



Thalidomide.

FIGURE 2.

taken during a sensitive period, can cause phocomelia. A single dose of thalidomide at the sensitive time is thought sufficient to damage the embryo.

The most conservative estimate is that by August 1962, 3,500 babies will have been born in Germany with phocomelia; two-thirds of whom will live. England will probably have several hundred. The drug was not passed by the U.S. Food and Drugs Administration; therefore, its use was not permitted to the U.S. Army of Occupation in Germany, and consequently the wives of men in our Armed Forces have been spared. There were 16,000 births in 1961 among the wives of the Army of Occupation, and no cases had been reported up to March 10, 1962. The U.S. Army Headquarters had no knowledge of cases of phocomelia which might have occurred among German wives of American soldiers who were cared for by German doctors.

Although our law requiring careful tests on animals before a drug is released by the Food and Drug Administration has been a tremendous protection to our country, nevertheless, the routine testing of the effects of drugs on the offspring of pregnant animals is not regularly required. Needless to say, this experience in Germany and the British Commonwealth illustrates the need for stricter laws and for routine testing of the effect of all drugs on pregnant animals.

Definite proof that thalidomide does cause phocomelia must await further confirmatory animal experimentation or the cessation of the outbreak in August, 1962, which will be eight months after the withdrawal of the drug. Nevertheless, the circumstantial evidence is so strong that this drug does cause congenital malformations, and the effects on the children are so terrible that I feel that the situation should be brought to the immediate attention of the medical profession in this country. It is also important to remember that in many instances the damage is done before the mother knows she is pregnant. Therefore, young women must learn to be cautious about new drugs. Until research concerning the proper tests has been completed, doctors must bear in mind that sleeping tablets, tranquilizers, and other apparently innocent drugs may do terrible harm to the rapidly growing embryo and the unborn child.

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DANGEROUS TRANQUILITY

In late January 1962 my attention was attracted to an outbreak of congenital malformations in children in Germany and its possible relation to a specific drug. Because of my interest in congenital malformations of the heart I decided to examine the situation myself.

The malformation was phocomelia, which is characterized by reduction in the length of the long bones of the arms or legs, or both. In extreme cases the appendages are reduced to completely functionless nubbins. Occasionally the external ear is absent, and in the most severe cases the visceral organs are badly malformed.

Phocomelia has long been known as a rare malformation. In Germany, a few cases were seen in 1959, more were seen in 1960, and cases in "epidemic" numbers were seen in 1961. By November 1961, W. Lenz of Hamburg and W. G. McBride in Australia suggested that the outbreak was connected with the use of a new sleeping pill and tranquilizer containing thalidomide [alpha-(N-phthalimido)glutarimide]. A. Spiers in Scotland confirmed the relation by show-