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Diethylene glycol (DEG) kills

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Mrs Zainab Wai-Lansana holds bags of drugs given to treat diabetes and hypertension exactly as given to her uncle by a hospital pharmacy in Freetown, Sierra Leone in 2010. Miss Zain is a patient-care coordinator at King's County Hospital and Executive Director of Amuloma Development Foundation.

Drugs Contaminated with Diethylene Glycol (DEG) Imported from China

Reported 04 Jul 2007 by Kathia Martinez of The Associated Press

Ms Martinez reported that the Panama prosecutor claimed to have evidence that at least 94 humans died from drugs contaminated with since Jul 2006, that 293 more deaths are under investigation, and that deaths continued after the medicine was pulled from shelves in Oct 2006.

DEG was in cough syrup, antihistamine tablets, calamine lotion and rash ointment made in a Panama government laboratory.

The prosecutor's office found that DEG was made by a Chinese company which lied that it sold 99.5% pure glycerin to a Spanish company. That company sold what this to Panama's Medicom SA, which sold in turn it to a government laboratory.

Officials in Panama exhumed and tested humans who had swallowed medicines containing DEG and who died last year, and reported finding the medicines killed them.

The 293 suspected cases were brought to the police by family members, but the causes of death had not yet been confirmed forensically.

Three Medicom executives were imprisoned, charged with crimes against public health.

Poisoned medicine from China?

Reported by Debo Abdulai's in "Poisoned medicine from China?" in Nigerian newspaper Tribune

Mr Abdulai reported that Nigeria has been open to China since the economic depression started. Drugs from China are cheaper, easily found on drug shelves and come in approved by the National Agency for Foods Drugs Administration and Control (NAFDAC). He claims that almost every Nigerian has used Chinese products to fight diseases.

In July 2007, the former head of China's top food and drug safety agency was executed a few days after being sentenced to death after pleading guilty to corruption and accepting USD850,000 in bribes (see page 188). Zheng Xiaoyu was commissioner of the Food and Drug Administration from its founding in 1998 until mid-2005, and was arrested Feb 2007 as part of a government investigation into corruption at the agency. The government is now reviewing more than 170,000 production licenses issued by the food and drug agency over the past decade.

In 2007, 2 Chinese companies were accused of shipping contaminated food ingredients to the United States, leading to a nationwide pet food recall.

The Chinese government is investigating how DEG ended up in cough syrup and toothpaste in Latin America. This deadly adulteration led to more than 365 deaths in Panama last year after officials unwittingly mixed DEG into 260,000 bottles of cold medicine. Toxic toothpaste was removed from drug shelves in Dominican Republic and Nicaragua.

In China, tainted injections were reported to have killed 11 persons, and 6 were reported to have died and 80 sickened after taking an antibiotic that was produced with what was later discovered to be a substandard disinfectant.

According to Mr Abdulai: "Effects of China's unsafe drugs are not recent. In 1998, 155 Americans were sickened by impure gentamycin sulfate made by a Chinese firm. Around the same time, 89 children died in Haiti after taking cough medicine made with antifreeze from China.

"The danger to Nigerians is therefore grave. We are open to Chinese drugs which incidentally are relatively cheaper; we are no longer sure if the drugs we use are not made in Onitsha, Lagos or Kano markets while those from Europe are out of the reach of the common man because they are very expensive. God save us all."

FDA Advises Manufacturers to Test Glycerin for Possible Contamination. Glycerin Contaminated with Diethylene Glycol Remains a Potential Health Hazard to Consumers

From FDA press release

The United States Food and Drug Administration (FDA) is warning pharmaceutical manufacturers,

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suppliers, drug repackers, and health professionals who compound medications to be especially vigilant in assuring that glycerin, a sweetener commonly used worldwide in liquid over-the-counter and prescription drug products, is not contaminated with diethylene glycol. This is a known poison used in antifreeze and as a solvent. Today, the agency is issuing guidance to industry recommending methods of testing glycerin and other controls to identify any contamination with DEG before use in the manufacture or preparation of pharmaceutical products.

