

ing that the mothers of at least eight out of ten of the affected babies had taken the drug. Thalidomide was on trial in the United States, but fortunately it had not been approved for use by the Food and Drug Administration, owing to the fact that polyneuritis developed in some users and owing also to Dr. Frances O. Kelsey's doubt about the safety of its use in pregnancy.

The drug was first marketed in Germany in 1958, and by 1960 it had become Germany's most popular sleeping tablet and tranquilizer. It was sold without prescription until the polyneuritis showed up; thereafter it was sold freely on prescription.

Thalidomide was withdrawn from the market in Germany by November 1961 and slightly later in England, Australia, and Canada. Much additional circumstantial evidence of the relation between thalidomide and phocomelia has now been collected. Lenz (personal communication) has studied 50 cases of women whose offspring have phocomelia and who had also taken the drug during pregnancy. He finds that the period of sensitivity is between days 30 and 60 after the last menstrual period, and that in most cases the drug had been taken between days 30 and 50. In those cases in which the date of conception was known, the period of sensitivity was from the 28th to the 42nd day.

The most conservative estimate is that by August 1962 some 3500 babies with phocomelia will have been born in Germany and several hundred will have been born in England and elsewhere.

Definite proof that thalidomide does cause phocomelia must await further confirmatory animal experimentation or cessation of the outbreak in August 1962, 8 months after withdrawal of the drug. Nevertheless, the circumstantial evidence that this drug does cause congenital malformations is so strong, and the effects on the children are so terrible, that I feel the situation should be brought to the immediate attention of the public 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 new laws have become effective, and indeed until research for the proper tests on pregnant animals has been completed, physicians 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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(*This editorial is based on a longer editorial to be published soon in the New England Medical Journal.*)

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PHOCOMELIA AND THALIDOMIDE

To the Editors:

This is a comment with reference to the article, "Phocomelia," by P. M. Dunn, A. M. Fisher, and H. G. Kohler of Birmingham, England, as well as your editorial in the same issue (August 1). As part of a government mission to Europe to inspect these babies, I think the magnitude of the tragedy can scarcely be overstated.

At the end of November, 1961, when the possible relation between thalidomide and phocomelia was reported, the drug was withdrawn from the West German and British markets. Nevertheless, the incidence in West Germany is terrific. The most conservative estimate is that a minimum of 3,500 infants will be born with phocomelia by August, 1962, 8 months after the withdrawal of the drug.

Phocomelia has appeared where the drug has been available. Thus, the British Commonwealth has several hundred cases of phocomelia. Sweden has reported 25 cases with 100 per cent history of Contergan. Belgium has a number of such cases; Softonon is sold there. Italy has recently reported 5 cases in 5 weeks. Brazil has an epidemic of phocomelia related to thalidomide. Canada had both Talimol and Kevadon and, unfortunately, these drugs were not withdrawn until April 1, 1962; therefore, it will be November before the last of these unfortunate babies have been born. The United States Army of Occupation in West Germany has been spared because the United States Food and Drug Administration refused the application of the Merrill Company to market Kevadon and no drugs are permitted in the United States military services which have not been approved by the Food and Drug Administration. A few cases, however, will undoubtedly occur in the United States as travelers from other countries have bought the drug abroad and brought it to this country.