PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

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FDA Device Regulation Leaves Unsafe Products on Market: Public Citizen Petitions for Better Rules

In recent months, the death of 21-year-old college student Joshua Oukrop due to the failure of a defibrillator manufactured by the Guidant Corporation has brought increased scrutiny to the regulation of medical devices.

A *New York Times* investigation into the events surrounding Oukrop's death revealed that for at least three years, Guidant had failed to notify doctors and the FDA about the flaw that ultimately resulted in the student's death. Further investigation by the *Times* revealed that Guidant had continued to sell faulty defibrillators even after it had corrected the problem and built new devices. A later story showed that the FDA had been notified of the problem with the device a month prior to Oukrop's death, but it, too, failed to act to warn doctors or patients, perhaps because the information about failures provided to the agency was buried in a routine regulatory disclosure.

The fact that the agency was informed of the problem and did not in turn inform doctors or patients raises serious questions about how the FDA handles information it receives from device manufacturers. Guidant notified the FDA of the high rate of device failure in its required annual report, portions of which the agency regards as proprietary. Dr. Daniel Schultz, the director of the Food and Drug Administration's Center for Devices and Radiological Health (CDRH), indicated to the *Times* that it would "tie up too many resources" to discern which portions of the thousands of reports the FDA receives each year can be released to the public. As a result, absent a Freedom of Information Act request, nothing is disclosed.

But regulatory failures and poor corporate conduct are nothing new where medical devices are concerned. In 1999, patient Mark Gleeson was implanted with a faulty St. Jude pacemaker despite the fact that the company was already selling an updated, FDA-approved version of the device that did not have the defect.

Citing the Guidant problems and describing Gleeson's experience in detail, Public Citizen filed a petition with CDRH on September 14th calling on the FDA to strengthen the regulations that govern how medical devices are reviewed and recalled once they are on the market. It asks the FDA to institute new procedures to ensure automatic, mandatory review of older devices as newer ones with improved safety and/or efficacy are brought to market.

Under current regulations, the petition argues, companies are permitted to delay (or even prevent) the removal

continued on page 2

CONTENTS

Dangerous Drug Interaction
Do not take the antibiotic clarithromycin with the anti-gout drug colchicine 3

Recalls
August 20-September 26
Dietary supplements, children's jewelry, and gas grills are on the list this month....4

Direct-To-Consumer Deception
Three deceptive ad campaigns from pharmaceutical companies....9

Insurers Get It Wrong
Ads dramatically overstate the costs of medical malpractice....10

Outrage of the Month
PhRMA's DTC guidelines do little to rein in drug ads 12

MEDICAL DEVICES, *from page 1*

from the market of a flawed device as physicians continue to use up the remaining inventory. The manufacturer can wait until the new device has an established market before it recalls the older version, all the time depleting its inventory of older, inferior devices. Although this practice benefits the manufacturers and distributors, the patients who receive these inferior products are potentially placed in grave danger.

In the case of the failed St. Jude pacemaker, the FDA was not only aware of the problem but had formally approved a corrected device for sale. Neither the FDA nor the company took steps to inform doctors or patients of either the malfunction or the redesign until a recall was issued in July 1999, by which time the number of short-circuits reported had climbed to 88. The problematic St. Jude pacemakers continued to be implanted in patients for at least six weeks after the new, improved devices became available.

Mark Gleeson was one of these patients. He had a St. Jude Trilogy 2364L pacemaker implanted in February 1998. One year later, in February 1999, the new pacemaker failed. Fortunately, the pacemaker failure was detected by his physician, and Mr. Gleeson underwent surgery on March 1, 1999. The defective pacemaker was replaced with another St. Jude Trilogy 2364L.

When a pacemaker fails prematurely, it is routinely sent back to the company for evaluation. The company sends the explanting physician a "failure analysis report" explaining what went wrong. In this case, St. Jude reported that metallic weld spatter between the battery pin and the battery case caused a dangerous electrical connection between the positive and negative terminals of the battery, causing the battery to short-circuit and therefore deplete prematurely.

In 1999, patient Mark Gleeson was implanted with a faulty St. Jude pacemaker despite the fact that the company was already selling an updated, FDA-approved version of the device that did not have the defect.

Concerned by the early failure of the device (pacemakers have an expected battery life of 5-6 years) and the fact that he had received a replacement from the same series, Mr. Gleeson filed a complaint with the FDA and submitted his explanted pacemaker for further investigation.

