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Medicines: Birth Defects & Risk Management Programs

In 1958, a year before thalidomide was first marketed there was virtually no controls in the use of medicines and the side effects. The drug thalidomide, which was named the wonder drug and ideal for pregnant woman to relive the effects of morning sickness, according to the medical profession and the pharmaceutical company Chemie Grunenthal the manufactures. Thalidomide was given a product licence in the UK in 1958. Distillers Biochemical the UK suppliers of thalidomide advertised that if a full bottle of the tablets had been taken by a child that it would not have caused the child any harm. The so-called wonder drug caused 1,300 babies to die before their first birthday and left a further 458 severely deformed in the UK alone. Germany had the highest number of babies born with deformities with the UK being the second

When I founded Thalidomide UK in 1993, our aim was to get further monies for people, who had been damaged by the drug thalidomide born between 1959 and 1962. The extra money that was needed would help the survivors, because there health was deteriorating and there needs were becoming far greater.

Over the years, I have taken a personal interest in medicines and there side effects especially when they could cause birth defects if taken while pregnant. You would think that since thalidomide was first marketed over forty-six years ago that the medical profession would have learnt there lesson. We are more at risk now of seeing a larger thalidomide tragedy than ever before with the way science has considerably moved forward, which includes more medicines being available.

Hundreds of drugs still pose the risk of birth abnormalities. **Accutane**, or **Roaccutane** (generic name **isotretinoin**) , is a member of a family of drugs called retinoids which are known to cause a number of very serious birth defects, and has been implicated as a possible cause of cleft lip and cleft palate. Isotretinoin is derived from vitamin A. Outside the UK; medicines are easily available without prescription. All medicines should be controlled equally in all European countries.

Medicines that may be at risk to the foetus can be controlled easier under three categories.

- Medicines that are not known to cause birth defects and that have been used for a long time could stay under the current regulations.

- Medicines that may well possibly cause birth defects taken during pregnancy should be observed by a standard risk management program.

- Medicines that incorporate a high risk of birth defects should be monitored by a very tightly controlled risk management program.

When medicines demonstrate signs that they may cause birth defects, a special body set up by the European commission, which could consist of their representative's, members of the medical profession, patients and a victim representative could decide which category of risk management program should be incorporated

Source: Freddie Astbury

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