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July 25, 2008



**American Association of Poison Control Centers**

## **Weekly Update on Toxin News, Product Recalls, Medical News & Health Care Policy**

### **Medicare to Pay Doctor Bonuses for 'E-Prescribing'**

Starting in 2009, doctors can earn additional money from Medicare if they use electronic prescribing systems, HHS officials announced July 21, 2008. The bonus program, which will continue for four years, is designed to streamline the prescription process and cut down on errors. In 2009 and 2010, Medicare will give doctors an additional 2 percent bonus on top of their fee for "e-prescribing." In 2011 and 2012, the bonus will drop to 1 percent, and in 2013, the bonus will drop again to 0.5 percent. After five years, bonuses for e-prescribing will be phased out; doctors who haven't adopted e-prescribing will be reimbursed at lower rates. There will, however, be exceptions for doctors who have legitimate reasons for not complying.

**For more information:** <http://www.washingtonpost.com/wp-dyn/content/article/2008/07/21/AR2008072102035.html>

### **Epilepsy Drug Topiramate May Increase Birth Defect Risk**

Pregnant women who use the epilepsy drug topiramate alone or in combination with other epilepsy drugs may be increasing their risk of birth defects, according to a report published in the July 22 issue of *Neurology*. Topiramate (brand name Topamax) is a common anti-seizure medication used by many with epilepsy. It's also used to treat migraine headaches. Many similar drugs also increase the risk of birth defects, but until this report, the link between birth defects and topiramate had not been well studied. For the study, the researchers collected data on women who became pregnant while taking topiramate alone or in combination with other epilepsy drugs. The incidence of birth defects among women taking topiramate was higher than the rate of birth defects in the general population, which is about 1 percent to 2.5 percent. And there were more birth defects among women taking topiramate along with the epilepsy drug valproate, compared with women taking topiramate and another epilepsy drug.

**For more information:** <http://www.washingtonpost.com/wp-dyn/content/article/2008/07/21/AR2008072101827.html>

### **Serious Warnings on Abacavir (Marketed as Ziagen) and Abacavir-Containing Medications**

FDA has informed health care professionals that serious and sometimes fatal hypersensitivity reactions (HSR) caused by abacavir therapy are significantly more common in patients with a particular human leukocyte antigen (HLA) allele, HLA-B\*5701. FDA reviewed data from two studies that support a recommendation for pre-therapy screening for the presence of the HLA-B\*5701 allele and the selection of alternative therapy in positive subjects. Genetic tests for HLA-B\*5701 are available and all patients should be screened for the HLA-B\*5701 allele before starting or restarting treatment with abacavir or abacavir-containing medications. Development of clinically suspected abacavir HSR requires immediate and permanent discontinuation of abacavir therapy in all patients, including patients negative for HLA-B\*5701.

**For more information:** <http://www.fda.gov/medwatch/safety/2008/safety08.htm#Abacavir>

### **U.S. Spends Twice as Much on Health Care Than Most Other Industrialized Nations**

The U.S. spends twice as much on health care per capita than most other industrialized nations but ranks lower than those nations on a number of criteria, according to a report released July 17 by the Commonwealth Fund. For the report, the Commonwealth Fund ranked the health care systems of the U.S. and several other industrialized nations based on 37 criteria. The report found that, although the rate of preventable deaths among U.S. residents younger than age 75 decreased from 115 per 100,000 in 2001 to 110 deaths in 2006, the U.S. ranked last among all industrialized nations.

**For more information:** [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?DR\\_ID=53347](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=53347)

### **West Virginia State Indigent Prescription Drug Program Shows Success & Growth**

West Virginia Rx, a new state-managed prescription drug program that allows uninsured state residents to obtain medications at no cost, is on track to enroll 10,000 people within its first year. Uninsured residents between ages 18-65 with annual incomes less than 200% of the federal poverty level are eligible to purchase the drugs that are donated by pharmaceutical companies. Each resident must pay a \$30 annual processing fee. About 200 people signed up when program was launched, but it has grown quickly through a Web site that allows physicians to enroll patients in about one minute.

