4. We are planning new strategy for sorting out IND's to differentiate between individual physician research and complex commercial investigations. Both should benefit. We are tightening internal quality controls through mandatory 90-day review of all working NDA's. We are soliciting new ideas from industry, from academia, from professional societies and from within FDA through conferences such as that recently concluded at Airlie House near Washington.

5. We are asking major FDA Advisory Committees for ideas and review of criteria for judging efficacy; for example, the amphetamines. We have now completed the assignment of a statistician to every NDA review team to insure the statistical quality and completeness of every submission. This has major implications because it means still another specific check and balance for data quality. We are taking necessary steps to simplify as much as possible the approval of "me-too" drugs through the Abbreviated NDA procedures.

Let us sum up: We now have 10 years of invaluable experience under Kefauver-Harris. It is no exaggeration to say that this has been the most dramatic period of progress in the drug area in FDA's 66-year history. It has been a tough but useful period of on-the-job training for FDA and industry alike. Many problems remain but much progress has been made toward the goal of better drugs and better therapeutics for the American people.