

We are very pleased this morning to have the Commissioner of the Food and Drug Administration, Dr. Ley, before the committee. He has a long and distinguished career in public service, and a national reputation of high repute.

And we are pleased to have you here this morning, Doctor, to discuss the fixed combination of antibiotic drugs.

You may present your statement as you please. All of it will be printed in the record. If at any time you wish to elaborate on anything in the statement, feel free to do so. I assume you have no objection to questions?

Dr. LEY. None whatsoever.

Thank you, Mr. Chairman.

STATEMENT OF DR. HERBERT L. LEY, JR., COMMISSIONER OF FOOD AND DRUGS, CONSUMER PROTECTION AND ENVIRONMENTAL HEALTH SERVICE, PUBLIC HEALTH SERVICE, U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE; ACCOMPANIED BY WILLIAM W. GOODRICH, COUNSEL, OFFICE OF GENERAL COUNSEL; DR. JOHN JENNINGS, ACTING DIRECTOR, BUREAU OF MEDICINE, FOOD AND DRUG ADMINISTRATION; AND DR. PAUL BRYAN, DIRECTOR, BUREAU OF MEDICINE TASK FORCE, FOOD AND DRUG ADMINISTRATION

Dr. LEY. Before I begin I would like to introduce the members of the staff of the administration whom I have brought with me.

On my left is Mr. William Goodrich, of the Office of the General Counsel of the Department of Health, Education, and Welfare.

On my right is Dr. John Jennings, Acting Director of the Bureau of Medicine of the Food and Drugs Administration.

And immediately behind him is Dr. Paul Bryan, who is head of the task force that is responsible for the drug efficacy study implementation.

We welcome this opportunity to join in the discussion, which was started before this committee 3 weeks ago, about combination antibiotic drugs, the review of their effectiveness by the National Academy of Sciences-National Research Council Drug Efficacy Study Group, and the follow-up steps that FDA is required to take to remove these products from the prescription drug market.

Let me begin with two general observations. First, we are most fortunate to have had the assistance in the effectiveness review of medical scientists of the stature of the witnesses who appeared before this committee earlier. These five panel chairman, as I'm sure the committee noted, are not cloistered academicians aloof from the realities of treating infectious diseases. To the contrary, they have been and are now working at the frontiers of the treatment of the most complicated of infectious diseases. Their contributions, which led to their selection as panel chairmen by the NAS/NRC, clearly establish their excellent qualifications to make efficacy judgments for this class of drugs.

Second, we cannot overemphasize the importance of the drug efficacy review in terms of better patient care. The implementation of