

Thalidomide Experience Reveals Need for Tighter Drug Regulations

Editor's note: This is the last of three dispatches on the Thalidomide tragedy. It spells out existing government rules for regulating new drug products and explains new legislative proposals being advocated for protection of the public.

By RONALD H. NESSEN
Washington — (UPI) — America's narrow escape from the tragic consequences of Thalidomide on newborn infants paradoxically shows both the effectiveness of current drug laws and the need for tighter restrictions.

Existing regulations, enforced with dogged determination by Dr. Frances O. Kelsey of the Food and Drug Administration, blocked the sale in this country of the German-developed sedative which has been blamed for the birth deformities of children in Germany, England and Canada.

But there were no rules to prevent the American manufacturer, W. S. Merrell Co., of Cincinnati, from sending Thalidomide to 1,231 doctors for testing on human patients.

There is no rule requiring that patients be advised when they are given an experimental drug. There is no rule requiring that the government be notified in advance when a manufacturer distributes medicine for so-called "clinical testing" on human beings.

Procedures Considered
President Kennedy told his news conference last week the government was considering how to tighten administrative procedures to make the testing of new drugs on humans less dangerous.

Kennedy also urged Congress to approve this year the legislation he proposed to toughen safeguards against dangerous and useless drugs.

The bill is needed, he said, "to prevent even more serious disasters" in the future. No drug may be sold in the United States unless it is approved by the Food and

Drug Administration. About three in every 10 drugs submitted to the FDA are rejected. It takes the agency an average of 62 days to approve a new drug. However, many cases stretch out for six months or more and in some instances the process takes two or three years.

Tested on Animals
Before applying to the FDA, a manufacturer tests a new drug on several species of animals. If no ill effects show up, the next step is to try out the compound on humans.

This is done by sending the drug to a selected list of doctors who agree to give it to their patients and report back the results.

Kennedy, FDA officials and others feel this is one of the most dangerous points in the drug testing process.

Among the new administrative moves under consideration by the FDA to make this step safer is stricter policing of doctors supplied with experimental drugs to make sure they have adequate test facilities and submit meaningful reports to the manufacturer.

When the 60-day period after which the firm automatically could have marketed the drug expired, she ordered an extension. She did this again and again with the backing of her superiors.

In February, 1961, Dr. Kelsey changed to read in the British Medical Journal a report suggesting that use of Thalidomide over a long period might lead to a condition marked by numbness and itching in the hands and feet.

This was the first hint that the drug might have toxic effects.

Then, Merrell was notified from Europe late last November that Thalidomide given to mothers in the early months of pregnancy was suspected of causing phocomelia — a heretofore rare malady in which babies are born with flipper-like arms, missing limbs and other deformities.

Application Withdrawn
On Nov. 30, 1961, Merrell notified the FDA of this report and withdrew its application for approval to sell the drug in the United States.

At the same time, the company contacted the doctors testing Thalidomide on humans and warned them not to give it to women of child-bearing age.

Rate Hearings For Truck Freight To Be Continued
Salem — (UPI) — Another phase of the hearings to raise truck freight rates in the state 10 per cent has closed.

Salem hearings on the request of the Pacific Inland Tariff Bureau against Western Land, which have been going on all this month, resume in Portland Aug. 15.

The proposed rate increase would include all truck freight shipments in the state.

The increase is sought to offset higher labor costs brought about by a recent contract.

It would replace a temporary additional per shipment charge now in effect pending the outcome of the present hearings before a Public Utility Commission examiner.

PUC officials said that if the requested rate increase is granted it would boost truck rates above the present temporary level.

Most of the witnesses who have appeared before Hearing Examiner Malcolm Jones so far have been representatives of the trucking firms who have favored the increases.

Opponents are expected to be heard at the coming Portland session. In addition to the 10 per cent rate hike to increase shipments of 20,000 or more pounds three cents per hundred and increase the present \$2.50 minimum shipping charge to \$3.

