MEDICINE

Public Wary of Research

➤ PUBLICITY from the thalidomide disaster has made the public wary of research with all experimental drugs. The result may be more lawsuits, physicians were warned.

The "rash of emotional writings" exposed the details of poor clinical investigation for the first time and will undoubtedly make the public "suit-conscious," Dr. George E. Schreiner of Georgetown Hospital, Washington, D. C., said. The president of the American Federation for Clinical Research spoke at the American Medical Association's National Medicolegal Symposium at Miami Beach, Fla.

The National Institutes of Health and the Food and Drug Administration also were implicated in the present situation in which the clinical investigator is "out on a legal limb."

The rapid growth of clinical research centers sponsored by NIH appears to be a good thing on the surface, Dr. Schreiner said. But NIH has never made a clear statement as to the legal liability for admitted mistakes or for the consequences of negligence in human research.

Health insurance plans also have not clearly accepted liability for such accidents, mistakes or even illnesses during the course of experiments, he said.

One of the loopholes allowed in the FDA technical directions for clinical investigators is that consent of the subjects or their representatives must be obtained, except where this is not feasible or, "in the investigator's professional judgment, is contrary to the best interests of the subjects."

No investigator can now know how the courts will accept this exception, Dr. Schreiner said.

But the purpose of clinical research is not necessarily to remain safe, to please lawyers, to satisfy bureaucrats, to avoid controversy or even to avoid lawsuits, he stated. One can avoid them by not doing clinical investigation. The purpose of drug investigation is to acquire and interpret reliable data that may lead to the proper application of new therapeutic agents. However, the investigator must take full responsibility for his professional decisions.

• Science News Letter, 83:178 March 23, 1963

BIOCHEMISTRY

Antibodies "Blueprinted"

➤ LIVER CELLS seem to play a role in "blueprinting" the human body's germ-fighting antibodies, two University of California, Los Angeles, bacteriologists, Drs. Donna Vredevoe and Eric Nelson, suggest.

This new evidence may lead to a possible shortcut in immunization.

When germs or other "outsiders" invade the body, they are identified as invaders because of certain foreign materials in their makeup known as antigens.

Each "outside" substance has its own characteristic antigens. It is these foreign materials that stimulate production of germ-destroying antibodies against a particular disease organism.

For some time it has been known that liver cells take up large amounts of antigen. But there has been no evidence that the liver itself makes antibodies. The UCLA bacteriologists wanted to determine what role, if any, the liver played in antibody production.

They injected an antigenic material, serum albumin from cattle, into mice. They later extracted liver cells from these mice and placed the cells in small chambers whose walls had microscopic pores.

The chambers were then implanted in mice that had not been injected with albumin. These mice developed antibody responses just as if they had been injected with the antigenic albumin originally.

This suggested that the implanted liver cells had blueprints for antibodies against the albumin and sent them out through the tiny pores in the chamber wall. Antibody mechanisms of the mice were then able to make antibodies from the blueprints.

The UCLA bacteriologists said that if the blueprint substance could be isolated chemically, this might lead to a shortcut in the immunizing process. It might be possible to make a vaccine of the blueprint substance itself rather than of the antigenic material, such as killed viruses, now used.

A faster antibody response should occur with this type of vaccine.

• Science News Letter, 83:178 March 23, 1963

PUBLIC HEALTH

Antibiotic Resistance Raises Pneumonia Deaths

➤ PNEUMONIA deaths have risen in the past few years, probably because of increased prevalence of organisms resistant to antibiotics. Staphylococcus aureus is believed the culprit. Bronchopneumonia has shown the largest increase, with 34,405 deaths in 1960, an increase from 12.3 per 100,000 population in 1954 to 19.2 per 100,000.

This leaves out influenza with pneumonia and pneumonia of the newborn, under four weeks. It also omits Army, Navy and Marine Corps statistics.

Dr. Clara E. Councell, deputy chief of the Office of Health Statistics Analyses of the Public Health Service, reported the study on recent trends for pneumonia mortality in Public Health Reports, 78:178, 1963.

• Science News Letter, 83:178 March 23, 1963

MEDICINE

Heart Disease Attacks Inactive, Indolent Men

➤ THE POPULAR conception of the person likely to have a heart attack as tense, driving and ambitious has been shown to be wrong in a community study. Indolence characterized the patients preceding their attacks.

The study, reported in the New England Journal of Medicine, 268:569, 1963, was undertaken to get information concerning fatal coronary disease, affecting the arteries supplying the heart muscle, in patients between 32 and 50 years old.

Of the 122 male patients studied, 68% worked indoors exclusively. Sixty-six percent customarily got their recreation from television, reading and visiting.

Only 10 of these men were alcoholic but 111 were smokers, 89% of them for 20 years. Only 12 had used cigars or a pipe.

A unique feature of this study was that an entire community—Seattle-King County, Wash.—was covered. Fatal heart cases were taken from recorded deaths in one year in this community of one million persons. Response to detailed questionnaires sent to relatives of the deceased was 100%.

Among 11 women studied, nine had not yet reached the menopause, which contradicts the theory that female hormones, estrogens, reduce the occurrence of hardening of the coronary arteries. The other two women had had hysterectomies but ovarian tissue remained, which probably formed hormones.

The report from the Seattle-King County Department of Health was by Dr. Cedric R. Bainton, assigned from the Heart Disease Control Program, U.S. Public Health Service, and Dr. Donald R. Peterson of the local health department.

• Science News Letter, 83:178 March 23, 1963

BIOCHEMISTRY

Chemical Reduces Fever, Inflammation

➤ MORE EFFECTIVE relief from fever and inflammation is given in actual treatment of human patients by a new chemical that is 10 to 85 times more potent than a drug now used, phenylbutazone.

Tests on patients show that the new compound for rheumatic arthritis is about one-fourth to one-half as potent as the favorite drug, cortisone, which is a steroid, or hormone.

The new material does not seem to depend on the pituitary and adrenal glands, as hormones do, because it acts in animals whose adrenal glands have been removed. It is reported to be relatively free of side effects.

Called indomethacin, its chemical composition is 1-(p-chlorobenzoyl)-5-methoxy-2-methylindole-3-acetic acid, Drs. T. Y. Shen and Charles A. Winter of Merck Sharp & Dohme Research Laboratories, reported in the Journal of the American Chemical Society, 85:488, 1963.

• Science News Letter, 83:178 March 23, 1963