PUBLIC HEALTH

# Drug Safety Meeting

## Drug Court Planned

➤ A SUPREME COURT on drug safety will be set up in September by the National Academy of Sciences and the National Research Council. It will be a neutral body to which both Government and the drug industry can turn for help.

The existing Commission on Drug Safety set up last August as a result of the thalidomide tragedy will go out of existence.

"The drug safety problem is much wider than the Food and Drug Administration," Dr. R. Keith Cannan, chairman of the National Research Council's division of medical sciences, said. "As the pressure of urgency over thalidomide levels off, interpretations of the wording of the FDA regulations will have to be made and, in the nature of things, adjustments will have to be made."

Gripes against the FDA regulations were aired in Chicago at the first conference of scientific and professional societies since the thalidomide tragedy. But a panel of the 14 societies represented on the Commission on Drug Safety showed a disposition to cooperate.

The present committee will issue reports from 17 subcommittees before it dissolves. The Pharmaceutical Manufacturers Association gave a grant to the Commission on Drug Safety.

If existing Food and Drug Administration regulations really become a bottleneck to the development of new drugs beneficial to mankind, they can and will be modified, Boisfeuillet Jones, special assistant to the Health, Education and Welfare Secretary on health and medical affairs, declared.

• Science News Letter, 84:21 July 13, 1963

## Improve FDA Staff

➤ GUIDANCE in new drug regulations and testing, not policing of the manufacturers, is needed from the Food and Drug Administration.

This will be possible only with an improved FDA staff, said Dr. Thomas Francis Jr. of the University of Michigan's School of Public Health.

"FDA's purpose should be to encourage investigation of high standards in research, not just to prevent poor procedures," Dr. Francis told the Commission on Drug Safety's first conference of professional and scientific societies since the thalidomide episode.

"In an epidemic or catastrophe it is common practice that an aroused public opinion votes money for changes," Dr. Frances pointed out. He said the "scientist's back is bent by the evangelical storm and orderly procedure is lost in expediency."

Consultation and discussion are needed between basic and clinical scientists, drug producers and Government agencies.

"When a Government agency draws up restrictive regulations without this consultation," Dr. Francis said, "the policing is uppermost and the guiding philosophy breaks down."

The responsibility to review procedures and improve knowledge for the betterment of mankind should not be lost in regulations, he warned.

About 300 representatives of scientific, medical, pharmaceutical and governmental organizations met in Chicago to "get a sense of direction" in the problems of drug safety.

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## FDA Rules and Research

➤ DR. FRANCES O. KELSEY, who got a medal from the President for keeping the deforming drug thalidomide off American drug counters, defended new Federal drug laws against claims that they will obstruct research.

She told delegates at the Commission on Drug Safety's Chicago conference of professional and scientific societies that recent criticisms by drug manufacturers and clinical investigators are based on "a misunderstanding or a misinterpretation" of the new regulations.

Congress recently tightened restrictions on the use of experimental drugs, following the tragic births in Europe of a great number of badly deformed babies whose mothers had taken thalidomide during pregnancy.

Dr. Kelsey, chief of the Food and Drug Administration's investigational drug branch, recalled that drug makers "expressed fears" about the effects of stronger regulations on research when the drug act was amended in 1938.

"Despite this, the intervening years have shown great progress in the development of new drugs," she said, "and it is now generally recognized that these advances were aided rather than hindered by the regulations."

She said some people are misinterpreting the new laws to mean that any drug used in research on humans must get special FDA clearance. The law applies, she said, only to experimental drugs.

She said it is "very far from the truth" that the FDA cracked down on the use of thalidomide on experimental animals.

"Even at the time that the supplies of thalidomide distributed for purposes of testing the drug as a hypnotic and sedative were being recalled, active clinical investigation with thalidomide in the treatment of cancer was underway," she said. "Animal work with thalidomide was pursued in many centers using various species of animals."

She said she has been asked frequently what FDA would do if permission were asked to market thalidomide as a sleeping drug for older people.

She pointed out that reports had indicated thalidomide used over long periods causes severe polyneuritis which was "apparently quite disabling and possibly not completely reversible in all cases."

She said this aspect of the drug has drawn little attention compared with its deforming effects.

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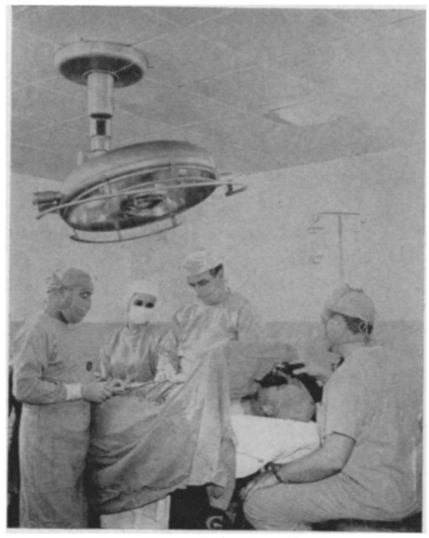

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## Babies Need Own Drugs

➤ DRUGS FOR BABIES have too often been hand-me-downs from adult medications, Dr. Harry Shirkey, head of Children's Hospital, Birmingham, Ala., reported.

"We have been cutting daddy's coat to fit his child," the pediatrician charged, "and only when children die from taking too much aspirin has there been any interest shown in drugs tailored to fit babies."

One advantage of the new Food and Drug Administration's regulations, he said, is that more research will be done on drugs suited to premature and newborn infants. It is not enough to cut down the dosage of an adult drug—many tiny babies have died from this practice, he said.

The Academy of Pediatrics, whose drug safety activities Dr. Shirkey reported in Chicago at the Commission on Drug Safety's conference of scientific and professional societies, has just appointed a committee to advise FDA on the effect of drugs on the fetus and newborn child as well as on infant diseases and poisoning of children.

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