**For more information:** [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?DR\\_ID=53410](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=53410)

### **Disease Prevention Programs Generate Substantial Savings in Health Care Costs**

Investing \$10 per person per year in community disease prevention programs may save the U.S. \$2.8 billion in health costs over two years & \$16.5 billion over five years, according to a study released July 17 by the Trust for America's Health. The report provides state-by-state findings that community health programs could reduce rates of diabetes and high blood pressure by 5% within two years & the incidence of some forms of cancer and arthritis within 10 to 20 years.

**For more information:** [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?DR\\_ID=53375](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=53375)

### **EPA Determines Regulation Not Needed for 11 Potential Drinking Water Contaminants**

On July 24, the EPA made a final determination not to regulate 11 contaminants on the second drinking water contaminant candidate list (CCL 2). The agency has concluded that the contaminants do not occur nationally in public water systems, or occur at levels below a public health concern. The 11 contaminants include naturally occurring substances, pesticides, herbicides, and chemicals used (or once used) in manufacturing. While none of the contaminants were found nationally at levels of public health concern in public water systems, EPA is updating health advisories for seven of the contaminants to provide current health information to local officials for situations where the contaminants may be present. EPA is updating health advisories for boron; dacthal mono- and di-acid degradates; 1,3-dichloropropene (Telone); 2,4-dinitrotoluene, and 2,6-dinitrotoluene; and 1,1,2,2-tetrachloroethane. EPA has determined that updated or new health advisories are not needed for 1-dichloro-2,2-bis(p-chlorophenyl) ethylene (DDE); s-ethyl propyl thiocarbamate (EPTC); Fonofos; and Terbacil, because the national monitoring data showed almost no occurrence at levels of public health concern.

**For more information:** <http://www.epa.gov/safewater/ccl/index.html>

### **FDA Releases Guide for Safe Storage of Food**

To avoid food-borne illnesses, the FDA released an information resource guide called: *Are You Storing Food Safely?*

**For more information:** <http://www.fda.gov/consumer/updates/foodstorage072108.html>

### **EPA Acts to Address Carbofuran Residues in Food**

EPA is revoking the regulations that allow carbofuran residues in food. Even though carbofuran is used on a small percentage of the U.S. food supply and therefore the likelihood of exposure through food is low, EPA has identified risks that do not meet its food safety standards. In addition, EPA is proceeding on the path toward cancellation of the pesticide registration that will address the risks to pesticide applicators and birds in treated fields.

**For more information:** [http://www.epa.gov/pesticides/reregistration/carbofuran/carbofuran\\_noic.htm](http://www.epa.gov/pesticides/reregistration/carbofuran/carbofuran_noic.htm)

### **Federal Authorities Seize Xiadafil VIP Dietary Supplement Tablets After Company Refuses to Recall Product**

At the request of the FDA, U.S. Marshals have seized nearly \$74,000 worth of Xiadafil VIP tablets, Lots 6K029 and 6K209-SEI, distributed by SEI Pharmaceuticals, Inc. of Miami, FL. Although marketed as a dietary supplement to treat erectile dysfunction (ED) and for sexual enhancement, these lots represent an illegally marketed drug containing an undeclared ingredient. The action follows a formal FDA request to SEI Pharmaceuticals (SEI) on May 27, 2008, to recall the lots of Xiadafil VIP tablets. The products were given away at trade shows and sold in eight tablet bottles (Lot # 6K029) and blister cards of two tablets (Lot # 6K029-SEI) bearing an expiration date of September 2009 (09/09). The company, however, refused to recall these products, making the seizure action necessary to prevent additional, illegal Xiadafil VIP products from entering the marketplace. The FDA's chemical analysis of Xiadafil VIP tablets Lots # 6K029/6K029-SEI found that the product contains hydroxyhomosildenafil, which is chemically similar to sildenafil. Sildenafil is the active ingredient in Viagra, an FDA-approved prescription drug for ED. The FDA has not approved Xiadafil VIP for ED or any other drug use, and the safety and effectiveness of this product is unknown. Although offered for sale as dietary supplements, the seized articles are new drugs that may not be introduced into interstate commerce without an approved new drug application filed with FDA.

