

entirely safe, if taken at the critical time during pregnancy could severely injure the fetus. The usual adult dose was 100 mgm. The medicine was considered safe, so safe that man could not commit suicide by overdose, yet one dose of 50 mgm. could cause a serious malformation in the unborn child. Indeed, nine doses of 30 mgm. have been known to injure the fetus seriously. Moreover, I believe that only one of the degradation products of thalidomide injures the fetus and that product is only in the blood stream for an hour or two. Hence it is not a cumulative effect but rather it would appear that each of the nine doses of 30 mgm. injured the embryo at a particular stage in fetal development and the result was a severely damaged child (no arms or legs). The evidence is overwhelming that a single minute dose of a toxic substance can be highly injurious. The embryo is tiny and only a minute amount of a toxic material is required to injure it at a specific point. Another thing learned from thalidomide was that a chemical may have an entirely different effect on an embryo or a fetus than on a person after birth. Thalidomide was found to react with mesenchymal tissue (the forerunner of muscle and bone) in the embryo and on nervous tissue of the adult.

In addition it is extremely important to appreciate that the medical profession now recognizes that a number of conditions are the late effects from an earlier insult. When the late result becomes manifest that is the starting point for the investigation. In the case of thalidomide the starting point was the malformed infant. The natural supposition was that something had injured the fetus during pregnancy. Drugs may not be the only thing which could cause injury, some element in detergents might, some food preservative might, air pollution might. Indeed such possible sources were investigated in Germany. Today we are discussing drugs and how best to have drugs both as potent as possible and as safe as possible. The problem is how to detect the injurious reaction or side effect to the drug when they do occur. Clearly the more names the offending agent is distributed under, the more difficult is the problem of detection. The difficulty in the detection of a drug sold under trade names is illustrated by the fact that not until August 1962 was it discovered that thalidomide was sold under five different names. Moreover, a surprise search by the health authorities resulted in the confiscation of two and one-half million pills (or boxes of pills), 46,000 flasks containing thalidomide, and 96,000 kilograms of the pure substance in Sao Paulo. Thus, it is obvious to everyone that if an epidemic is nationwide or worldwide and the cause of the epidemic lies in the product which is sold or distributed under 100 different names, the detection and recognition of that product is extremely difficult. I shudder to think that if a drug was ever produced which was a tranquilizer, a good tonic, or a drug claimed to increase virility and it affected the sperm in such a manner as to injure the brain or even the reproductive organs of the fetus, how difficult it would be to trace that drug and how virtually impossible if the drug masqueraded under 500 different names! This is not an impossibility nor in truth is it more improbable than landing a man on the moon seemed thirty years ago. Hence, the value of having the generic name on the label seems incontrovertible.

Absolute safety cannot be guaranteed for any new product or drug. The major risks can be detected by careful testing. Furthermore, testing in primates was required to demonstrate clearly that thalidomide produced phocomelia. Perhaps every drug cannot be so tested but, nevertheless, elementary precautions can be taken. Drugs can and should be tested on a variety of animals and a variety of ages, for infants, the pregnant mother, and the aged are known to react differently to drugs. Although a drug may be tested and tried for a specific disease in a specific age group, if the drug is effective, almost inevitably the use of the drug will be extended beyond its original purpose both by the medical profession and by lay people who so glibly take a drug recommended by a friend.

Again, one basic simple elementary precaution is to have the generic name on every drug and when the drug is a compound of various preparations it should have each of the substances *clearly* listed so that the lay person and the physician may have the opportunity to know what the preparation contains. The inactive ingredients, too, should be listed as some people may be allergic to the inactive ingredient, but they should not be listed as conspicuously as the active ingredients.

Now let us be fair to the drug companies for they have produced many valuable drugs. The wonder drugs of today have altered the face of medicine. Private enterprise and the competition which results therefrom has been and is a tremendous stimulus. We want progress to continue. Quite rightly, if a pharmaceutical manufacturer produces a superior product they wish their name on the product. It could be either a name that catches the imagination or it could be the