

Sun Times: Focus: Sick children pay high price for use of adult drugs

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From: Sufaud (sufaud_at_hotmail.com)

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Focus: Sick children pay high price for use of adult drugs

Doctors are using adult medicines to treat children — often with tragic results, writes Camillo Fracassini

DRESSED in a white tutu, Emma Frame smiles as she dances across the stage in a grainy home video shot when she was a pretty five-year-old.

A few months after the video was made she died when she was prescribed a huge dose of a powerful steroid — up to 10 times above the maximum safe level set when the drug was licensed.

Emma, who had been taking the drug for 3½ years, suffered a fatal drop in her blood sugar level. A month later her brother Callum, 7, who had been taking the same drug, was taken to hospital suffering from the same symptoms. He spent three days on a ventilator in intensive care before his life was saved by an emergency operation.

Emma's parents claim they were never warned of the risks associated with the off-licence use of the drug and were only told that their children's growth might be stunted.

However, it has emerged that five years before Emma died in 2001 doctors had given a warning that Flixotide, one of the most commonly used asthma inhaler medicines, could kill children in high doses.

"Emma's death was the worst thing that could ever happen to a parent," said her father Stewart at the family home in Strathaven, Lanarkshire. "It is impossible to explain how we felt, having lost our daughter, to have our son in intensive care knowing there was a very high possibility that he would die."

Each year 900 children in Scotland are admitted to hospital because

they have suffered adverse reactions to prescription medicines. Many cases are due to "off-label" prescribing by doctors who give medicines to patients outside the terms of the drugs' licences.

Doctors are allowed to prescribe adult medicines for children and determine the dosage because few children's drugs have been tested and approved by the government's Medicines and Healthcare Products Regulatory Agency.

About 40% of the drugs used in paediatric medicine are not licensed for children. For infants the figure is 65%. Because children absorb drugs in a different way to adults, side effects are often unknown.

"If medicines are used off-label in children then the frequency of adverse drug reactions is higher and these can range from a minor skin rash to death," said Dr James McLay, a clinical pharmacologist at Aberdeen University.

Many doctors accuse the pharmaceutical industry of dragging its heels. Without legislation forcing firms to conduct clinical trials on children, there is no incentive for them to undertake the expensive and time consuming tests.

Concern over the lack of licensed medicines for children was addressed in America 10 years ago. The US government offers drug firms financial incentives and extended patents to test drugs on children. The European Union is to offer similar incentives, but not until 2006.

Last month the Department of Health said it intends to publish a book to advise doctors which medicines should be given to children. It will also promote research into such drugs. The Scottish executive is understood to have committed money to the project.

A spokesman for GlaxoSmithKline (GSK), the manufacturer of Flixotide, said: "The safety profile of Flixotide within licensed doses is well established and it has been used to treat more than 250,000 children in the UK. It's also the most widely used inhaled corticosteroid in severe asthma.

"GSK does not and cannot promote out-of-licence use of its medicines, but we recognise that in certain instances asthma experts may be faced with very difficult clinical decisions about the most appropriate dose of medicine needed to treat a serious disease."

<http://www.timesonline.co.uk/newspaper/0,,176-1258046,00.html>