I always, in discussing that, said what this means is there. Is a yellow light of caution being exhibited by this committee?

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 had options. "These are not safe," and then the Commissioner might have to take them off the market if he believed us. We can say "these are safe," and our scientific data did not really permit that kind of statement.

I took it upon myself to look into, as I am sure you have, the Kefauver-Harris amendments that regulate the actions of the Food and Drug Administration at the present time. As I indicated here, although those amendments are specific when they talk about food additives and were made much more specific by the Delaney amendment, which talks to this point. When they talk about safety of drugs, they face the same kind of dilemma that the committee faced.

They say safety pertains to the health of human beings.

Now, the Congress, the 88th Congress, was perplexed about this point and they called the Commissioner to a hearing to testify. What the Commissioner pointed out was very obvious, that any drug, no matter whether it is sold over the counter or whether it is sold by a prescription, if it is effective, it is going to have adverse reactions, and no drug can be absolutely safe.

And I give you but one example of a very pervasive drug sold over the counter, aspirin. We had in the United States in 1967 approximately 200 deaths from aspirin.

So that you keep coming up against this problem. The Commissioner said in his testimony that the safety of a drug cannot be weighed on any yes-no, black-white answer, but must be weighed according to the ratio between benefits and risk.

I therefore wrote the sentence that has caused you and Mr. Gordon and other people some difficulty. I take full responsibility for writing the sentence, "Safe within the intent of the legislation." But I did have consultation in writing that sentence. I did not just dream it up sitting up in Maryland. It was read to the committee and discussed. They approved it but they said, you must clear this statement with two people. It must be cleared by the Commissioner of the Food and Drug Administration, and it must be cleared with legal counsel of the Food and Drug Administration.

Mr. Goodrich and I went over the statement and he said that it was OK, and obviously I discussed it with the Commissioner.

I do not know anything other that I could have said about the oral contraceptives. I think it implied, that there are problems with these drugs. And if you read this report, you cannot escape the fact that there are problems. I think, though, that you have to look at benefits.

Now, benefits are of two kinds when you are discussing a drug. There are benefits to the population as a whole. I do not want to go into the population problem, but I will say that the introduction of modern contraceptive methods has made the problem of population control immeasurably easier. With the traditional methods of contraception, it is very difficult, as you must have seen in India, to get any response out of the impoverished people. They have neither the time nor the privacy