

it, has been the relative safety of oral contraceptives and a concern for public understanding of the risks associated with them.

We have, needless to say, carefully followed the progress of these hearings. You have heard a wide range of opinion concerning the safety of oral contraceptives. The opinions of these witnesses have been expressed intelligently and sincerely. They certainly merit serious consideration, both by you and by the Food and Drug Administration.

However, the expression of an informed opinion is not the same as making a decision. We, in the Food and Drug Administration, also have expert opinions; but it is our responsibility to study the available scientific data, consider the advice of our consultants and render a decision on the safety and efficacy of new drugs under the Federal Food, Drug, and Cosmetic Act.

At this point I wish to summarize the Food and Drug Administration's current position. I would like to emphasize "current", because this is a situation that can change from month to month, year to year. However, our position is that the oral contraceptives are an effective and safe method of birth control, but as with other potent drugs there are both contraindications and complications.

Women whose history and present medical condition include thromboembolic disorders, impaired liver function, known or suspected cancer of the breast, estrogen dependent tumors, and abnormal bleeding should not take oral contraceptives.

Senator NELSON. Doctor, may I ask a question at this point?

Dr. EDWARDS. You certainly may.

Senator NELSON. On the use of the word "safe" in respect to the oral contraceptives, I think that there is considerable confusion within the medical profession and the public alike as to how the word "safe" was being used when the Hellman committee came to that conclusion and used the phrase "Safe within the intent of the law."

I would just like to read to you what Dr. Hellman said before the committee, and ask for your comment on it. I shall read out of context a couple of excerpts of his testimony.

This is Dr. Hellman speaking when he appeared before the committee—

It is quite apparent if you read the report, in the first report the committee recognized certain very serious problems with oral contraceptives. They, however, were unwilling, and rightfully, I believe, to say these things ought to come off the market.

Now, I skip down further where Dr. Hellman states:

Now, in discussing the Chairman's report, the second report, with the committee, I said to them that a more forthright statement has to be made. We cannot just hide behind rhetoric, we are going to have to say something and we have an option. These are not safe and then the commissioner might have to take them off the market, if you believe this. We can say these are safe, and our scientific data really did not permit that kind of statement.

I doubt whether one doctor in 10,000 in the country knows that this was what Dr. Hellman, the Chairman, said and understands the context within which the word "safe" was used in reaching the conclusion when the Chairman of FDA's Advisory Committee said "safe within the meaning of the intent of the law."