With the great deal of critically important work which lies ahead of this agency in the drug area, we recognize our responsibility to take all steps necessary to assure the soundness of our scientific judgments and the efficiency of our operations. To accomplish this, we have taken the following steps:

1. In the past 2 years, we have not only strengthened our own internal staff, but we have called upon the expertise of the medical and scientific community to assist us in strengthening our scientific reviews.

2. Today, a total of 260 experts serve on 26 advisory committees, and another 200 advisers will be added to this total as the over-the-counter (OTC) expert review panels are organized. In addition, the Bureau of Drugs expects to add five new advisory groups in the coming fiscal year. Just this past week, the first meeting of the National Drug Advisory Committee was held in Washington. This newly formed group is intended to serve as the top policy drug advisory committee to the Food and Drug Administration.

3. We are taking a number of steps to eliminate the time, cost, and delay that may affect New Drug Applications. First, we have set up a Task Force to help detect any faults in our internal procedures; we have matched this in recent weeks with a major contract to conduct an extensive study of these same internal FDA procedures.

With industry and with academic help, we are developing guidelines of clinical research. These guidelines will, we hope, assist individual investigators as well as industry to more clearly understand what FDA expects—and to gain this understanding during the work-up of a New Drug Application.

We have this year established a pilot plan for joint Industry-FDA conferences at designated points, points during the investigational stage of new drugs and again prior to submission of New Drug Applications. The purpose is to speed the overall process by earlier understanding, better information, and, hopefully, fewer signal changes in mid-stream, and also to improve the overall quality of the scientific information generated about a drug.

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.

So, in summing 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