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CONGRESSMAN'S REPORT

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THALIDOMIDE: A CRIPPLING DRUG PROMISES GREATER PROTECTION FOR CONSUMERS

Thalidomide -- a tranquilizer and sleep drug -- has caused several hundred malformed babies in Europe and produced the Sherri Finkbine case in Arizona. But a by-product of these tragedies may be an improved set of laws affecting every American who uses prescription drugs.

Present drug laws and regulations are not as extensive as most Americans might suspect. And they are administered by a Food and Drug Administration which is understaffed.

The American manufacturer of thalidomide distributed his product to 1,248 American doctors who in turn gave it to more than 15,000 women. There was nothing illegal about this procedure. Under present FDA regulations a manufacturer need not even notify FDA when the firm sends trial samples to physicians in the "clinical investigation" phase of new drug development. Now the agency proposes to tighten its regulations to give the federal government a greater role in planning and watching the testing process.

However, FDA did keep thalidomide off the general prescription market. If it had not, thalidomide might have been prescribed by your doctor or mine and we would have had many thousands of additional women wondering about their coming babies.

Credit for this action goes to Dr. Frances Kelsey, a "bureaucrat" if you please, of the FDA. Despite considerable criticism and pressure, she kept thalidomide out of the corner drug store. Her stubborn skepticism saved many hundreds of babies from possible deformity and earned her the President's Award for Distinguished Federal Civil Service, highest honor for federal workers.

New Regulations and Laws

The thalidomide tragedy seems certain to result in better enforcement of existing laws, and passage by Congress of new laws aimed at further insuring public safety. No one wants any unnecessary regulation of any part of our lives; but failure to enact measures to protect us from preventable disasters is equally bad.

The Kefauver Investigation

Sen. Estes Kefauver of Tennessee has long been concerned with the high cost of some new miracle drugs and the laws regulating manufacture and prescription. In 1960 he held extensive hearings which disclosed a need for changes in the law. While American doctors have been

scrupulously careful with new and untested products, Senator Kefauver has questioned what he believes are some manufacturers' high-pressure advertising tactics directed at doctors as well as patients.

Regarding prices, it was pointed out, for example, that prednisolone costs 1.6 cents per tablet to make, sells to wholesalers at 14.3 cents and by the time it reaches consumers the price hits 29.8 cents or 1,763 per cent above manufacturing cost. The Committee figured an arthritic patient using prednisolone steadily would pay out $30 a month for a drug which cost $1.50 to manufacture.

As a result of his studies, Senator Kefauver introduced a highly controversial bill; President Kennedy supports some of its provisions; still other proposals have been made by different members of Congress. The drug manufacturers themselves have supported some of the proposed changes while opposing others.

Some Proposals

Here are some of the important changes being considered:

* Drugs would have to be shown to be EFFECTIVE as well as meeting present requirements for safety. Since 1913, hog, sheep and cattle owners have been not only protected against dangerous serums for their livestock but against worthlessones as well. The same protection would be provided for people who buy drugs for their own use.

* New drugs would not be placed on the prescription market until FDA approved them. At present, a new-drug application is automatically effective unless FDA acts against it.

* The FDA would be authorized a 25 per cent increase in staff.

* Advertising and information sent with drugs would be required by law to clearly state possible adverse effects.

* Manufacturers with drugs on the market would be required to report any information bearing on the safety or effectiveness of these products and the government could withdraw unsafe ones immediately.

* Patents on newly developed drugs would be exclusive only for three years (as against 17 years now), after which the patent holder would have to let other firms, for a fee, make and sell the drug.

* The generic name would be prominently displayed along with the brand name. This would enable persons to know what they are buying and would mean that if more than one manufacturer makes a drug, buyers could choose the brand with the lowest price. The Kefauver committee found that one drug could be purchased for $1.75 per 100 tablets if the prescription specified its generic name of prednisone whereas it cost $17.90 for 100 tablets if prescribed by a highly advertised brand name.

* The FDA would be given greater authority to institute inspection of manufacturers.

* A better system of preventing illicit use of barbiturates (sedatives) and amphetamines (stimulants) would be instituted.

Until thalidomide Sen. Kefauver was going nowhere with his proposals. Now the picture is altered. While not all of these changes will be approved, it is likely that before adjournment the Congress will make some needed revisions in the law. And for this, at least, we can thank thalidomide.