

Senator McINTYRE. I wonder if, when you speak about the intent of the legislation, what you really mean, or the attorneys who assisted you meant, is the interpretation which the FDA has placed on the law and the methods by which it has proceeded to make these benefit-risk decisions? Would that not be a better statement rather than the intent of the legislation?

Dr. HELLMAN. Well, you know, you have me in an area where I cannot even claim to be very knowledgeable. All I can tell you is that Mr. Goodrich said that this was testimony before the Congress and was accepted as a *modus operandi* for the Food and Drug Administration after that testimony.

Senator McINTYRE. Well, it just seems to me that it might have been more accurate to say that the pill was safe within the interpretation that the FDA had commonly placed upon the legislation.

Just one other comment and question: Since some segments of the news media chose to seize upon the term "safe" without all the qualifications stated in the committee report, do you think in retrospect, Doctor, that it might have been better to avoid the term "safe" or "unsafe" altogether?

Dr. HELLMAN. I would have liked to have avoided the chairmanship of that committee altogether.

Senator McINTYRE. But you were the chairman and you did have to face it. But now in retrospect, do you think it would have been better if, despite the qualifications you put into the committee report, you had done your utmost, even more than you did, to get away from this term "safe" or "unsafe" with regard to this contraceptive?

Dr. HELLMAN. I am afraid that this sentence reflects my personality. I do not like a hedge, and this was a hedge, and the words in there are mine and I am not going to retract them.

Senator McINTYRE. Thank you very much. I have no more questions.

Senator DOLE. Mr. Chairman?

Senator NELSON. Go ahead.

Senator DOLE. Do you see any reason today, Dr. Hellman, to change the wording of this sentence?

Dr. HELLMAN. No; I do not see any reason to change the wording. There will be other reports. The FDA Committee is going to continue to meet. It met yesterday. And Dr. Edwards has indicated that it probably will meet more frequently. I think you can expect an interim report in 6 or 7 months. There is a lot of data that we do not have. We do not have anything on the British data at the present moment.

Senator DOLE. Was there any scientific data that warned of finding the pill was not safe?

Dr. HELLMAN. Any more than in here?

Senator DOLE. Yes.

Dr. HELLMAN. At yesterday's meeting?

Senator DOLE. I mean when you made this finding.

Dr. HELLMAN. I think within that hedge, the sentence expressed what the committee felt.

Senator DOLE. Will you talk about potential hazards. Others say they are not potential, they are very real. Do you consider the hazards potential or real?

Dr. HELLMAN. Well, some of the hazards are real. There is no question about the thromboembolism. And the report does not equivocate there. Some of the other hazards are potential.