

■ U.S. Suspends All Research At Johns Hopkins After Death Of Asthma Study Participant

The Associated Press reports on July 20, 2001 that after an improperly administered asthma study at Johns Hopkins University in Baltimore, MD caused the death of a healthy, 24 year-old participant, all human research at the school has been suspended by the U.S. Office of Human Research Protection (OHRP). The research ban was lifted on July 23, 2001 after weekend meetings resolved the OHRPs concerns.

Study participant Ellen Roche, 24, died on June 2, 2001 after inhaling the drug hexamethonium, which was being used to induce asthma attacks in healthy people so doctors could learn how the body fights asthma attacks. Hexamethonium was widely used in the 1940s and 1950s in tablet form for the treatment of hypertension but the U.S. Food and Drug Administration (FDA) later pulled its approval of the drug. Hexamethonium was never approved by the FDA to be used as an inhalant.

In a letter to the school that outlined the reasons for the suspension, the OHRP says that researchers did not sufficiently warn participants in the asthma study of the dangers and "continued to expose additional subjects to inhaled hexamethonium before the symptoms in the first subject were resolved and before reporting the event" to a university review board.

The University's own internal review of the incident stopped short of blaming the lead researcher, Dr. Alkis Togias, who remains on staff and faces no other disciplinary action. The same review went on to conclude that the experiment was "well-supervised".

By way of commentary, we feel that Ellen Roche would likely disagree with that conclusion.

■ Claritin Maker Accused Of False Advertising

Reuters Health news service reports on August 9, 2001 that The Prescription Access Litigation Project (PAL), a Boston advocacy group, announced that it has filed a class action lawsuit against Claritin maker Schering-Plough over deceptive direct-to-consumer (DTC) advertising.

According to the complaint, Schering-Plough "falsely promises all Claritin purchasers complete relief from their allergy symptoms, without qualification, when in fact a large percent of Claritin users report no benefit at all."

The complaint goes on to say that the company's ads "effectively portray Claritin as the cure for everyone's allergy-related symptoms" even though Schering-Plough's "own studies indicate that Claritin does not work for between 50% and 55% of all potential customers."

■ Allergies And Asthma Linked To Antibiotic Use In Infants

On October 1, 2003, HealthDayNews highlighted research reported at a conference of the European Respiratory Society in Vienna, Austria finds that children who take antibiotics are more likely to develop Allergies and Asthma later in life.

In the study, researchers from the Henry Ford Health System in Michigan examined information from earlier research that followed 448 children from infancy to the age of 7. All the children had taken antibiotics for one reason or another and all had been tested for allergies.

By the age of 7, 38% of them developed allergies to pets, ragweed, grass and dust mites. 5% of them had asthma. Children who had taken antibiotics within the first six months of life were 1.5 times more likely to have developed allergies and 2.5 times more likely to develop asthma.

In the past few years, scientists have been coming to the conclusion that human immune systems are more likely to develop the way they are supposed to as long as they are exposed to germs during infancy.

It's felt that antibiotic use in infants may help allergies develop by killing off the normal bacteria in the intestines that are important in proper immune system growth and function. As a result, there is a higher occurrence of allergies.

Acknowledging that the overuse of antibiotics has also been shown to lead to antibiotic-resistant strains of bacteria, Dr. Keoki Williams, researcher and clinical epidemiologist, concludes the findings of this study indicate "there's potentially more than one reason to use antibiotics judiciously in young children."

■ Oral Steroids No Help For Viral Wheeze In Children

In the November 1, 2003 issue of The Lancet British researchers report that in children with colds who develop a wheeze, oral steroid therapy does not have any effect.

Many doctors routinely prescribe oral steroids if children develop wheezing during the course of a cold or other upper respiratory infection.

In this study, 120 children between one and five who had previously been hospitalized because of a viral wheeze were followed. 51 of the children were given oral steroids and 69 were given a placebo. Parents were asked to keep a diary of their children's daytime and night-time symptoms over a seven day period. At the end of the seven days, the researchers found that symptom diaries of both groups of children were similar.

According to the researchers, oral steroid therapy for viral wheezing needs to be re-evaluated "since there are no clear benefits to balance potential risks."

■ Non-breastfed babies have higher risk for asthma

A study in the September 25, 1999 issue of the *British Medical Journal* found that babies who were fed milk other than breast milk experienced a substantially higher risk of developing asthma.

The study involved infants who were only breastfed for the first four months of their life compared with infants who were fed non-breast milk.