FDA has no reason to believe that US glycerin is contaminated, though the agency knows of recent reports from other countries of deaths from DEG-contaminated glycerin. FDA emphasizes the importance of testing glycerin for DEG because of the severity of the problem.

DEG poisoning is an important public safety issue and FDA is exploring how supplies of glycerin become contaminated. In addition, FDA is working with manufacturing and pharmacist organizations to raise awareness of this risk and to put into place controls to ensure that this problem does not happen in the U.S. or elsewhere.

The most recent incident was in Panama in Sep 2006 and involved DEG-contaminated glycerin used in cough syrup, which resulted in dozens of hospitalizations for serious injury and more than 40 deaths. In late 1995 and early 1996, at least 80 children died in Haiti from DEG-contaminated glycerin in acetaminophen syrup. Between 1990 and 1998, similar incidents of DEG poisoning were reported from Argentina, Bangladesh, India, and Nigeria and resulted in hundreds of deaths. In 1937, more than 100 people died in the United States after ingesting DEG-contaminated Elixir Sulfanilamide, a drug used to treat infections. These deaths led to the enactment of the Federal Food, Drug, and Cosmetic Act, which is the nation's primary statute on the regulation of drugs.

Guidance for industry Testing of Glycerin for Diethylene Glycol

posted on

http://www.fda.gov/OHRMS/DOCKETS/98fr/07D-0135-gdl0001.pdf

All pharmaceutical manufacturing operations, including the re-packaging and re-labeling of ingredients like glycerin, must conform to current good manufacturing practice (CGMP). The guidance provides recommendations for complying with CGMP and is intended to help manufacturers, compounders, repackers, and suppliers avoid the use of glycerin that is contaminated with DEG and prevent incidents of DEG poisoning.

DEG POISONING IN NIGERIAN CHILDREN

Summary of article abstract by Okuonghae HO, Ighogboja IS, Lawson JO, Nwana EJ in Ann Trop Paediatr. 1992;12:235-8; Dept Paediatrics, Jos Univ Teaching Hosp, Nigeria.

From Jun to Sep 1990, 47 children died at Jos University Teaching Hospital, Nigeria after ingesting paracetamol syrup adulterated with DEG. Children's symptoms included anuria, fever, vomiting, diarrhoea, convulsions, tachycardia, acidotic breathing, pallor, oedema, and hepatomegaly. Laboratory findings included hyperkalaemia, acidosis, elevated creatinine, and hypoglycaemia. Treatment was to correct dehydration and acidosis plus administration of antibiotics; none were given kidney dialysis. All died within 2 weeks of admission.

DEG KILLED PATIENTS IN THE US IN 1937

Summary of article by Carol Ballentine in FDA Consumer Magazine, June 1981

Sulfanilamide was a wonder drug in the 1930s, the precursor to more powerful antibiotics, and it was delivered in tablet form. The manufacturers SE Massengill Co, in Bristol, Tennessee, were asked by patients to manufacture it in liquid form. The company chemist dissolved sulfanilamide in DEG, compounded the solution and sent 633 shipments around the country.

The first shipments were sent out in early Sep 1937. On 11 Oct 1937, the American Medical Association (AMA) received reports from physicians in Oklahoma, that an unfamiliar sulfanilamide compound had killed patients. The AMA asked for samples of the drug and wired the Massengill Co, requesting the composition of the compound. The AMA laboratory isolated DEG as the toxic ingredient and immediately issued a warning, through newspapers and radio, that Elixir Sulfanilamide was toxic and deadly.

The Food and Drug Administration was told about the deaths on the 14 Oct 1937 by a New York physician. An inspector from the agency's Kansas City Station confirmed that 8 children and 1 adult died after taking a product labeled "Elixir Sulfanilamide, the SE Massengill Co, Manufacturing Pharmacists, Bristol, Tenn.-Va."

