ious studies, can you name any one or two of these studies that FDA has supported?

Dr. SCHROGIE. Among the witnesses?

Senator MCINTYRE. From the witnesses who have been here.

Dr. SCHROGIE. Dr. Spellacy has been under support from the Food and Drug Administration since 1967.

Senator MCINTYRE. Any others?

Senator DOLE. How about Dr. Wynn?

Dr. SCHROGIE. Dr. Wynn is funded by the National Institute of Child Health and Human Development. I would add in terms of timing, both Dr. Wynn's study of carbohydrate metabolism and lipid metabolism, and also the prospective multiphasic study of oral contraceptive users being conducted at the Kaiser Permanente Foundation at Walnut Creek, Calif., were initiated by NIH around 1966.

Senator MCINTYRE. You have now described to me all of the studies that FDA has supported among the witnesses who have appeared here and described their studies for this committee.

Dr. SCHROGIE. To the best of my present recollection, yes.

Senator MCINTYRE. Well, to me anyway—I may be wrong, in 1960, the drug went on the market. And FDA seems to be getting into the act by 1966, in a concerted way by starting some of these studies. Anyway, on page 5, you quote the conclusions of the Hellman committee's second report, that:

> When these potential hazards and the value of the drugs are balanced, the ratio of benefit to risk is sufficiently high to justify the designation safe within the intent of the legislation.

Now, I appreciate that you probably touched on that before I got here. Now, this last phase, "safe within the intent of the legislation," has given us in this committee considerable concern, because we could not know exactly what it means. The law itself does not define the word "safe". Although Dr. Hellman confirmed that he wrote the statement, he says he obtained this phrase from Mr. Goodrich.

So perhaps Mr. Goodrich will tell us what it means and cite for us the appropriate reference in which the legislative intent was stated.

Now, I do not know whether you got into this before I got here.

Mr. GOODRICH. We did, but I do not mind repeating it, Senator.

Senator MCINTYRE. In deference to the members of the committee, you can make a succinct reply.

Mr. GOODRICH. I will do that. The issue balancing benefit to risk in reaching a safety decision came to the Food and Drug Administration very shortly after the enactment of the first new drug provision in 1938. We could never have approved a number of classes of drugs, such as the corticosteroids, without balancing benefit to risk.

When Dr. Hellman called me, he asked if there was in the legislative development anywhere that I knew of a discussion of this point. It happened that there had been a very comprehensive discussion of this before the Intergovernmental Relations Subcommittee of the House and before the Committee on Interstate and Foreign Commerce and before the Antitrust Subcommittee at the time of the enactment of the 1962 Drug Amendments.