Oregon Highway Group Sells Timber
Salem — (UPI) — The State Highway Commission Thursday sold for \$386,000 timber on land that it bought for less than \$3,000 in the 1930s.

The timber is located on three of five tracts bought for right-of-way and forest waysides on the Carpenterville-Brookings section of the old Coast highway.

The high offer in competitive bidding came from Brookings Plywood Co. No offers were made on the other two tracts.

The commission will keep the land.

Also said to be under study are new regulations to require drug makers to notify the FDA when they start testing a new medicine and to inform the agency immediately if any injurious side effects turn up during tests.

Under current procedures, a drug manufacturer comes to the FDA only after tests on animals and humans are complete and the firm is seeking approval to market the product.

Permission Asked
In September, 1960, the Merrell Co applied to the FDA for permission to market Thalidomide, a drug widely used in Germany and elsewhere abroad as a sleeping pill which left no hangover and was free of the danger of overdose.

The application was handed over to Dr. Kelsey, a Canadian-born pharmacologist and physician. It was her first assignment upon joining the FDA.

In the face of what she recalls as Merrell's "very anxious" desire to win approval, Dr. Kelsey was not convinced by the data the company submitted claiming Thalidomide was completely safe.

Dr. Brown, formerly graduate research professor in the psychology department at the University of Florida, received his master's degree from the University of California and his doctorate from Yale university.

Before joining the University of Florida staff he was on the faculty of both Harvard and Yale universities and the State University of Iowa.

Dr. Brown, author of the book, "The Motivation of Behavior," is a Fellow of the American Psychological Association, an honorary life member of the Midwestern Psychological Association and a charter member of the Psychonomic Society.

Motivation Authority Joins Medical Staff
Portland — Dr. Judson S. Brown, nationally recognized authority on motivation, has been appointed professor of medical psychology at the University of Oregon Medical School, according to an announcement by Dr. D. W. E. Baird, dean.

Dr. Brown, formerly graduate research professor in the psychology department at the University of Florida, received his master's degree from the University of California and his doctorate from Yale university.

Before joining the University of Florida staff he was on the faculty of both Harvard and Yale universities and the State University of Iowa.

Dr. Brown, author of the book, "The Motivation of Behavior," is a Fellow of the American Psychological Association, an honorary life member of the Midwestern Psychological Association and a charter member of the Psychonomic Society.

Dr. Brown, formerly graduate research professor in the psychology department at the University of Florida, received his master's degree from the University of California and his doctorate from Yale university.

Before joining the University of Florida staff he was on the faculty of both Harvard and Yale universities and the State University of Iowa.

Dr. Brown, author of the book, "The Motivation of Behavior," is a Fellow of the American Psychological Association, an honorary life member of the Midwestern Psychological Association and a charter member of the Psychonomic Society.

Dr. Brown, formerly graduate research professor in the psychology department at the University of Florida, received his master's degree from the University of California and his doctorate from Yale university.

Before joining the University of Florida staff he was on the faculty of both Harvard and Yale universities and the State University of Iowa.

Dr. Brown, author of the book, "The Motivation of Behavior," is a Fellow of the American Psychological Association, an honorary life member of the Midwestern Psychological Association and a charter member of the Psychonomic Society.

Dr. Brown, formerly graduate research professor in the psychology department at the University of Florida, received his master's degree from the University of California and his doctorate from Yale university.

Before joining the University of Florida staff he was on the faculty of both Harvard and Yale universities and the State University of Iowa.



WALKS OUT — John Albert Kerr, 46, whose death sentence was commuted by California Gov. Earl Warren in 1953, is shown as he walked out of San Quentin Prison, subject to parole supervision for life. Kerr was convicted of first degree murder in the slaying of Troy R. Buckles, Fresno grocer, in 1950. Kerr will not be permitted to return to Fresno. (UPI)

EXTRA

POCKET MONEY...

can make for a trunkful of good times this summer. Whenever you're vacation takes you, take enough money. One-visit service.

