PHARMACOLOGY

Computer Drug Control

The new drug regulations, with stricter control over investigational use of drugs and record-keeping, will probably require an enlarged computer system, Faye Marley reports.

➤ THE FOOD AND DRUG Administration will probably need an enlarged computer system to take care of the reports required under the new regulations for clinical investigation of new drugs effective Feb. 7.

Dr. Frances O. Kelsey, of thalidomide fame, now director of the new investigational drug branch, told SCIENCE SERVICE that the FDA would "have a lot more information than we ever have had before" and that she looked forward to an expanded computer system.

Since 1938 when the original drug division went into effect, FDA has reviewed more than 13,500 applications and approved around 9,000 drugs, including such products as the dental anesthetic, carbocaine; the tranquilizer meprobamate and the antibiotic erythromycin.

Thousands of new drugs a year are being tested, and the enormity of the paper work will increase under the new regulations. They stipulate that FDA must be given full details about the distribution of drugs for investigational use and about clinical investigations which must be properly conducted by qualified investigators.

Clinical investigations must be based on adequate study of animals to assure safety.

Dr. Kelsey said that although animals never "mirror thoroughly a human being," they provide vital background research.

Doctors trying out "investigational" drugs must get their patients' consent under the new drug regulations.

However, physicians will be allowed to use their judgment in case the consent is "not feasible or is contrary to the patient's best interest."

Both doctors and pharmaceutical industry spokesmen said that the revised regulations, originally proposed in August 1962, are a great improvement over previous ones.

Commenting on the influence of thalidomide in bringing about the Kefauver-Harris Amendments of 1962, Dr. Karl Bambach, executive vice president of the Pharmaceutical Manufacturers Association, said the old law had kept many tragedies from occurring in this country.

"It is typically illogical thinking in the U. S. that because something happened in Europe we should change the laws here," Dr. Bambach said in an interview.

Commissioner George P. Larrick of the Food and Drug Administration said the newly issued regulations "provide strong and necessary controls over the investigational use of new drugs and meet all of the new provisions" in the 1962 amendments.

Of the 300 written comments received by FDA during the waiting period before the final regulations were issued, 100 were filed by the pharmaceutical industry, setting forth step-by-step objections that have now been largely overcome. Dr. Bambach said.

An American Medical Association representative said that although the final form of the regulations has softened the "impingement upon the physician-patient relationship" relating to inspection of clinical records, the doctors are divided and there may be more "screams" from some of them.

The record-keeping requirements have been modified in two ways in response to objections. The original proposal called for "complete" records to be kept at every stage. Now "adequate" and necessary records are required.

Increased leeway is provided in making it possible to make extremely important new drugs, not yet approved for general distribution, available to patients "who might need them urgently as a life-saving measure."

Several drug firms had stated that they wished to import new foreign drugs for investigation without becoming the agent of the "foreign principal," as originally required. This is now permitted.

One objection was met to make it clear that treated animals "could be used for food if there was adequate evidence that no drug residues" were present in edible tissues or in eggs or milk from these animals.

In the first two phases of testing drugs on human volunteers, known as clinical pharmacology, the number of patients will be limited, with professional controls exercised by the organization doing the research to assure a large measure of safety.

Investigating physicians will be required to fill out forms regarding their education and experience to prove they are qualified.

Phase three is the clinical trial, in which a larger number of patients are given investigational drugs used by different physicians following substantially the same procedures.

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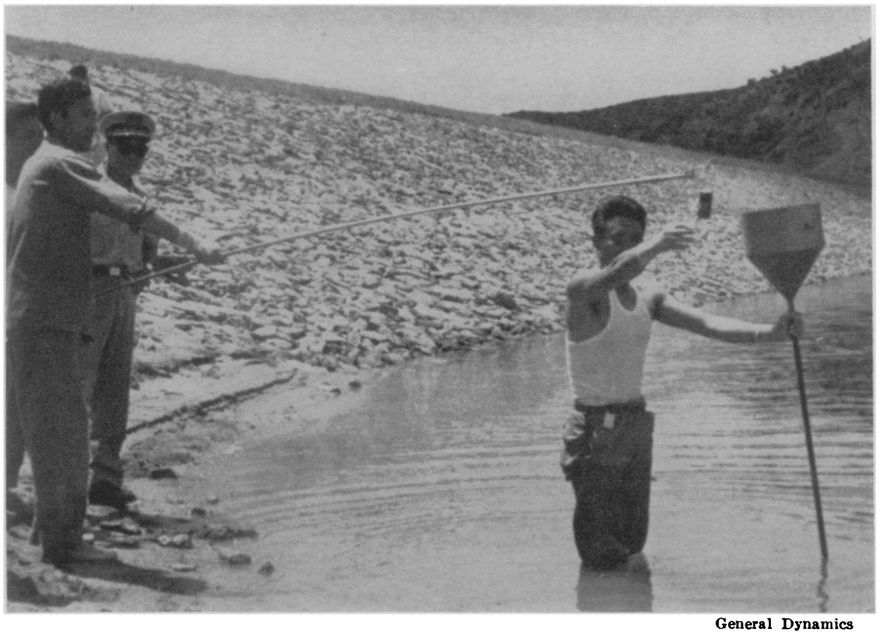

General Dynamics

RICE-PADDY LEAKAGE—Radioisotopes produced in the Republic of Korea's first atomic reactor, an American-made TRIGA, deposited in Kihung reservoir south of Seoul, solved the puzzle of water leakage from rice paddies that had baffled the Ministry of Agriculture for two years.

MEDICINE

New Anticancer Drug Prolongs Animal Survival

➤ A NEW ANTICANCER drug, MPT, has been reported by scientists working at the Lederle Laboratories, Pearl River, N. Y.

This drug has resulted in longer survival time for mice with breast tumors than any other cancer-fighting drug observed in those laboratories. It is still in the stage of animal experimentation and no plans have been made for human trials.

The chemical composition of MPT, which also has the advantage of causing no bone marrow destruction, is 1,4-dimethyl-1,4-diphenyl-2-tetrazene.

MPT-fed mice survived 100 days in contrast to mice surviving 50 days when treated with Thio-tepa, another Lederle drug that has also been used on humans with some success.

Drs. Adolph W. Vogel, Adolph E. Sloboda, Andrew S. Tomcufcik and Ralph G. Child, who reported preliminary findings in Nature, 197:85, 1963, said they are preparing extensive reports on this promising new drug.

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