**For more information:** [www.fda.gov/consumer/updates/erectiledysfunction010408.html](http://www.fda.gov/consumer/updates/erectiledysfunction010408.html).

### **Warnings on Therma Power and Grenade Fat Burner Weight Loss Products**

On July 24, 2008, Health Canada advised consumers not to use Therma Power and Grenade Fat Burner, which are promoted for weight loss. Therma Power comes in two varieties: Therma Power "red," which contains Ephedra, and Therma Power "blue," which is Ephedra-free. The U.K. Medicines and Healthcare products Regulatory Agency (MHRA) has warned consumers not to use the ephedrine-containing products Therma Power (red variety) and Grenade Fat Burner after the products were associated with serious adverse reactions, including a report of death. MHRA has also warned consumers about the ephedrine-free (blue) variety of Therma Power, because it contains synephrine and caffeine, a combination that has been associated with cardiovascular adverse reactions. Synephrine is a substance similar to ephedrine and may have similar cardiovascular adverse effects that could lead to stroke, heart attack and/or death. Caffeine is a stimulant that can significantly increase the effects of synephrine. Possible Side-Effects: Ephedra is a plant source of the active ingredient ephedrine. Side-effects associated with the use of ephedrine include dizziness, headache, decreased appetite, anxiety, restlessness or nervousness, digestive problems, irregular or fast heartbeat, insomnia, flushing, sweating, high blood pressure, stroke, seizures, psychosis and death.

**For more information:** [http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/fpa-ape\\_2008/2008\\_120-eng.php](http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/fpa-ape_2008/2008_120-eng.php)

### **Warning on Foreign Product Wodibo**

On July 24, Health Canada advised consumers not to use Wodibo, which is promoted as an all-natural Chinese product used for the treatment of erectile dysfunction. The Danish Medicines Agency has warned against the use of Wodibo because it was found to contain sildenafil and tadalafil.

**For more information:** [http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/fpa-ape\\_2008/2008\\_118-eng.php](http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/fpa-ape_2008/2008_118-eng.php)

### **Warning on Viril-Ity-Power (VIP) Tabs**

On July 24, Health Canada advised consumers not to use Viril-Ity-Power (VIP) Tabs. Viril-Ity-Power (VIP) Tabs (560 mg/serving) is promoted as an all-natural dietary supplement used for sexual enhancement and the treatment of erectile dysfunction. Viril-Ity-Power (VIP) Tabs are packaged into 2-capsule blister packs and 8-capsule bottles. The FDA has warned against the use of Viril-Ity-Power (VIP) Tabs after a sample of the product was found to contain hydroxyhomosildenafil, a compound similar in structure to sildenafil. The product has been recalled by the manufacturer in the U.S.

**For more information:** [http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/fpa-ape\\_2008/2008\\_119-eng.php](http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/fpa-ape_2008/2008_119-eng.php)

### **Agricola Zaragoza, Inc. Recalls Jalapeno Peppers Because of Possible Health Risk**

On June 21, Agricola Zaragoza, Inc. of McAllen, TX, issued a recall of Jalapeno Peppers distributed since June 30th, 2008, due to potential Salmonella contamination. The Jalapeno Peppers were distributed to customers in GA and TX. The Jalapeno Peppers being recalled were shipped in 35lb. plastic crates and in 50lb. bags with no brand name or label.

**For more information:** [http://www.fda.gov/oc/po/firmrecalls/agricola\\_zaragoza07\\_08.html](http://www.fda.gov/oc/po/firmrecalls/agricola_zaragoza07_08.html)

### **Sau-Sea Foods, Inc. Issues Allergy Alert on Undeclared Egg in Smoked Salmon Spread**

On July 18, Sau-Sea foods, Inc, of Water Mill, NY, issued a recall for all tubs of SMOKED SALMON Spread with the sell by dates as follows: 072308, 082708, 092408, 1 12508, 03 1309. People who have an allergy or severe sensitivity to egg run the risk of serious or life threatening allergic reaction if they consume these products. SMOKED SALMON SPREAD was distributed throughout the Northeast through retail stores. The SMOKED SALMON SPREAD comes in 3 7.5 ounce, semi rigged plastic tub with a snap on lid and was sold under the name Sau-Sea. No illnesses have been reported to date.