LOCAL IDAN
535 E. JACKSON BLVD.
Medford Shopping Center
Phone: 773-7456 Dick Webb, Mgr.
Open Friday Evenings 'Til 7

STAR GAZER

By CLAY R. POLLAN
Your Daily Activity Guide According to the Stars.
To develop message for the Saturday, read words corresponding to numbers of your Zodiac birth sign.

| | | | |
|-------------------|----------------|-----------------|---------------|
| ARIES | 1 Work | 21 Support | 61 Pattern |
| APR 21 | 2 Your | 22 Faces | 62 In |
| MAY 21 | 3 Change | 23 Be | 63 And |
| 7-19-30-41 | 4 Keep | 24 Just | 64 Surround |
| 24-27-27 | 5 Do | 25 Money | 65 Money |
| TAURUS | 6 Do | 26 Show | 66 To |
| APR 21 | 7 Some | 27 See | 67 Today |
| MAY 21 | 8 New | 28 Expects | 68 Let |
| JUNE 21 | 9 Figure | 29 New | 69 Daydream |
| 7-14-25-36 | 10 Friends | 30 Think | 70 Be |
| 47-58-67 | 11 Work | 31 Or | 71 Will |
| CANCER | 12 Personal | 32 And | 72 You |
| JUNE 21 | 13 Advice | 33 Let | 73 You |
| JULY 21 | 14 Advice | 34 The | 74 You |
| 3-18-29-40 | 15 Advice | 35 Let | 75 You |
| 61-71-79-83 | 16 Results | 36 Let | 76 You |
| LEO | 17 Friendships | 37 Results | 77 Health |
| AUG 23 | 18 Good | 38 Prosperity | 78 Community |
| 23-24 | 19 Good | 39 And | 79 Definitely |
| 8-17-28-39 | 20 Good | 40 Conversation | 80 Air |
| 30-60-81-86 | 21 Peace | 41 Money | 81 Prosperity |
| VIRGO | 22 To | 42 Money | 82 Involved |
| AUG 23 | 23 To | 43 Where | 83 Plans |
| 30-60-81-86 | 24 Chances | 44 Goals | 84 Plans |
| WISCONSIN | 25 Writing | 45 Goals | 85 Benefits |
| AUG 23 | 26 And | 46 Limerick | 86 Indicated |
| 30-60-81-86 | 27 Oh | 47 Today | 87 Tide |
| 27-28-29 | 28 And | 48 Don't | 88 Others |
| 29-30 | 29 Your | 49 The | 89 Turn |
| 31-32-33-34-35-36 | 30 News | 50 Opening | 90 To |
| 37-48-88-90 | 31 Good | 51 Advice | 91 To |
| | 32 Good | 52 Advice | 92 To |
| | 33 Good | 53 Advice | 93 To |
| | 34 Good | 54 Advice | 94 To |
| | 35 Good | 55 Advice | 95 To |
| | 36 Good | 56 Advice | 96 To |
| | 37 Good | 57 Advice | 97 To |
| | 38 Good | 58 Advice | 98 To |
| | 39 Good | 59 Advice | 99 To |
| | 40 Good | 60 Advice | 100 To |

SEA SIREN OR CREST

FORMERLY 85c ea.
2 for 85c

CLOSE OUT SWIM CAPS WHILE STOCKS LAST

OREGON HIGHWAY GROUP SELLS TIMBER

Salem — (UPI) — The State Highway Commission Thursday sold for \$386,000 timber on land that it bought for less than \$3,000 in the 1930s.

REGRETTABLE WE FORGOT ABOUT XMAS CARDS IN OUR XMAS SALE

SO HERE THEY GO —
2 FOR THE PRICE OF 1

PACKING SUPPLIES

As in the past Western Thrift has a complete line of quality packers supplies at the lowest prices.

