COMPARATIVE PHARMACOLOGY

Researcher Proposes Human Testing First

The doctor wrote out the prescription: Three times a day. A couple of days later he had another patient with much the same general complaint. He prescribed the same drug, three times a day. The first patient was a 250-pound man. The second patient was a 125-pound woman. Some of the data on the drug might have been derived from tests on a 40-pound dog.

In the case of the woman the dose could have been toxic. In the case of the man it might well have not been enough. It might have cured the dog.

With the object of examining these problems and of eventually being able to deal with just such situations, three of the National Institutes of Health called an international meeting on comparative pharmacology recently.

Doctors are slow to recognize how much variation there is between individuals and how much this influences the action of drugs in their patients, declares Dr. Bernard B. Brodie of the National Heart Institute.

But while these factors can be controlled by alerting physicians and pharmacologists to this possibility, the real problem facing the conferees was the information that could be obtained from animal drug studies.

For drug testing purposes there is no animal that is like man anywhere, Dr. Brodie says. This means that there is an almost insurmountable barrier to drug development because the traditional method of testing in animals is not always applicable.

Perhaps our philosophy of drug screening needs re-evaluation, he suggests. Instead of screening new drugs in animals to see if they are worth trying out in man, perhaps we ought to screen them in animals only when we have data from man.

It is a fact that many drugs would never have been discovered if animal screening alone had been the deciding factor. Phenylbutazone, one of the non-addicting pain-killers, widely used now as an antirheumatic agent, is one such compound. It is metabolized so quickly in most laboratory animals that it has no effect. But in man it lasts for three days.

On the other side of the coin are drugs that are so stable that their effect lasts for much longer than might be suspected. Procaine for example, given to racehorses to anesthetize them against pain from leg injuries, lasts so long it acts as a stimulant, not just an anesthetic. Horses so doped would go on to win their races, sore legs and all.

In another instance the drug chloramphenicol, an antibiotic, was once thought to cause a special disease that kills the newborn. Actually, it was eventually discovered that the drug is metabolized so slowly in children that they died of overdosage.

We are coming more and more to realize that it is necessary to treat patients individually, Dr. Brodie declares. We must learn to calculate drug dosages for each individual in order to take advantage of these newer drugs which, while they may be increasingly more effective, are also increasingly more toxic.

"If we don't learn how to control them, we won't be able to take advantage of them," he says.

CANCER VACCINE

FDA Seizes Anticancer Drug

A 10-year-old Austrian boy dying of leukemia traveled from his home in Neuegg to Cleveland where he received an anticancer vaccine he hopes will save his life.

The vaccine, called the Rand Coupled Fortified Antigen, has been the object of worldwide attention as the result of newspaper and magazine stories in the last few months reporting dramatic remissions of disease in terminal cancer patients in initial human tests of the drug.

While Reinhard Kreutzer was waiting to see what effect the vaccine might have on him, agents of the Food and Drug Administration seized vials of the alleged cancer cure in New York and Miami on grounds that its shipment in interstate commerce violates FDA's prohibition against its use.

In New York, 35 vials were confiscated from Dr. J. Ernest Ayre, a pioneer in research leading to the pap test for cervical cancer. Dr. Ayre also owned the 88 vials seized in Miami at the May B. Stewart Laboratories.

Under Federal food and drug law, before a product can be approved as an investigational new drug for use in controlled clinical studies, it must meet Government standards for safety and efficacy in extensive animal experiments. This drug has not gone through such a regimen to the satisfaction of scientists at FDA and the National Institutes of Health.

The Rand Development Corporation of Cleveland, manufacturer of the new vaccine, submitted an application that was turned down because of insufficient scientific data. The company has not yet submitted additional material in support of its claims that the product is safe for use on humans.