Inspectors were dispatched to the firm's headquarters in Bristol and to branch offices in Kansas City, New York, and San Francisco. They found that the firm had already learned of the poisonous effects of the liquid sulfanilamide and had sent telegrams to

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more than 1,000 salesmen, pharmacists, and doctors. The telegrams requested the return of the product without saying say that the drug was lethal. At FDA's insistence, the firm sent out a second wave of messages: "Imperative you take up immediately all elixir sulfanilamide dispensed. Product may be dangerous to life. Return all stocks, our expense."

FDA then tried to retrieve all the drug. Most of the 239 FDA inspectors and chemists was assigned to retrieve all drug. State and local health officials joined the search. Newspapers and radio stations continued to issue warnings.

The staff checked the company's shipping records and the distribution lists in the 4 distributing houses and in a number of wholesale and retail drugstores. Thousands of order slips were examined. In one establishment, 20,000 sales slips were checked.

FDA employees tracked down the firm's 200 salesmen and questioned them about the dispersion of shipments and physician samples. Finding the salesmen was the first problem. Once found, salesmen were not all forthcoming about their distribution information. One man in Texas gave the necessary information after being jailed by state authorities.

In some drugstores, the solution had been sold without prescriptions to unknown purchasers. Additionally, physicians had incomplete records of the names and addresses of patients for whom they had prescribed.

Even when the purchaser was located, the inspectors frequently had trouble finding what happened to the drug. Many doctors and pharmacists did everything in their power to recover the drug. One physician postponed his wedding to help an FDA chemist search for a 3-year-old boy.

Other physicians lied that they had prescribed the drug, or lied about their patients' subsequent health. One inspector was told that a shipment of 1 gallon had been returned to the manufacturer after only 1 dose had been dispensed. The manufacturer reported that 3 doses had been dispensed and subsequent questions determined that 2 patients had died. Similarly, a physician told an inspector that none of the 5 patients dispensed the medicine had died, however, after asking questions, the inspector found that 4 of them died.

Victims of poisoning were ill 7 to 21 days. All victims, which included children, had kidney failure: urine flow stopped, severe abdominal pain, nausea, vomiting, stupor, and convulsions. They were in intense, unrelenting pain before death.

Tests on experimental animals would have demonstrated the lethal properties of the liquid sulfanilamide. A review of the current existing scientific literature would have shown that other studies had reported that DEG was toxic and could cause kidney damage or failure. But in 1937 the law did not prohibit the sale of dangerous, untested, or poisonous drugs.

Through the persistence of federal, state, and local health agencies and the effects of the AMA and the news media, most liquid sulfanilamide was recovered. Of 240 gallons manufactured and distributed, 234 gallons and 1 pint was retrieved; the remainder was consumed.

Twenty-five seizures were made under federal law. The charge was misbranding. "Elixir," FDA said, implied the product was an alcoholic solution. If the product had been called a "solution" instead of an "elixir," no charge of violating the law could have been made. FDA would have had no legal authority to ensure the recovery of the drug and many more people probably would have died.

FDA Commissioner Walter Campbell: "It is unfortunate that under the terms of our present inadequate Federal law, the Food and Drug Administration is obliged to proceed against this product on a technical and trivial charge of misbranding. ...[The Elixir Sulfanilamide incident] emphasizes how essential it is to public welfare that the distribution of highly potent drugs should be controlled by an adequate Federal Food and Drug law. ... We should not lose sight of the fact that we had many deaths and cases of blindness resulting from the use of another new drug, dinitrophenol, which was recklessly placed upon the market some years ago. Deaths and blindness from this [drug] are continuing today. We also should remember the deaths resulting from damage to the liver that have occurred from cinchophen poisoning, a drug often recommended in such painful conditions as rheumatism. We also have unfortunate poisoning, acute and chronic, resulting from thyroid and radium preparations improperly administered to the public.

"These unfortunate occurrences may be expected to continue because new and relatively untried drug preparations are being manufactured almost daily at the whim of the individual manufacturer, and the damage to public health cannot accurately be estimated. The only remedy for such a situation is the enactment by Congress of an adequate and comprehensive national Food and Drugs Act which will require that all medicines placed upon the market shall be safe to use under the directions for use. ..."

The liquid sulfanilamide experience resulted in the 1938 Federal Food, Drug, and Cosmetic Act.

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