

child. Therefore permission for sale of the drug as a sedative would have been granted; it was an excellent sedative and appeared to be safe.

In the U.S. there have been only a few cases of the syndrome—two of them the twin offspring of a German woman who had married an American and brought Contergan with her to the U.S. Even the families of U.S. personnel stationed abroad have escaped—with one exception. At the U.S. Army headquarters in Heidelberg, in March, Thomas W. Immon was able to assure me that not one of the 16,000 babies born in U.S. hospitals in Germany during 1961 had phocomelia. More recently, however, he has had to report the birth in a U.S. Army hospital of one infant with phocomelia. The mother, a German, reported that she had taken Contergan in the early weeks of her pregnancy.

Unfortunately the people of Canada have had a different experience, even though the Dominion Government has a drug-regulating agency like that of the U.S. With two thalidomide preparations on the market in 1961, many pregnant women were exposed to the drug. At least 12 have delivered offspring afflicted with deformed arms and legs. The manufacturers issued a warning to physicians in December, advising them not to prescribe thalidomide for pregnant women. It was not until March, however, that governmental authorities asked the manufacturers to withdraw the drug entirely. Between now and the fall there will undoubtedly be additional casualties.

A generation ago new drugs, particularly those for relatively minor complaints such as insomnia, only gradually achieved widespread popularity. The rather small number of people using them in the first few years provided, albeit unwittingly, test cases not only for the efficacy but also for the long-term safety of the drug. Today "educational" representatives of drug houses visit each physician regularly. Pounds of lavish and expensive drug brochures assault the physician by mail. Most medical journals are crowded with handsome advertisements, many printed in full color on heavy cardboard or metallic paper, extolling the virtues of this year's model or modification of some recently invented tranquilizer, diuretic or antihypertensive compound. New drugs thus find huge markets within a few months.

In most countries, with the exception of Canada, governmental regulation of the pharmaceutical trade is less stringent than it is in the U.S. The Food and Drug Administration, however, is limited to considering only the safety and not the efficacy of a drug, and it exercises no control until the drug is ready for sale. During testing, conducted by and for the drug houses, a new compound may be distributed for clinical trial to many physicians. They are supposed to warn patients that the drug is experimental and to obtain a release signed by the patient. Not all physicians keep careful records of the cases in which they have distributed such test drugs. Clearance by the Food and Drug Administration, which rests on evidence of safety submitted by drug companies, must often be based in part on reports from observations made under clinical conditions that are, to say the least, not ideal. Certainly the procedure needs strengthening here.

Until recently no thought had been given to the need for the testing of drugs for potential harmfulness to the human embryo. In my laboratory at the Johns Hopkins School of Medicine I have not been able to obtain abnormalities in baby rabbits with thalidomide primarily because the massive doses I have used bring on so many abortions. This illustrates one of the problems of testing new drugs: what size dose in animal makes for a fair test? As thalidomide shows, animals may not react at all like humans.

Of course, no drug can ever be certified as completely safe. But all the hazards of a given drug should be established before it is marketed. In dealing with cancer and other serious diseases there is some justification for taking chances with new drugs. The less serious the illness is, the more certain it should be that the drug is harmless as well as effective. In the case of thalidomide, I wonder how long it would have taken to determine the cause of the malformations if the drug had produced some more common but less spectacular congenital defect. Any drug labeled safe should be relatively harmless for all people of all ages, including the unborn. Married women of childbearing age should avoid drugs as much as possible, particularly new ones.

For most people the story of thalidomide has ended. The tragedy will go on, however, for the infant victims of the "harmless" sedative and their families for the rest of their lives.