

So we have a task force or a committee report saying it is safe on balance within the intent of the legislation, and the chairman of the committee saying if he were a young lady concerned about cancer he would use an intrauterine device.

(1) is there anybody who isn't concerned about cancer, and (2), how does one make a judgment about that? I gather that what Dr. Hellman is saying is that if he were a young lady, he wouldn't use it.

Dr. HERTZ. I believe that the statements you have just cited are sufficiently out of context as to impute a paradox which Dr. Hellman is not characteristically disposed to.

Senator NELSON. I want to say for the record all I have is an excerpt from a quote from the news article.

Dr. HERTZ. That is right.

Senator NELSON. So it might be out of context, and I don't know out of what context.

Dr. HERTZ. Neither do I and so I would hesitate to use the basis of the two specific excerpts that you have cited as an indication of any inconsistency in Dr. Hellman's view.

I would like, however, to point out, Senator Nelson, that in the second report on the oral contraceptive which you quoted from page 9, Dr. Hellman is stating, as is clearly labeled on page 1 of the report a portion of what is labeled as the "Chairman's Summary."

Now, the committee was called upon to review this "Chairman's Summary" and unanimously, under Dr. Hellman's eminently fair and objective evaluation, agreed to the content of this "Chairman's Summary" in the sense, not that all of us agreed with its content, but in the sense that we did unanimously agree that Dr. Hellman had conveyed in his summary the consensus of opinion of the overwhelmingly large proportion of the committee.

Senator NELSON. You were a member of the committee. Do you agree with that last sentence on page 9 yourself?

Dr. HERTZ. I do not, quite obviously. However, there is no inconsistency here in the sense that this represents the Chairman's Summary. However, I would emphasize, in fairness to Dr. Hellman, this was unanimously approved by the committee in open vote as representing an adequate statement of the consensus of the committee which is the same as, I would suppose, I would expect, your committee in reaching some analysis of this would also do.

Senator NELSON. I understand.

The statement raises a question I don't think we have ever dealt with before, that is on page 9 when it says "When these potential hazards and the value of the drugs are balanced, the committee finds the ratio of benefit to risk sufficiently high to justify the designation safe within the intents of the legislation." Now, I am not really sure what safe means under the legislation. I assume that the committee, since they used the word "safe" within the intent of the legislation, discussed that aspect. But let me just pose a question to you that puzzles me when we say safe within the intent of the legislation.

I have assumed from looking at the statute and from viewing the, what I would assume is the, intent of Congress within the context of the passage of the law, that when the law in 1938 required that there had to be proof of safety, I assumed when Congress passed the law, Congress meant safe on balance weighing the illness of the patient versus any known risks from taking the pill.