James Fleckenstein, the reviewing officer in the FDA's Los Angeles district office, reported that Mr. Gleeson's pacemaker was one of the faulty units whose design problems had been remedied by an FDA-approved manufacturing change. St. Jude received FDA approval for its solution to the defect in November 1998, according to Fleckenstein's review. The change was not introduced into production until January 6, 1999, with the first new unit entering market channels in early February.

The unit Mr. Gleeson was to receive completed production on January 11th, five days after the new unit began production. When Mr. Gleeson had his replacement unit implanted on March 1st, the corrected devices had been available for almost a month. Fleckenstein concluded that "[I]t seems clear from my review of the management controls within the quality system that top management [at St. Jude] was aware of the premature battery problem in 1997 and monitored it until July 1999."

St. Jude finally recalled the faulty device in July 1999, four months after Mr. Gleeson received a replacement pacemaker that did not did not contain the available FDA-approved fix. Ironically, Mr. Gleeson had received

continued on page 3

THE PUBLIC CITIZEN HEALTH RESEARCH GROUP
Health Letter

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Antibiotic Clarithromycin (BIAXIN) Can Have Deadly Interaction with Anti-Gout Drug Colchicine

Using the antibiotic clarithromycin (BIAXIN, BIAXIN XL) in combination with the gout drug colchicine increases the risk of death because of colchicine toxicity, a recent study shows. Research staff from the University of Hong Kong published their findings about this dangerous interaction in the August issue of the journal *Clinical Infectious Diseases*. The potential for harm is especially high in patients with kidney problems.

Both clarithromycin and colchicine are very popular drugs in the U.S. In 2004, the total number of clarithromycin prescriptions exceeded five million. More than 2.3 million prescriptions for colchicine were dispensed during the same year. Colchicine is also available in combination with another anti-gout medication called probenecid. This combination is sold as COL-PROBENECID.

Colchicine toxicity manifests itself as abdominal pain, vomiting, diarrhea, and fever. It can damage the bone marrow's ability to make all types of blood cells, technically referred to as pancytopenia. This decrease in blood cells causes severe anemia (low red blood cells) and seriously low numbers of white blood cells. White blood cells are important for fighting infection.

The researchers identified 116 patients admitted to their hospital between February 1997 and September 2004 who had been prescribed both colchicine and clarithromycin. They compared the clinical outcomes of patients who took the two drugs simultaneously and those who were prescribed the drugs sequentially, having had a prescription for one drug started only after the course of therapy with the other drug had been completed.

In the 88 patients who received the two drugs together, nine (10.2 percent) died. Only one (3.6 percent) of the 28 patients who received the two drugs sequentially died. The risk of death was greatest in those with kidney problems and with the loss of the bone marrow's ability to make blood cells.

This drug interaction appears to occur because clarithromycin simultaneously increases the amount of colchicine that is absorbed into the blood stream and decreases its breakdown by the liver, leading to the accumulation of dangerous amounts of colchicine in the blood. The accumulation of colchicine is even greater in patients with kidney problems because their ability to excrete the drug in the urine is decreased.

The study's authors' straightforward and sound advice is that colchicine and clarithromycin not be taken together. They also recommend that for patients who need colchicine and require an antibiotic similar to clarithromycin, azithromycin (ZITHROMAX) may be substituted. Azithromycin does not increase the absorption of colchicine or inhibit its breakdown by the liver.

What You Can Do

You should contact your physician immediately if you are taking colchicine and clarithromycin together. ■

MEDICAL DEVICES, *from page 2*

one of the faulty pacemaker models as the replacement for another faulty pacemaker. Overall, at least 180 faulty devices have been explanted. Fortunately, Mr. Gleeson's pacemaker has continued to function adequately.

The Guidant defibrillator problems led a private group, the Heart Rhythm Society, to hold a hearing on cardiac devices. At the September 16th meeting, the FDA released data from a study that showed an increasing rate of cardiac defibrillator and pacemaker failures over a ten-year period, with 50 percent of the defibrillator malfunctions occurring in the last three years. There were 61 deaths as a result of pacemaker or defibrillator malfunction over the study period.

Public Citizen's petition to the FDA notes that in circumstances where an approved device has harmed patients or has the potential to harm patients, the Medical Device Amendments to the Food, Drug, and Cosmetic Act's notification, replacement, and recall provisions ensure that the FDA can act promptly to minimize or eliminate the risk of future harm. While St. Jude may not have been *required* by existing regulations to recall the faulty model, this example highlights the way in which current FDA policy defies common sense, despite the availability of adequate regulatory authority.