**For more information:** [http://www.fda.gov/oc/po/firmrecalls/sausea07\\_08.html](http://www.fda.gov/oc/po/firmrecalls/sausea07_08.html)

### **Magnets Recalled Due to Violation of Lead Paint Standard**

On July 24, the CPSC announced a voluntary recall of Classic Horseshoe Magnets. The plastic coating on the magnets contains excessive levels of lead. Incidents/Injuries: None reported. Description: This recall involves the Classic Horseshoe Magnets. The 6-inch tall horseshoe magnet has a red plastic coating on the "handle" end. Each "foot" of the magnet has an engraved "S" or "N." Sold at: Specialty retail stores and educational supply distributors nationwide from March 2003-April 2008 for about \$10. An additional voluntary recall of U-shaped Magnets, Bar Magnets, Magnet Sets and Magnet Needle Sets due to paint on the magnets containing excess levels of lead. Incidents/Injuries: None reported. Distribution: Sold through distributors that sell to educational institutions and educational stores nationwide from April 2000-February 2008 for about \$9. Description of Magnets:

- "Large" and "Small" U-shaped Magnets: These magnets are in the shape of a "U" or horseshoe. One half of each magnet is painted red and is imprinted with the letter "N"; the other half is painted blue, and is imprinted with the letter "S".
- "Large" and "Miniature" Bar Magnets: These magnets are in the shape of a bar. The magnets are painted half red and half white. The red half is imprinted with the letter "N" and the white half is imprinted with the letter "S".
- Magnet Sets: This set contains a small u-shaped magnet, two small bar magnets, and two small compasses. All magnets are painted half red and half white. The red half is imprinted with the letter "N" and the white half is imprinted with the letter "S". The package is labeled "Magnets & Compasses."
- Magnet Needle Sets: This set contains 10 sets of small cone-shape bases and elongated-diamond-shaped magnets which can be fastened into the bases. The magnets are painted half red and half white.

**For more information:** <http://www.cpsc.gov/cpscpub/prereel/prhtml08/08344.html>

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### **FDA Labeling Revisions, Generic and New Drug Approvals**

#### July 24, 2008

- Coreg (carvedilol) Tablets, GlaxoSmithKline, Labeling Revision
- Duac (benzoyl peroxide and clindamycin phosphate) Gel, Stiefel Laboratories, Inc., Labeling Revision
- Januvia (sitagliptin phosphate) Tablets, Merck & Co., Inc., Labeling Revision
- Januvia (sitagliptin phosphate) Tablets, Merck & Co., Inc., Supplement
- OVCON 50 (ethinyl estradiol and norethindrone) Tablets, Warner Chilcott, Labeling Revision
- SPECTRACEF (cefditoren pivoxil) Tablets, Cornerstone BioPharma, Formulation Revision
- Zolanza (vorinostat) Capsules, Merck & Co., Inc., Labeling Revision

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- CANCIDAS (caspofungin acetate) I.V. Injection, Merck Research, Labeling Revision
- Kinlytic (urokinase) Injection, ImaRx Therapeutics, Labeling Revision
- Mirena (levonorgestrel) Intrauterine Device, Bayer Healthcare, Labeling Revision
- Natacyn (natamycin) Ophthalmic Suspension, Alcon, Labeling Revision
- Tekturma HCT (aliskiren hemifumarate and hydrochlorothiazide) Tablets, Novartis Pharma, Labeling Revision
- ZIAGEN (abacavir sulfate) Tablets, GlaxoSmithKline, Efficacy Supplement with Clinical Data to Support
- ZIAGEN (abacavir sulfate) Oral Solution, GlaxoSmithKline, Efficacy Supplement with Clinical Data to Support

**For more information:** <http://www.fda.gov/cder/whatsnew.htm>