

Stubborn Woman Doctor Credited With Preventing A U.S. Tragedy

(EDITOR'S NOTE: This is the story of a woman who refused to let criticism sway her doubts about a new drug. Her refusal to approve its sale in the United States may have prevented thousands of babies from being born with deformities.)

By LEON BURNETT
United Press International
WASHINGTON (UPI) — Dr. Frances Oldham Kelsey of the Food and Drug Administration (FDA) has been called a stubborn woman. She also has been called an unreasonable bureaucrat.

But Assistant FDA Commissioner Winton B. Rankin says the American public owes her a vote of thanks for that stubbornness. Rankin confirmed that Dr. Kelsey may have prevented "an American tragedy" by her steadfast refusal to allow the marketing in this country of a sleeping pill later linked to grotesque deformities in newborn children.

The 47-year-old drug specialist withstood a barrage of criticism before a medical investigation eventually proved that her suspicions were well-founded. The story, which was related Sunday by the Washington Post, involves a drug with the chemical name thalidomide and a rare type of birth defect known as phocomelia.

West German Development
Thalidomide was developed in 1954 by a West German firm but was discarded because it showed no effect on test animals. In 1958 another German firm found that it produced ever — no hangover, no danger in overdoses.

Under the trade name of Contergan the drug found a booming

market in West Germany. It was sold in Britain as Distaval, in Portugal as Softenon, and in Canada as Talimol.

In September 1960 the William S. Merrell Co. of Cincinnati asked the FDA for clearance to market the compound in the United States.

The thalidomide application became the first assignment for Dr. Kelsey who had just joined FDA. Along with the application came data claiming the drug to be safe for use. But Dr. Kelsey was not convinced. She repeatedly refused to approve the drug and her superiors backed her up. Dr. Kelsey says there were insinuations that she was a hairsplitter, an unreasonable bureaucrat that she was stupid. But she refused to budge from her position.

Affliction Becomes Common
In 1961 West Germany found itself confronted by a vexing medical problem. Phocomelia, an affliction so rare that some medical dictionaries do not even list it, was becoming all too common.

Ordinarily, a victim of phocomelia is missing one arm and small rudimentary fingers grow from the stub. But the cases in Germany were worse. Some infants were born with both arms or legs missing, others with three limbs and a few with none at all.

A variety of possible causes, from heredity to radioactive fallout, were considered and discarded. Then last November Dr. W. Lenz, a Hamburg pediatrician, conducted a study which showed that about 20 per cent of the mothers of deformed infants whom he treated had taken thalidomide. After further investigation, he found the rate went up to 50 per cent.



TRAGEDY PREVENTED — Dr. Frances Oldham Kelsey is shown with her two daughters, Christina, 12, left, and Susan, 15, right, in their home Sunday. Dr. Kelsey, a 47-year-old specialist on drugs with the Food and Drug Administration, was reported to have prevented "an American tragedy" — the birth of perhaps thousands of babies with missing arms and legs. Dr. Kelsey prevented the marketing of a sleeping pill, Thalidomide, later linked to deformities in the newborn. (UPI Telephoto)

tion, he found the rate went up to 50 per cent.

The drug was found to be dangerous to the unborn when taken by the mother within 20 to 40 days after conception. During this period, Dr. Lenz believes, the chances are at least two in five that the baby will be affected.

Removed From Market
Thalidomide was removed from

the market in Germany and elsewhere. But it is estimated that by the end of August the number of deformed children born in West Germany will be between 3,500 and 6,000. One of three is expected to die.

Dr. Kelsey, wife of another pharmacologist, F. Ellis Kelsey, special assistant to the surgeon general, and the mother of two daughters, 15 and 12, had this to

say about her role in keeping the drug off the American market:

"They certainly thought I was unreasonable. But I didn't feel the material to back it up was very adequate."

"The company was very anxious to get the stuff on the market, but this was routine." The whole general tenor of the criticism of her "was sort of a 'stubbornness,'" she said.

Crucial Senate Vote Scheduled On Compromise Aged Care Bill

WASHINGTON (UPI) — The Senate today will put in its last day of debate before it casts a crucial vote on a compromise medical care bill.

Administration forces planned to spend the day lining up every bipartisan proposal. A hairline close contest was forecast on a motion to table — or in effect, kill — the measure. The outcome possibly will be decided by only one or two votes.

