

10484 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

Commissioner for Medical Affairs of FDA. On my left, at the far end, is Mr. Vince Gardner, the Chief of the Drug Studies Branch of the Social Security Administration. Next to him is Mr. Frank Samuel, Deputy Assistant Secretary for Legislation. And on my immediate left is Dr. Keith Wiekkel, the Associate Administrator for Planning, Evaluation and Legislation of the Health Services Administration.

Senator NELSON. Go ahead, Doctor. Present your statement however you desire.

Dr. EDWARDS. Thank you, Mr. Chairman. We are delighted to have the opportunity to discuss with you this morning the issue of our drug quality assurance programs and the effect these may have on Federal procurement policy. We are also pleased to have this opportunity to update the Congress on the implementation of the revised drug reimbursement policy that was announced by Secretary Weinberger in December.

Your most recent investigation of the first of these issues began February 20 when Dr. Alexander Schmidt of the Food and Drug Administration outlined the quality control and other regulatory activities of the Department of Health, Education, and Welfare which serve to guarantee the safety and efficacy of pharmaceutical products sold throughout the United States. These include many different programs—inspection of drug manufacturers, monitoring of marketed drugs, batch certification, adverse reaction reporting, to mention only a few. I will not add further to that testimony except to restate our belief that these activities have served and continue to serve the quality control needs of all drug purchasers in this country.

As you know, Mr. Chairman, the GAO report of December 1973 recommended that separate quality assurance activities of the Defense Department, Veterans Administration and the Food and Drug Administration be consolidated into one organization. We believe this is an excellent recommendation and that the FDA is the appropriate and the obvious organization to carry this out. The FDA has already begun discussions with representatives of the Defense Department and the Veterans Administration. These discussions will continue, and we expect that positive actions can be taken in the very near future.

Senator NELSON. This will involve all the agencies of Federal Government that procure drugs?

Dr. EDWARDS. Yes, sir.

Senator NELSON. Mainly DOD and VA?

Dr. EDWARDS. Primarily VA and DOD.

Senator NELSON. If I recall the testimony correctly, the other day Dr. Lee of the VA said that they do rely or intend to rely or will be relying, I believe, exclusively upon FDA. Is that correct?

Dr. EDWARDS. That is correct. We have more and more taken over this function for the VA and I think for all practical purposes it is fairly complete at this point in time.

Senator NELSON. Do you have any target date on reaching this arrangement with the DOD?