As both the Guidant and St. Jude cases demonstrate, the benefits of lifesaving technologies such as pacemakers and defibrillators are limited when industry prioritizes market share and product continuity over patient safety and the FDA does not force patient safety to the forefront. The FDA should do more to evaluate what the approval of a new device, or improvement of an older device, means in terms of the devices that came before it. If a newer device is safer or more effective, whether made by the same company or not, the companies with less-desirable products should be forced to recall unimplanted versions of the older product. Patients and doctors should be informed so that they can make their own decisions about the wisdom of explantation.

Public Citizen's petition is available on the web at http://www.citizen.org/publications/release.cfm?ID=7401. ■

Product Recalls

Aug 20 — Sept 26, 2005

This chart includes recalls from the Food and Drug Administration (FDA) Enforcement Report for drugs and dietary supplements, and Consumer Product Safety Commission (CPSC) recalls of consumer products.

DRUGS AND DIETARY SUPPLEMENTS

The recalls noted here reflect actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request or by FDA order under statutory authority. A Class I recall is a situation in which there is a probability that the use of or exposure to the product will cause serious adverse health consequences or death. Class II recalls may cause temporary or medically reversible adverse health consequences. A Class III situation is not likely to cause adverse health effects. If you have any of the drugs noted here, label them "Do Not Use" and put them in a secure place until you can return them to the place of purchase for a full refund. You can also contact the manufacturer. If you want to report an adverse drug reaction to the FDA, call (800) FDA-1088. The FDA Web site is *www.fda.gov*.

CLASS I Recalls

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
a) **Double Deers Formula brand Expellin Extract (Concentrated)**, Dietary Herbal Supplement, Chuang Cha Tiao Wan (160 mg each) Chinese mint (above ground parts), Fragrant angelica (root), Notopterygium (root & rhizome), Ligusticum wallichii (rhizome), Siler (root); b) Cardioflex (Guan Xis Su He Wan) Dietary Supplement (500mg Each), Santalum wood (Santali lignum)(root), Aristochia root (Radix aristolochiae)(root), Myrrh resin (Myrrha) (root), Scarlet root (Salvia militorrhiza)(root), Styrax resin (Styrax obassia)(root), Class I, FDA's analysis revealed that the products contain Aristolochic Acid, a potent carcinogen and nephrotoxin found in certain plants and botanicals.	All lots; a) 9,600 bottles distributed nationwide, b) 4,562 bottles distributed nationwide; Kingsway Trading Inc., Brooklyn, NY.
Nature's Plus(r) brand Animal Parade Children's Chewable Calcium Tablets, Natural Vanilla Sundae Flavor, Class I, Product contains undeclared sodium caseinate, a milk derivative which poses a health risk to individuals that are allergic to milk.	Lot numbers 03703A, 1037089, 14204A, 19703C, 27203A, 32103A, A31902; 128,915 bottles and 73,134 sample packets distributed nationwide and internationally; Natural Organics, Melville, NY.

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Albuterol Sulfate Inhalation Solution, 0.083% (2.5mg/3mL), Rx Only, For Oral Inhalation Use Only, Class II, Discoloration.	Lot # W12241 and W12242; 3,540 cartons (60 x 3mL Unit Dose Vials per carton) distributed nationwide; IVAX Pharmaceuticals, Miami, FL.
Anagrelide Hydrochloride Capsules, 0.5 mg (base), Platelet-Reducing Agent, Rx only, Class II, Dissolution failure.	Lot 358001V, exp. date 06/2006; 6,180/100 tablet bottles distributed nationwide; Boehringer Ingelheim Roxane, Inc, Columbus, OH.
a)**Econopred plus (prednisolone acetate) Sterile Ophthalmic Suspension**, 1%, Rx only, also under other label as Prednisolone Acetate Ophthalmic Suspension1%; b)**TobraDex (Tobramycin 0.3% (3mg) and Dexamethasone 0.1% (1mg)) Sterile**	a) Lot numbers: 70020F, 68154F, 71266F, and 71267F (all 4 lots are samples); 72489F, and 82236F (both lots are samples); 69081F; 71281F and 70591F; b) Lot number: 72950F; c) Lot number: 70029F; d) Lot number 70739F; 548,869 units distributed nationwide and inter-

