at all. But when he did, Last Dec. 3, he, too, focused on unsatisfactory testing of drugs.

"I must tell you frankly that we have not seen the degree of improvement in the quality of clinical data from drug investigations that we would like," Dr. Ley told an educational conference sponsored by the FDA and the Food and Drug Law Institute.

He documented his point with a capsule review of the 406 drug-marketing applications received by the agency in the fiscal year ended last June 30. Only 59 were approved—about one-fifth as many as were so low in quality as to be "not approvable." Of the rejected applications, Dr. Ley said, more than half "suffered from deficiencies in clinical studies and inadequacies in efficacy data."

"I intend to give this matter renewed attention * * * and possibly call upon experts outside the agency as well to see if we cannot find means to correct existing shortcomings," he said.

As if to underscore his point, the FDA soon thereafter disclosed that it intends to halt the sale of six antibiotic-containing combination drugs for which investigation showed there was little if any scientific evidence of efficacy—but which nonethless were widely advertised and, over the years, prescribed for millions of patients.

Two days after Dr. Ley spoke, support came from an unexpected quarter. In the Dec. 5 *Medical Tribune*, spokesmen for two major pharmaceutical houses were reported to have made a joint statement in Geneva, Switzerland, that despite improvement in recent years, "the vast bulk of clinical work with new drugs that is published is of abysmally low quality."

This fact often is held against the drug industry, Drs. H. Bloch of CIBA, Ltd., in Basel and G. E. Paget of Smith Kline & French Laboratories, Ltd., acknowledged at a meeting sponsored by the Council for International Organizations of Medical Sciences in cooperation with the World Health Organization and the United Nations Educational, Scientific and Cultural Organization. But, the two doctors said, "it is as much to industry's disadvantage as to medicine's that this situation exists. This unsatisfactory state of affairs does not come about because industry seeks third-rate investigators to carry out these [drug testing] trials in the hope that they will thereby obtain an unreasonably favorable outcome . . . It arises because of the dearth of investigative facilities and first-class investigators throughout the world." As they saw it, the answer lies in "a complete revolution in the attitude of medical schools and teaching hospitals to the clinical investigation of drugs and the training of investigators."

Their advice is not out of proportion to the seriousness of the problem. But alone it is not enough. The Government might well look upon the training of drug investigators as a public health necessity and pay the bill. Apart from that, as witnesses have told the continuing drug hearings led by Sen. Gaylord Nelson, steps must be taken to eliminate the possibiltiy of bias in testing. As it is, manufacturers commission testing. Those who do it know what company is paying the bill, whether a gift to a favored medical school may somehow be in the balance, whether there will be such forms of ego massage as honorariums for speaking at a conference in a distant city, whether a favorable result will cause a rise on the stock market from which personal advantage may be derived.

One way or another, testing should be done by specialists who do *not* know the identity of the manufacturers, who *cannot* benefit financially from the result, who are *not* motivated even subconsciously by a desire to get anything but the truth. If war is too important to be left to the generals, so is drug testing too important to be left to manufacturers and to investigators who have not been immunized against possible bias.

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DRUG TESTING: IS TIME RUNNING OUT

(By William M. O'Brien)

(NOTE.—Dr. O'Brien, who is associate professor of preventive and internal medicine at the University of Virginia, Charlottesville, discusses the hazard of drug testing in the diseased human being. He contends that the FDA should be strengthened by improving its scientific status and upgrading the quality of its scientists; that drug testing should be taken out of the hands of the pharamaceutical industry, which he criticizes for showing unwarranted optimism about drugs.)