lan (D-Ark.), it would create change but leave the system basically untouched, a pleasing thought to conservative Patent Commissioner William E. Schuyler Jr., who succeeded the more liberal Edward J. Brenner.

One of the recommendations of the President's commission ignored by McClellan's bill was the suggestion that patents be granted to the first man to file an application rather than the one able to prove he had the idea first as is now the case. The proponents of first-to-file argued that it would encourage prompt disclosure of newly discovered technology, provide a fair and economical way of determining patent rights without going to court and bring the United States into line with most European countries.

Opponents of the first-to-file method —and they included the American Bar Association, the Electronic Industries Association, the Manufacturing Chemists Association, the American Chemical Society and most of the titans of U.S. industry—contend that such a law would work against the careful and diligent inventor who takes his time and would promote a rash of incomplete, inadequate and low quality applications flooding the Patent Office.

They argue further that it would mean more paperwork for inventors.

A major recommendation of the President's commission that is rejected in the bill—only about 10 out of 35 recommendations were accepted—concerns a clause stating that foreign inventors seeking to establish a date of invention in a contested case here cannot cite work done in their country prior to the filing of the application, while Americans contesting the claim can refer to laboratory notebooks and other prior evidence.

No one denies that the clause is discriminatory, and despite previous urging from the Johnson Administration, it remains in the bill, thanks to a private conversation between Schuyler and McClellan, who had included it in an earlier draft. Although, in fact, only a few dozen contested patent cases each year require invoking the clause, the concern is that retaining it might adversely affect present efforts to obtain an international Patent Cooperation Treaty (SN: 6/21, p. 596). Such a treaty, if enacted, could be the first step on a long road to a standard international patent for all nations.

The chances are that the bill will be reported out of the Senate Subcommittee on Patents, Trademarks and Copyrights sometime in the fall. It will go to the Senate Judiciary Committee and then to the Senate floor, where most likely it will be voted upon before year's end. Chances are that the House will not get it until 1970.

DRUG TESTING

Palliatives and revolution

When a drug company decides to test a new compound as a potentially marketable drug, an extensive series of chemical and animal tests is undertaken. When there are substantial data to show that the initial trials justify human experimentation, an application describing the drug and including the background of the drug-company-appointed researcher—physician or firm —who will test the drug on human volunteers is submitted to the Food and Drug Administration.

If the FDA approves the application, testing proceeds under the supervision of the sponsor—the drug company, not the FDA. After the initial testing period with individual and group volunteers, the results are compiled by the investigator, sent to the drug company, evaluated and submitted to the FDA for approval.

The FDA may reject an investigator if his background is not sufficient to test the drug properly. Or the agency may later reject the drug because of unfavorable test results.

The system doesn't work too well, and last week proposals were being made to change it.

The investigative studies, says FDA Commissioner Dr. Herbert L. Ley Jr., "should be undertaken primarily by an individual qualified to observe subtle pharmacologic effects during initial trials." Sen. Gaylord Nelson (D-Wis.) believes that "the accuracy and objectivity of some of these drug testers leave much to be desired."

Nelson points out that a physician may be tempted to turn in falsified reports so that his contract with the drug company can be renewed. "The dangers involved in the dependence on drug firms to perform, direct or arrange for the testing of drugs in which they have a financial interest," says Nelson, "is obvious."

On-site inspections of clinical investigators and their facilities are supposed to be conducted by an FDA physician and an inspector. Of over 100 inspectors only one or two actually go out into the field and that usually results from suspicious reports or findings. Approximately 15,000 clinical investigators have been testing drugs since 1966. "Obviously," Dr. Ley told Nelson's small business subcommittee last week, "this number is too large to permit routine investigation."

Since 1962 only 11 cases have been detected in which an investigator has been declared ineligible to carry out the human testing phase. Evidence that this number should be substantially higher and that more control is needed in drug studies has been brought to the foreground.

To ease the situation, Dr. Ley says there is a regulation under development that would establish peer review committees to evaluate and review the investigational studies conducted in institutions. This would be similar to the groups currently evaluating any research work funded by the Public Health Service.

Dr. Ley also proposes fewer but better studies. This, Dr. Ley says, would "reduce the number of clinical investigators and patient exposure to drugs, promote better monitoring and provide more reliable data which could be reviewed much more rapidly by FDA."

But a total revision of the system, not just a palliative, is Nelson's aim. Under a bill he introduced last week, proposed after two and a half years of hearings on the drug control problem, the Federal Government would assume responsibility for testing of drugs.

Some of the testing would be done by a National Drug Testing and Evaluating Center, but the secretary of the Department of Health, Education and Welfare would be authorized to contract out investigation of new drugs at the expense of the sponsoring company.

"We must," says Nelson, "remove the responsibility for testing drugs from the applicant who has a financial interest in the drug, as well as from those who are paid directly by the company to evaluate it. This responsibility must be placed with an evaluating group which has no interest at all in whether or not the drug gets into the market other than the interest of the public."

BLAIBERG DIES

Borrowed time ends

The world's longest-surviving heart transplant patient died at 7:40 p.m., Sunday, Aug. 17, at Groote Schuur Hospital in Capetown, South Africa. Chronic rejection was the cause of death. Rejection problems have led to a decline in the number of heart transplant operations (SN: 6/21, p. 598).

Dr. Philip Blaiberg, the dentist whose own heart's failure would have cut off his life at the age of 58, lived to be 60 —19 and a half months after Dr. Christiaan Barnard transplanted the heart of 24-year-old Clive Haupt, who died of a brain hemorrhage. Dr. Blaiberg received his new heart on Jan. 2, 1968. He had pneumonia as well as kidney and liver failure when he died.

As of Aug. 18, 143 heart transplants had been performed; 38 survive. ◇