

The following is from a newspaper - The Guardian - date not known.

PILL COATING BLAMED IN CHILD SEIZURE SCARE

An epidemic of potentially lethal bowel seizures among children with cystic fibrosis may be linked to the plastic coating on the capsules they take to control their condition.

Over two years, 14 children with cystic fibrosis in England have had emergency surgery to eliminate scar tissue obstructing the large bowel. Officially, these cases remain a mystery. But Dick van Velzen, professor of foetal pathology at Liverpool University, has concluded from a detailed review of each case that medication, not the illness, causes the seizures.

In yesterday's Lancet, Professor van Velzen points out that all 14 children had been taking enzyme capsules with a plastic coating which account for 30 per cent of the market in this type of preparation. The coating contains methacrylic acid copolymer. Rats exposed to this substance have suffered chronic gastro-intestinal inflammation and ulceration. A study on the role of pancreatic enzyme supplements in cystic fibrosis is to be published this year.

Cystic fibrosis is the most common inherited life-threatening disorder. A generation ago, most sufferers did not live beyond childhood. New treatments have allowed two thirds to survive into adulthood. Although primarily a disease of the respiratory system, patients cannot digest fatty food without a supplement of pancreatic enzymes.

In response to early reports of bowel seizures, the UK Committee on the Safety of Medicines recommended in December 1993 that cystic fibrosis patients should switch to low-strength pancreatic enzymes. But in the past month, Professor van Velzen has reviewed two cases of severe

seizures in very young children from Southampton and Oxford. In each case, low-strength enzyme preparations were given at high doses.

'My concern is that we may have inadvertently continued to treat children with low-strength enzyme preparations coated with the copolymer in the belief that they were safe even in high doses,' he states.

The children whose cases have been studied all suffered an obstruction of the bowel wall through the build-up of scar tissue. Without emergency surgery, they would have died.

The most widely used enzyme preparation is Creon 25.000. During the epidemic, it has accounted for 70 per cent of the market. Its capsules do not contain plastic. None of the 14 children who suffered the bowel seizures was on Creon 25.000. The preparations that contain the coating are Pancrease HL, Nutrizym 22 and Panzytrat.

Professor van Velzen fears that, as a result of advice from the Committee on Safety of Medicines, many parents have been switching children to lower strength preparations but increasing the intake of capsules. A spokeswoman for the Department of Health said it was aware of a potential problem. 'The Committee on Safety of Medicines has sent a letter to doctors in the units where patients with cystic fibrosis are treated alerting them to these two cases. It has recommended that it would be prudent to avoid high doses, irrespective of the preparation used. Pancreatic enzymes are essential, but it is important the normal dose is not unnecessarily exceeded. We will continue to monitor the situation.'