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Ophthalmic Suspension, Rx only; c)**Neomycin and Polymyxin B Sulfates and Hydrocortisone Ophthalmic Suspension**, USP, Each mL contains Neomycin Sulfate (equivalent to 3.5mg neomycin sulfate base), polymyxin B sulfate 10,000 units, hydrocortisone 10mg, Rx only; d)**Ciprodex (ciprofloxacin 0.3% and dexamethasone 0.1%) Sterile Otic Suspension**, Rx only, Class II, Lack of assurance of sterility.	nationally; Alcon Research, Ltd, Fort Worth, TX.
Fougera Nystatin and Triamcinolone Acetonide Cream USP, Each gram contains 100,000 USP Nystain Units and I mg triamcinolone acetonide, Rx only, Class III, Subpotent.	Lot M303, exp date 08/2005. 64,662 tubes distributed nationwide; Altana Inc., Melville, NY.
Hemocyte Tablets (Ferrous Fumarate 324 mg) Folic Acid 1 mg, Class III, Mislabeling: The blister cards are printed with "Folic Acid 1 mg" as an ingredient, which in not in the Hemocyte Tablets.	Lot number: 050520-01, exp. date 05/2008; 7,391 cartons distributed nationwide; U S Pharmaceutical Corporation, Decatur, GA.
MINOXIDIL Tablets, USP, 2.5 mg, Rx only, Class II, Oversized tablets.	Lot L5A0061, exp date 01/31/2007; 7,685 bottles x 100 tablets distributed nationwide; Watson Pharmaceuticals, Inc., Corona, CA.
a)**Mirtazapine Tablets**, 30 mg, Rx only; b) **Mirtazapine Tablets**, 45 mg, Rx only, Class III, Dissolution failure.	a) Lot 556066A, exp. date 02/2007 Lot 556066B, exp. date 02/2007; b) Lot 556247A, exp. date 04/2007; 69,913 units distributed nationwide; Boehringer Ingelheim Roxane, Inc, Columbus, OH.
Nature Throid NT-1, Thyroid, U.S.P. (TAN, C.T.), 1 Grain (64-8 MG), 100 Tablets, Class II, Mislabeled: bottles labeled to contain Nature-Throid NT-1 actually contain Nature-Throid NT-1/2.	Lot # M012Q-5D11; 94 bottles distributed nationwide; RSJ Inc, Phoenix, AZ.
a)**Pain Reliever** — Infant Drops, Acetaminophen 160 mg per 1.6 ml 1/2 fl oz (15 mL), Cherry Flavor, Use Only With Enclosed Syringe. Directions: Weight under 24 lb or Age Under 2 years — ask a doctor; b)**Pain Reliever** — Infant Drops, Acetaminophen 160 mg per 1.6 ml 1/2 fl oz (15 mL), Grape Flavor, Use Only With Enclosed Syringe, Directions: Weight under 24 lb or Age Under 2 years — ask a doctor. c)**Cough & Cold Concentrate Infant Drops**, Acetaminophen 160 mg per 1.6 ml, Dextromethorphan BBr 5 mg per 1.6 ml, Pseudoephedrine HCl 15 mg per 1.6 ml; 1/2 fl oz (15 mL), Cherry Flavor, Use Only With Enclosed Syringe, Directions: Weight under 24 lb or Age Under 2 years —ask a doctor. d) Decongestant & Cough Infant Drops, Dextromethorphan BBr 5 mg per 1.6 ml, Pseudoephedrine HCl 15 mg per 1.6 ml; 1/2 fl oz (15 mL), Cherry Flavor, Use Only With Enclosed Syringe, Directions: Age Under 2 years — ask a doctor. Class II, Although the labeled directions for use are consistent with the labeled dosage directions; the product is also intended for use by infants under 2 years of age, and the dosing syringe included with the product is not appropriate for the dosage levels generally directed by doctors for infants under 2 years of age.	All lots with a syringe for dosing affected; each recalled item is distributed as multiple generic forms and as the store brand of multiple grocery stores and pharmacies. Contact the manufacturer to determine if your product is affected. 1,072,098 bottles distributed nationwide; Perrigo Company, Allegan, MI.
a)**Paxil Tablets** (paroxetine HCl) 10 mg, Rx only, also labeled as Paroxetine HCl Tablets, 10 mg; b) Paxil Tablets (paroxetine HCl) 20 mg, Rx only, also labeled as Paroxetine Tablets, 20mg; c) Paxil Tablets,	a) Lot # F61-5B10 exp. date 02/2008 Lot # 1-5Z76 exp. date 03/2008; b) Lots # 203-5B11 & 202-5B11 exp. date 01/31/2008; c) Lots # 503-4B12, F503-4B12, 504-4B12, M504-4B12 & I504-4B12 exp. date