The authors surmised that non-breast milk does not provide the same protective agents that are naturally found in breast milk. Non-breast milk also contains more potential allergic components that can lead to health problems such as asthma.

■ Cesarean Section Linked To Asthma And Allergies

Research reported in the October, 2000 issue of the *Journal of Asthma* finds that children born through special medical procedures as a result of obstetric complications have a higher incidence of asthma and allergic disorders later in life.

The study, performed at the Imperial College School of Medicine in London, England, followed 8088 Finnish children from birth to the age of 7. The researchers found that babies whose birth involved the use of cesarean section or forceps were at a greater risk for developing asthma and allergies.

A previous study hints that the mechanism most likely involved is damage to the babies' brain stem or spinal cord from the trauma of the interventions which is known as Traumatic Birth Syndrome (TBS). According to a literature review in the October, 1993 issue of the *Journal of Manipulative and Physiological Therapeutics* cases of TBS are going unreported and as a result, undertreated. The report goes on to say that manual treatment (such as Chiropractic care) would be beneficial to patients suffering from TBS related injuries.

By way of commentary, all babies need to have their spines checked as soon after birth as possible to prevent future health problems from surfacing. Even a "normal" birth can cause tremendous stresses on the fragile spines of infants. Chiropractors are uniquely qualified to detect and correct the spinal damage that occurs in TBS.

■ C-Section Babies More Likely To Develop Asthma

An interesting article in the April, 2001 issue of the *Journal of Allergy and Clinical Immunology* reports that children born by C-section are likely to develop asthma than children born vaginally.

In the study, done in Finland, researchers were able to obtain data from the National Public Health Institute on asthma, allergic disorders and obstetric history for 2000 people born in 1966 who survived to age 31. C-section was done in 5.3% of the population studied and was strongly associated with current doctor-diagnosed asthma. In fact, the C-section patients were three times more likely to develop asthma than normal birth patients. No strong relationships were noted between C-sections and allergies, hay fever or allergic eczema.

It was noted that C-sections performed in Finland in the 1960s were almost always the result of emergency situations.

By way of commentary, there is a common misconception that C-section births are less traumatic to the baby. This is not necessarily the case. C-sections put tremendous forces on the baby's spine and spinal cord as they are forcibly extracted from the womb. Subluxation injuries to the brain stem and spinal cord in the neck have long been associated with respiratory disorders.

Acetaminophen Use Linked To Asthma

The April 1, 2004 issue of the American Journal of Respiratory and Critical Care Medicine reports that people taking acetaminophen on a regular basis suffered a greater incidence of adult-onset asthma.

Acetaminophen is the active ingredient in Tylenol and other over-the-counter pain relievers. In the study, 299 patients newly diagnosed with adult-onset asthma were asked about acetaminophen use. 108 used no acetaminophen while 191 used the drug from 1 to more than 22 times per month.

Acetaminophen has been known to produce spasms of the bronchial tubes in the lungs leading to airway restriction and symptoms of asthma.

■ Drug Company Misled FDA, Doctors And Patients About Safety Of Asthma Drug

The health care consumer group Public Citizen published a letter in the October 7, 2005 issue of the British medical journal the Lancet that reports drug maker GlaxoSmithKline misled the U.S. Food and Drug Administration (FDA) by presenting study results showing the popular asthma drug salmeterol was safer than it actually is. The drug is sold under the brand names Serevent and Advair.

In 1996, a 28 week study involving tens of thousands of asthma patients taking either salmeterol or a placebo was begun. That study showed that patients taking the drug salmeterol ran a higher risk of death than the placebo patients but the results of that study were never published. In August 2003, the drug company submitted final study data that included the six months after the study, after the patients quit taking the drug.

By including this post-study information, the apparent dangers of salmeterol were reduced in four critical study outcomes, including asthma-related death.

Upon learning of the suspicious reporting, the FDA has recommended strengthening the warning on the labels of Serevent and Advair but has yet to actually require it.

Epidemiologist Dr. Peter Lurie, deputy director of Public Citizen's Health Research Group says, "the behavior of GlaxoSmithKline in submitting these faulty data is deplorable. Absent greater transparency at the FDA, we will never know how often this kind of self-serving data analysis occurs."

Public Citizen has listed Serevent as a "Do Not Use" drug on their website at www.worstpills.org.

Together, Serevent and Advair were dispensed more than 16.3 million times in U.S. Pharmacies in 2004.