The bill, although sponsored by some Republican as well as Democratic senators, is under strong attack by conservatives from both sides of the aisle.

The compromise plan retains the Social Security approach deemed essential by President Kennedy. This would provide for financing of the aged care program through the Social Security system.

In order to attract Republican votes, the administration agreed to broaden the plan so that initially it would be open to all of the nation's elderly, whether or not they were covered by Social Security.

EIGHT MINERS KILLED

ASHIBETSU, Japan (UPI) — Eight miners were killed and five others injured Sunday when accumulated coal gas exploded in a mine here, according to officials.

Investigators said they believed the blast was touched off by an electrical short circuit in the mine's ventilating system. It wrecked more than 600 feet of the mine.

Other congressional news:

Estes: A House government operations subcommittee will resume its inquiry into the operations of Billie Sol Estes as a Senate subcommittee takes a few days recess. Chairman L. H. Fountain, D-N.C., has called Agriculture Department officials to testify today in the case of the Texas farm financier. The Senate investigations subcommittee will start its hearings again on Wednesday.

Highways: The House highways

investigating subcommittee was scheduled today to start its second week of hearings into the federally assisted road building program of West Virginia. The subcommittee planned to question witnesses on previous testimony suggesting that on one project in Beckley, W. Va., the state roads commission appeared eager to pay property owners many times more than their property was worth.

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Weekend Highway Mishaps Claim Fifty-Two Americans

By United Press International
Americans died by the dozen in multiple death traffic accidents over the weekend.

Thirteen traffic accidents in 11 states claimed a total of 52 lives. A father and three sons drowned in Lake Superior.

Three persons were killed in a plane crash in upstate New York. The nation's worst weekend accident occurred near Fayetteville, Tenn., when seven members of a vacationing Albertville, Ala., family lost their lives Saturday. Their car crashed into a bridge, killing three women, three children and a man.

Georgia, Alabama and Oklahoma each had accidents which claimed five lives.

Five persons died Sunday night in the fiery collision of two autos on a city street in Mobile, Ala.

Four In Family Killed

A minister, his wife, two children and a friend of the family were killed and another of the clergyman's children injured when their auto collided with a Frisco Railroad train Sunday at Quapaw, Okla., while the six were en route to church services. All were from Quapaw.

A three-car accident near Glenview, Ga., Saturday night killed five persons and injured four.

Indiana, Kansas and Ohio each reported four-death accidents.

Four persons were killed and two others hurt Sunday in a two-car crash on U.S. 30 near Lima, Ohio.

Four persons were killed and four injured Saturday night when two cars collided at a county road intersection near Geneseo, Kan.

Four persons, including three young sisters, were killed and four others injured in a head-on collision southwest of Indianapolis Ind., Friday night. All were from Indiana.

California reported three separate three-death accidents.

Three persons were killed in a two-car collision Saturday night on the Eastshore Freeway near San Pablo, Calif., north of Oakland.

All the dead were Californians.

Three Generations Killed
A grandmother, daughter and granddaughter lost their lives Saturday when their car hit a tree along U.S. 101 in San Diego, Calif. All were from Los Angeles.

Three persons, all from San Diego, Calif., were killed Friday night when a stolen car crashed into their station wagon during a police chase in El Cajon, Calif.

Three persons were killed and two injured Sunday night when a car being pursued by police crashed into a station wagon at Cleburne, Tex.

Three persons, including a bride of 20 days, were killed in a two-car accident northwest of Denver, Colo., Sunday. Two other persons were injured. All were Coloradans.

Three men were killed Friday night in a one-car accident near Woodbine, Iowa.

Atmosphere Test Slated Wednesday

HONOLULU (UPI) — The United States may detonate its highest nuclear blast yet next Wednesday at Johnston Island, according to sources close to Joint Task Force 8.

Preparations were reported being made today for the fourth firing of a missile-borne nuclear device from Johnston.

Two of the previous firings were failures which were destroyed in flight. The third lit up the Pacific skies like a rainbow when it was exploded at a height estimated between 200 and 400 miles.

The next and possibly last shot of the Johnston series is expected to be detonated about 500 miles high, but with nuclear power far less than the shot last Sunday night.

The Atomic Energy Commission said that this year's series of tests at Christmas Island had been completed after 26 blasts.

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