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Children as Big Pharma Guinea Pigs: 98 Percent of Drug Trials on Children Have no Safety Checks

by David Gutierrez, staff writer

(NaturalNews) Fewer than 2 percent of drug trials conducted on children have independent safety advisory boards, a review published in the journal *Acta Paediatrica* has found.

Researchers from Nottingham University reviewed reports on 739 international drug trials that had been published between 1996 and 2002. They found that although 74 percent of studies described their safety monitoring procedures, less than 2 percent included an independent safety review committee.

Such committees are composed of independent health experts who can review the study data as it comes out and warn if the drug appears to be placing study participants at risk.

"It is invaluable to have an independent monitor who can swiftly question any adverse drug reactions or differences in illness and death rates between groups taking part in the clinical trials," said lead researcher Helen Sammons. "Parents also need to be made aware of the risks of adverse drug reactions when a child takes any medicine so that they can make informed decisions that balance those risks against the possible benefits the drug may provide their child."

The Nottingham University review also suggests that independent committees lead to more rigorous safety standards. Of the 13 studies with independent review committees, six were halted early due to highly toxic drug effects.

None of the studies without independent committees were stopped early.

Although the researchers looked only at studies conducted on children, they said the statistics for adult trials are probably similar.

"There is general agreement by pediatric health professionals, regulatory authorities and the pharmaceutical industry, as well as politicians and parents, that drug trials are essential in order to improve drug therapies," Sammons said. "We are calling for all pediatric drug trials to include independent safety monitoring committees to ensure that this vital work is carried out in a way that minimizes risks and maximizes benefits for the children taking part."

Adverse health effects were reported in the majority of drug trials, although not all of them were thought to be related to the drugs. A total of 70 percent of drug trials reviewed reported adverse effects, and 20 percent reported serious adverse effects. Almost 37 percent of drug trials reported side effects attributed to the drugs; 11 percent of trials reported moderate, severe or life-threatening side effects.

Adverse effects reported included bleeding, high blood pressure, seizures, psychosis, acute renal failure and suicide.

Deaths were reported in 11 percent of drug trials, particularly in those involving premature babies. A total of 56 percent of studies involving newborns involved deaths. Deaths were also reported in trials for drugs meant to treat infectious diseases and problems with the nervous system, respiratory system and kidneys.

Most cases of death were not thought to be caused by the drugs.

According to Sammons, the practice of conducting clinical drug trials on children is fairly new. In the past, drug companies only conducted safety tests on adults and doctors were left to guess at what drugs would work for children, and in what doses.

Five years ago, the United States began providing longer exclusive drug licenses to pharmaceutical companies that carry out drug trials on children as well as adults. In reaction to this incentive, the number of trials including children has increased. A similar incentive system is about to go into effect in the European Union.

It is important to conduct these trials, Sammons said, to decide if the benefits of drugs outweigh the risks.

"We need to test drugs on children, as the only other options are to use unlicensed drugs or prescribe drugs that have been licensed for adults," Sammons said. "But we feel that the small number of studies that reported having safety monitoring committees was unacceptable."
