

## MEDICINE

# Seek Drug-Review Panels

An advisory committee of top scientists from throughout the nation is being considered by the U.S. Food and Drug Administration to assure safer drugs for the public.

► TO INSURE SAFER drugs, the U.S. Food and Drug Administration is considering picking an advisory committee of top scientists throughout the country to help review drug applications.

Dr. Joseph F. Sadusk Jr., new director of FDA's bureau of medicine, told SCIENCE SERVICE that he hopes to call on such a committee for a series of panels to advise staff members in their drug-licensing job.

Dr. Sadusk's remarks coincide with a statement by Sen. Hubert H. Humphrey (D-Minn.) which says FDA has a "golden opportunity for improvement" under its new medical director.

The Senator, himself a pharmacist, is chairman of a Senate Government Operations Subcommittee, which recently released a 1,000-page volume related to hearings held during the past year on Federal drug problems.

Sen. Humphrey has made no attempt to conceal his dissatisfaction with FDA organization and procedures, although his suggestions include some of the very ideas that FDA hopes to put into effect.

"We desperately need the backing of Congress to obtain the necessary people and equipment to do our job," Dr. Sadusk said.



University of Michigan

**LABORATORY RIVER**—To study bacteria which cause harm in natural streams, scientists at the University of Michigan School of Public Health have built a miniature river in a laboratory that can simulate a variety of natural conditions. Jackson R. Pelton, research assistant, studies the running of the 15-foot-long river.

The new medical director's plans include allowing FDA staff scientists and physicians to spend a full day each week in Washington area universities. This will give them a chance to keep up to date and give FDA a better scientific reputation, he believes.

Dr. Sadusk himself plans to continue working 30 hours a month at George Washington University Medical School, Washington, D. C., with the approval of Secretary Anthony J. Celebrezze of the U.S. Department of Health, Education and Welfare. Dr. Sadusk is chairman of the GWU department of preventive medicine and director of university clinics.

"Good staff scientists can't be desk sitters," he said.

The Humphrey statement suggests that FDA "open a new era of dynamic cooperation with the scientific community." Together, he said, outstanding scientists of the food, drug, cosmetic and chemical industries, as well as in the universities, in private practice and Government should help "foster excellence in testing and evaluation."

One "disturbing" fact that Sen. Humphrey called attention to was that more than 15 drug companies have refused to furnish the FDA with information about fees they have paid to doctors for testing drugs. Although there is no legal reason for the companies to give these details, Sen. Humphrey urged them to comply with FDA requests.

"The size of fees paid for drug testing may or may not have an important bearing," he said. "But how can FDA possibly determine whether any improprieties or violations of the law have been committed if it cannot even get the elementary facts?" he said.

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## BIOCHEMISTRY

## New Birth Control Pill Ready After Ten Years

► A NEW PREGNANCY preventive, called Norinyl, available today for doctors' prescription, has had the longest testing of any birth control pill, ten years, to assure its safety as well as effectiveness.

Its major ingredient is a female hormone known as norethindrone, which is combined with a small amount of another female hormone compound, mestranol. These are the same ingredients that make up Ortho-Novum. Both pills have been licensed by the U.S. Food and Drug Administration.

Syntex Corporation in Palo Alto, Calif., which developed norethindrone, gives credit to Dr. Maximilian Ehrenstein, now at the University of Pennsylvania, for early work that led to the development of Norinyl.

Persons with the following conditions should not take the pill:

1. Thrombophlebitis, or vein inflammation, caused by a blood clot. This includes a history of this condition, or of lung embolism (clotting).
2. Breast cancer, or cancer of the reproductive tract.
3. Liver disease.
4. Heart abnormalities.
5. Kidney abnormalities.

Norinyl in two-milligram doses, which are prescribed for 20 days each month, was tested on 4,194 women of an average age of 26.6 years, who were known to be capable of bearing children. There was not one unplanned pregnancy for a period of 24,409 menstrual cycles.

When any of these women wanted to have a baby, conception took place promptly after they stopped taking the drug.

Numerous other clinical reports on 10 milligram doses of Norinyl showed it to be safe, with a few side effects.

Syntex Laboratories expect to continue testing Norinyl to learn the exact mechanism by which the drug combination works.

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## EMBRYOLOGY

## Lungs Act Like Kidneys In Baby Before Birth

► BEFORE BIRTH, the lungs of a baby seem to act as kidneys, perhaps filtering the blood to form a special lung fluid.

At that time, the lungs have no breathing function but may have an important role in maintaining the "bag of water" that insulates the unborn baby during pregnancy.

Dr. Forrest H. Adams and associates at the University of California at Los Angeles Medical School have produced experimental evidence to show that the fluid produced by the lungs appears to go out through the nose to help maintain the liquid environment of the fetus. This liquid environment is known as the amniotic fluid.

It has been believed by many medical scientists that the fetus actually breathes, but only as a sort of "tooling up" procedure, since breathing would serve no other function in the liquid environment. The fluid in its lung was considered to have been amniotic fluid inhaled by the fetus.

Evidence obtained by the UCLA investigators and others indicates that the baby does not normally attempt to breathe prior to birth.

It further indicates that the lung fluid not only contributes to the "pool" surrounding the baby but helps to condition the lung and windpipe for the job they have to do as soon as the baby is born. In less than a fifth of a second of the first breath the new-born's lungs are inflated and the lung fluid is dispersed.

The research has shown that the fetal lung fluid contains a soapy substance known as surfactant. It is this substance that lines the lung, and after birth facilitates the exchange of gases between the lungs and blood. This substance is not present in the baby with pulmonary distress syndrome, the disease also known as hyaline membrane.

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