Department of Pharmacy

BRAC UNIVERSITY
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PHARMA HIGHLIGHTS

ISSUE 46 | JULY 2018

FDA Recalls Common High Blood Pressure Drug with Valsartan Due to Cancer-Causing Ingredient

The U.S. Food and Drug Administration (FDA) announced a voluntary recall of several drugs containing valsartan as an active ingredient. Valsartan is commonly prescribed for the treatment of heart conditions like high blood pressure. The announcement was made a week after many countries, including Germany, the Netherlands, Ireland, and Spain had each conducted separate recalls of the same valsartan products. These recalls were made after a review from the European Medicines Agency (EMA). The review found that valsartan supplied by China-based company Zhejiang Huahai Pharmaceuticals, contained a cancer-causing substance, N-nitrosodimethylamine (NMDA). However, not all medications containing valsartan was recalled.

NMDA is an organic chemical used in the production of liquid rocket fuel, and lubricants and is also a byproduct of pesticide manufacturing. Previous animal trials revealed that NDMA can trigger the growth of tumors in the liver, kidney, and respiratory tract, making it a carcinogenic compound.

The FDA board primarily recalled the valsartan made by Major Pharmaceuticals, Solco Healthcare, and Teva Pharmaceuticals Industries Ltd. "We've found that the valsartan sold by these specific companies does not meet our safety standards. This is why we've asked these companies to take immediate action to protect patients," explained the director of FDA's Center for Drug Evaluation and Research.

However, patients are still advised to contact their health providers before deciding to stop taking valsartan products. The EMA has suggested that patients be provided with a safe valsartan medicine or an alternate product while they look for a strategy to reduce or eliminate the NDMA from subsequent valsartan products.

Source: techtimes.com

Genetic Mutation Provides Protection from Malaria

Smallpox, a contagious and sometimes fatal infectious disease was once a major endemic for which there is no known cure. Although the World Health Organization (WHO) declared that smallpox was eradicated in 1980, there have been numerous concerns that smallpox could be used as a bioweapon. Therefore, options have been needed in case smallpox makes a return. To help address this issue, The U.S. Food and Drug Administration (FDA) has recently approved the first drug for the treatment of small pox, TPOXX (tecovirimat). The FDA granted the approval of TPOXX to SIGA Technologies Inc.

In the animal studies conducted, animals were infected with viruses closely related to the smallpox variola virus. TPOXX's effectiveness was then determined based on the mean survival rates seen at the end of the studies. In general, more animals treated with TPOXX survived compared to the animals treated with placebo.

Since it is not feasible or ethical to conduct human efficacy trials for smallpox, TPOXX was approved under the FDA's Animal Rule, which allows approval of drugs based on efficacy findings from adequate and well-controlled animal studies. The safety of TPOXX in humans was then evaluated in 359 healthy human volunteers without a smallpox infection, after which the FDA determined that TPOXX was safe to be taken by human patients.

The FDA granted this application Fast Track and Priority Review designations. In addition, TPOXX also received Orphan Drug designation, which allows the development of drugs for rare diseases and a Material Threat Medical Countermeasure Priority Review Voucher as it could potentially hinder the threat of bioterrorism.

Source: fda.gov

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Rise in Vitamin D Intake Shows No Signs in Preventing Cancer

When exposed to sunlight or UV, skin cells naturally produce vitamin D which needs to be hydrolyzed to calcitriol in the body to be useful. Vitamin D is vital as it regulates bone growth, maintains phosphate and calcium homeostasis and cell growth modulation.

Vitamin D is appropriately measured using serum concentrations which account for dietary intake, supplements and endogenous formation of vitamin D from sunlight exposure. Having a short half-life, the active form of vitamin D needs monitoring and is maintained via calcium, hormone, parathyroid and phosphate.

People with insufficient levels of vitamin D are prone to developing cancers of the breast, colon, prostate and ovary. A report stated that individuals with vitamin D levels below 30 ng/mL make them twice as likely to develop colon cancer. Vitamin D prevents tumor angiogenesis and constrains the blood supply to cancerous cells, depriving them of the extra nutrients and energy needed for abnormal growth. Vitamin D also tightens the connectivity between cells which serves as a barrier for new tissue growth.

In post hoc analysis of a vitamin D study carried out in New Zealand, one group was given placebo and the other group received 100,000 IU of inactive form of vitamin D. After a follow up of 3 to 4 years, it was observed that the placebo group exhibited cancer incidence rate of 6.4% and the other group with vitamin D doses showed around 6.5%. From this data, it was concluded that vitamin D over 4 years is not a sufficiently preventive measure for cancer.

Satisfactory vitamin D levels in the body is not only a sign of healthy lifestyle but is also thought to be associated with reducing the risks of cancer.

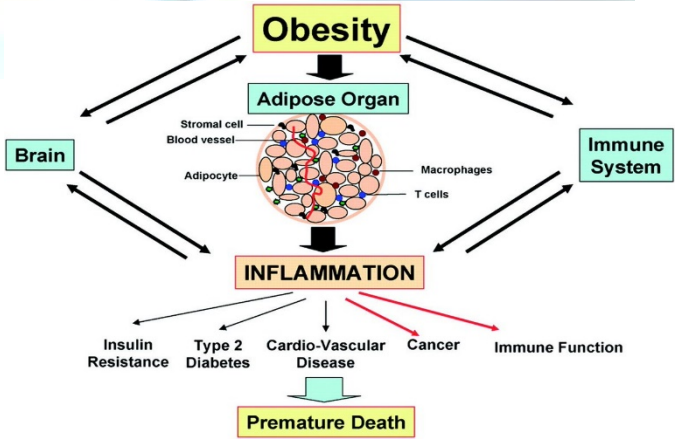
Source: American Journal of Public Health, NIH Office of Dietary Supplements, JAMA Oncology, Vitamin D and Cancer (pp 99-114).

Obesity Associated Inflammation Leads to Chronic Health Issues

According to WHO, obesity is defined as abnormal or excessive fat accumulation that presents a risk to health. A crude population measure of obesity is the body mass index (BMI). A person with a BMI of 30 or more is generally considered obese. Obesity is associated with several risk factors including cardiovascular diseases, diabetes, musculoskeletal disorders and certain types of cancers.

The causes of obesity include a number of factors such as environment, behavior as well as genetics. Recent research has demonstrated the reason why obesity causes harmful inflammation that can further lead to the development of non-communicable disease.

A study conducted at the University of Virginia School of Medicine suggested that immune cells in fat tissues become harmful in an obese person. The researchers stated that the damaging free radicals produced by our bodies interact with lipids inside of fat tissues. Attack by lipids evoke a natural immune response known as lipid oxidation producing oxidized lipids, one of which is beneficial, while the other is harmful. This mechanism is applicable for healthy individuals as well. The shorter lipids (truncated) are considered to exhibit a protective effect, whereas the longer ones are inflammatory, causing hyperactivity of immune cells. It was observed that the ratio of full-length to truncated oxidized lipids was altered in obese tissues when compared with healthy ones. Doctors may be able to treat chronic diseases by devising drugs that reduce the levels of full length lipids and thus correct the imbalance of the ratio which leads to unhealthy inflammation.



Source: World Health Organization, Center for Disease Control