty, but generally speaking, it is accepted that the ratio of potency is roughly comparable to the ratio in which they appear in these marketed products. That is, that the .05 milligrams of ethinyl estradiol is approximately equal to the .08 milligrams of mestranol.

Senator McIntyre. If this is so, if you decide to establish upper limits on the amount of estrogen in the pills, you will actually have to set different limits on each of the substances in order to assure comparability, will you not?

Dr. Jennings. Earlier in the testimony, Senator, we did discuss this to some extent, when we thought that the British data had not taken sufficient cognizance of this possibility to be directly applicable to our situation here.

Yes, I think that if we attempt to establish an upper limit, we will have to take into account not only the estrogenisity of the two estrogens, ethinyl estradiol and mestranol, but also when the products are used in combination, the estrogenisity of the progesterones, as well.

So, it may turn out to be a fairly complicated process.

Senator McIntyre. Thank you very much, Doctor.

Senator Dole. Just one or two questions.

Dr. Edwards, first of all, I appreciate your testimony and the testimony of Dr. Jennings and Mr. Goodrich. It has been very helpful to the committee.

Do you feel there be any implication of excessive risks because this reminder is inserted in every package?

Dr. Edwards. Well, as I said at the beginning, Senator, I feel that with any potent drug, like the drugs that are used in the oral contraceptive, there are significant risks.

Senator Dole. Are you saying that the risks are accepted as a medical fact by the FDA?

Dr. Edwards. I beg your pardon?

Senator Dole. Are we saying necessary risks set forth in the memorandum are accepted by FDA as a matter of fact?

Dr. Edwards. Yes. And under the right supervision, these are acceptable risks to take; right.

This is an informative process, as far as we are concerned, but within the conditions of labeling we feel these are acceptable risks to take.

Senator McIntyre. Mr. Chairman, at what now appears to be the conclusion of these hearings, I would like to say I am both surprised and disappointed to find that the Food and Drug Administration, which has legal responsibility for assuring the safety of all drugs on the market, after allowing the birth control pill to come on the market on the basis of questionable evidence, has also failed to take the lead in seeing that adequate studies are being done to answer the questions which have been raised about the safety of these drugs since they came on the market.

Instead, FDA's posture has consistently been one of reacting to studies done elsewhere, and in many instances, in other countries. I think these hearings have made it quite clear that there are a number of still unresolved questions about the safety of the birth control pill. I hope that in the future FDA will be more aggressive