versible—might not be due to intake of thalidomide. To her this was a danger signal.

She called the letter to the attention of the applicant. His investigators reported that the incidence was apparently negligible, one case among 300,000 adult users. Six months later, Dr. Kelsey said, the incidence among adults who took thalidomide regularly for months at a time was found to be 1 in 250.

But neither she nor the applicant yet had the slightest inkling that the drug could be responsible for the birth of malformed babies. That awful circumstantial evidence became known to the applicant—in a cablegram from Europe—on Nov. 29, 1961.

APPLICATION WITHDRAWN

He reported it to Dr. Kelsey early the next day. Although this was followed by a formal withdrawal of the application, as late as last month the applicant described the birth abnormalities as "alleged effects" of thalidomide.

The story begins, in 1954, six years before Dr. Kelsey, a pharmacologist as well as a physician, went to work in the FDA's Bureau of Medicine. She and her husband, F. Ellis Kelsey, a pharmacologist who is now a speical assistant to the Surgeon General of the Public Health Service, came here from the faculty of the University of South Dakota School of Medicine.

For the account that follows, the primary sources were Dr. Kelsey and reports by Dr. Helen B. Taussig to a medical meeting in April and in the June 30 issue of the Journal of the American Medical Association.

Dr. Taussig, professor of pediatrics at the Johns Hopkins School of Medicine in Baltimore, went to West Germany in January to investigate the relationship between thalidomide and an enormous increase in the birthrate of malformed infants.

Eight years ago a West German manufacturer conceived of the drug, synthesized it—and discarded it after discerning no effect on test animals. In 1958 another West German firm also developed thalidomide and found it to be, by all indications, the best sleeping compound ever devised.

LARGE SALE

The sale was tremendous. It even came to be used for grip, neuralgia, asthma, in cough medicines and to calm children before they were given electroencephalograms.

In Germany it was marketed as Contergan, in the British Commonwealth as Distaval, in Portugal as Softenon. Dr. Kelsey's native Canada accepted it on April 1, 1961, for manufacture by one firm under the name Talimol and by another firm, the William S. Merrell Co. of Cincinnati, under the name Kevadon. It was the 134-year-old Merrell firm that was seeking to market Kevadon as a prescription drug in the United States.

At this time—April, 1961—West German investigators were desperately groping for an explanation of an unprecedented outbreak of phocomelia, the malformation hitherto so rare that it isn't even listed in some medical dictionaries. An 86-year-old Gottingen specialist in human deformities told Dr. Taussig that he had in his whole lifetime "seen as many individuals with two heads as he had with phocomelia."

Usually, phocomelia deprives its victim of one arm. Rudimentary fingers that look, said Dr. Taussig, "like the flippers of a seal" arise from the stub below the shoulder.

CLINIC CASES

In eight West German pediatric clinics there were no cases at all between 1954 and 1959. In 1959 there were 12, in 1960 there were 83, in 1961 there were 302.

These were not the ordinary textbook cases. Not just one arm was affected. These children were without both arms, or without both legs, or without three limbs, or they were without any limbs at all.

In some, the external ear was missing and hearing was grossly impaired. There were deformities of the eyes, esophagus and intestinal tract; and even this is not a complete list.

Once the suspected link with Contergan was established, Contergan was taken off the West German market. The expectation is that the last mothers who could have taken it during early pregnancy, the danger period, will be delivered in August. The estimates are that by the end of next month the total of deformed