STATEMENT OF P. J. PALUMBO, M.D., ASSISTANT PROFESSOR OF MEDICINE, MAYO MEDICAL SCHOOL

Dr. PALUMBO. The comparison of treatment for a disorder can only be evaluated through controlled, randomized, clinical trials.

Hints and leads from retrospective studies can be extremely valuable in leading to a new hypothesis and may be the basis of justification of a randomized trial. However, standing alone they cannot form the basis of any firm conclusions concerning treatment effects.

The preliminary analysis of our data of the incidence, prevalence, and mortality of diabetes mellitus in Rochester, Minn., between 1945 and 1970 contains some hints that survivorship may be lower in diabetics on oral antidiabetic agents, and we grouped them all together: These are sulfonylureas and phenformin.

Mr. GORDON. About how many people were you following?

Dr. PALUMBO. We were following over 1,000 [1,090 to be exact] patients with diabetes over that 25-year period. There were only 138 on oral agents out of that group.

Mr. GORDON. How did they fare?

Dr. PALUMBO. Their survivorship was less, but however there are group differences that have to be taken into account, and therefore we cannot make any firm conclusions. Our statisticians are very loath to leave themselves open to the criticism that a retrospective study can lead to firm conclusions [regarding treatment].

All we can say is it suggests or hints that the oral agents plus other factors may affect survivorship of the diabetic. As a clinician—and I am deviating from my statement—as a clinician, I would expect that the oral agent group would be similar to the diet group, the same group, the same ischemic heart disease, the same hypertension, et cetera, and I would have expected them [patients on oral agents] to have the same survival curve as the patients on diet alone; that is, the oral agent group should have been similar to those on diet alone.

However, the survivorship of those patients on oral agents when compared with a group of the general population, similar in age and sex for our midwestern area, the death rate or rather relative survivorship for the group of diabetic patients showed that the oral agent group was much lower.

The CHAIRMAN. Now, wait a minute. You said the death rate and survival. You cannot have it both ways.

Dr. PALUMBO. Their survivorship was lower.

The CHAIRMAN. The higher incidence of death.

Dr. PALUMBO. That is right, and in the first 3 years there was a difference in the death rate for cardiovascular mortality in the oral agent group, or there was a higher death rate from cardiovascular deaths.

The CHAIRMAN. This was retrospective?

Dr. PALUMBO. This was retrospective. The groups are not comparable. The insulin group is younger, has a higher blood sugar, and in our study has a higher percentage of stroke, actually, which should favor a poor survivorship. The oral agent and diet group—