A FEW OF THE MANY ITEMS BEING FEATURED IN OUR COSMETIC DEPARTMENT AT VERY SPECIAL PRICES

COUNTLESS MARITZA

Summer Colognes **\$1.00**
5 POPULAR FRAGRANCES
A \$2.50 VALUE FOR

Tussy's Pink Cleansing Cream

PLUS SKIN LOTION OR SKIN FRESHNER **\$2.00**
\$3.00 VALUE BOTH

HEALTH EXAMS HELP THEM PASS SCHOOL EXAMS

INTRODUCING PERFECT-PAN

BLACK & WHITE FILM FINE GRAIN PANCHROMATIC
620 120 127 **3 Rolls 89c**

2 IN 1 FILM

BLACK & WHITE OR COLOR
620 120 127 **79c** Roll FREE DEVELOPING ON 2 IN 1 FILM THROUGH SEPT. 1

WE STILL HAVE A QUANTITY OF NICE TOYS AT 1/2 PRICE OR LOWER

land and other foreign countries. The new drug legislation Kennedy wants congress to approve would give the government control over manufacturing standards of medicine makers. The firms also would have to prove to the FDA that new drugs are effective as well as safe.

To accomplish this, the bill would require new drug applicants to open to government inspectors all records on the safety and effectiveness of a medicine.

Drug names would be standardized, the government would be given new authority to police the sale of barbiturates and stimulant drugs and a federal safety stamp would be required on cosmetics.

Could Order Withdrawal
The government would be able to order a drug withdrawn from sale if dangerous side effects showed up after the FDA had given its approval. At present, the government must seek a court order to halt the marketing of an approved drug.

The House Commerce Committee has held four days of hearings on the measure. A committee source says more hearings are planned but no date has been set. The outlook for the bill is not good.

The Senate Judiciary Committee has written its own drug bill which Kennedy says is too weak.

In criticizing this bill, Kennedy pointed to the complaints of Sen. Estes Kefauver (D-Tenn.), whose subcommittee conducted lengthy hearings on the drug industry.

Kefauver says the committee bill, a toned down version of his own recommendations, is weak because it lacks these provisions:
— A requirement that drug manufacturers meet specific production standards.
— A requirement that all drug advertising contain a

description of any side effects.
— A requirement that a new drug win positive FDA approval before it can be sold. This would replace the present practice of letting a manufacturer sell a medicine unless the FDA raises an objection within a specified period.

"MORE ECONOMY"

Memory Gardens

Memorial Park & Funeral Home
"A Name To Trust"
773-7338

Day or Night Service
Cemetery, Mortuary, Mausoleum, Cremations

MID-SUMMER SALE CLEARANCE SALE

REMEMBER
Prices listed in our XMAS in JULY SALE
Are in effect through Aug. 11th

A FEW CATS AND DOGS that need a new home

33c HAIR NETS

Popular Shades Pkg. of 6 **9c**

49c INSECT FOE

Liquid Bug Repellent..... **9c**

25c DR. BERRY'S

Complexion Soap..... **9c**

69c SKEETO-GO

Insect Repellent Stick..... **19c**

60c AMO-REX

Ammoniated Tooth Powder..... **19c**

19c ATLAS COMBS

Curl or Pocket Type..... **9c**

35c Combo Comb-Brush

All On One Handle..... **19c**

35c Goldie Shoe Kit

6 Individual Shines..... **9c**

25c LADIES' FOOT-SOX

Close Out Price..... **9c**

98c Wisley Bath Set

Miniature Cosmetics..... **29c**

98c BUBBLE BATH

Disney's Colorful Animals..... **29c**

WESTERN THRIFT

Medford's Original Discount Store
30 N. CENTRAL
773-5371

OPEN WEEK DAYS 8 TO 9—SUNDAYS 9 TO 2

RCA WHIRLPOOL Automatic Defrost Refrigerator With Freezer Below

TOTAL CAPACITY 13.8 cu. ft. FREEZER HOLDS 163 lbs.
32" wide 65" high

\$339.95
With Trade \$17.43 Month

Model HJ5148

JOHNSTON STORES 112 SOUTH RIVERSIDE
Soon To Be At The Medford Shopping Center