As I noted earlier, there have been a number of studies that showed significant differences in the bioavailability of marketed drug products and these differences reflected what we interpreted as inadequacies in the standards established by the compendia (the United States Pharmacopeia and the National Formulary) and/or the way in which those standards are applied. I will not go into the specifics of our criticisms. However, it was our view that considerable tightening of those standards should be effected and that it would be desirable for the improvement of those compendial standards to precede the development of a list of interchangeable products even though the development of such a list was considered the ultimate goal of a rational drug program.

When we presented our conclusions to Senator Kennedy's Subcommittee on Health, he pressed us for an answer to the question of whether one might not proceed with the list of interchangeable products without waiting for a general overhaul of the compendial standards. I believe all those members of the panel who were present conceded that for some of the drugs with wide margins of safety, one could draw up such a list without need for concern about therapeutic inequivalence. We all felt that without improved standards that list would be far more limited than it would be if standards were first drawn up that would give better assurance of bioequivalence. One would have to be more conservative under present circumstances than would be the case if improved standards had been established. I believe there was also some concern that once the list of interchangeable products had been established, much of the impetus for improved standards would have been lost and they might never be established.