continued on page 6

DRUGS AND DIETARY SUPPLEMENTS *cont.*

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
(paroxetine HCl), 30 mg, Rx only; d) Paxil Tablets (paroxetine HCl), 40 mg, Rx Only, Class II, Superpotent.	12/31/2007; d) Lots # 702-5B13 & 704-5B13 exp. date 03/31/2008; 290,704 bottles distributed nationwide; SmithKline Beecham Pharmaceuticals, Co., Cidra, PR.
Rite Aid brand Acid Reducer Tablets (Ranitidine USP), 75 mg, Class III, Mispacked; Lot was packaged without a desiccant.	Lot # 4MB0447; 22,188 bottles distributed nationwide; Leiner Health Products Llc, Carson, CA.
Toprol XL 50 mg tablets, Rx only, Class II, Mispackaging: bottles may also contain Toprol XL 100 mg tablets.	Lot # LF0012 exp. date 2/29/08; 94,776 bottles distributed nationwide; Astra Zeneca, Wilmington, DE.
Zovia 1/35E-28 Tablets USP (Ethynodiol Diacetate and Ethinyl Estradiol), Rx only, Class III, Out-of-specification result for total impurities at the 12-month stability test point.	Lot #38303H04; 14,880 cartons distributed nationwide; Watson Laboratories, Corona, CA.

CONSUMER PRODUCTS

Contact the Consumer Product Safety Commission (CPSC) for specific instructions or return the item to the place of purchase for a refund. For additional information from the Consumer Product Safety Commission, call their hotline at (800) 638-2772. The CPSC Web site is *www.cpsc.gov.*

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
AC adaptors. The recalled AC adaptors can overheat and melt. This poses the risk of fire, burn and shock injuries to consumers.	Certain AC Adaptors sold with slim version PlayStation(r) 2 Systems; about 843,000 sold at electronics, toy and computer game stores nationwide, as well as Web retailers, Oct 2004-Aug 2005; Sony Computer Entertainment America Inc., of Foster City, Calif.; (888) 780-7690 or www.us.playstation.com.
Avalanche transceivers. The batteries in these devices can become dislodged when the transceiver is struck sharply. The transceiver could fail to function properly in the aftermath of an avalanche, and result in the buried victim not being found in time to avoid serious injury or death.	Ortovox M1 and M2 Avalanche Transceivers; about 15,500 sold at outdoor specialty stores nationwide, Jan 1997-Jul 2005; Ortovox USA, of Hopkinton, N.H.; (888) 215-3131 or www.ortovox.com.
Bamboo torches and fuel canisters. The surface coating of some flame guards on these bamboo torches and replacement canisters can absorb the fuel and ignite. This can cause the torch and nearby combustibles to catch on fire, posing a risk of burn injuries and property damage.	Tiki® Bamboo Torches and Replacement Fuel Canisters; about 963,000 torches and about 18,000 replacement canisters sold at Wal-Mart, The Home Depot, Lowe's and other home and hardware stores nationwide, Dec 2004-Jul 2005; Lamplight Farms Inc., of Menomonee Falls, Wis.; (866) 239-6664 or www.lamplightfarms.com.
Bicycle helmets. Some of these helmets do not meet CPSC safety standards for bicycle helmets, which poses a risk of riders suffering head injuries.	Back Trails Jr. Toddler, Youth and Child Bicycle Helmets; about 494,000 units sold at Target stores nationwide, Apr 2004-July 2005; Target, of Minneapolis, Minn.; (800) 440-0680 or www.target.com.
Bicycles. The fork that holds the front wheel can separate at the weld, causing the rider to fall and suffer injuries.	Harley-Davidson 16-inch BMX Bicycles; about 25,000 sold at Toys "R" Us stores nationwide, July 2002-June 2005; World Wide Cycle Supply Inc., of Islandia, N.Y.; (800) 944-9951 or www.toysrus.com.
Bottle sipper tops. The pull-up valve can detach from the cap, posing a choking hazard to young children.	"Bottle Sippers" Pull-Up Bottle Caps; about 500,000 units sold at grocery stores nationwide, Jan 2002-Aug 2005; Bradshaw International Inc., of Rancho Cucamonga, Calif.; (800) 421-6290 or www.goodcook.com.

CONSUMER PRODUCTS *cont.*

Type of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Bracelet keyrings. The recalled jewelry contains high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects.	Disney Princess Bracelet Keyrings; about 145,000 sold at various retailers including Walgreen and Wal-Mart nationwide, Nov 2003-Jun 2005; Monogram International Inc., of Pinellas Park, Fla.; (800) 736-1941 or www.monogramdirect.com.
Chain saws. The flywheels on some of the chain saws may come apart during use, which could cause serious personal injury.	DOLMAR and Makita chain saws; about 1,300 DOLMAR units and 3,400 Makita units sold at outdoor power equipment distributors and industrial suppliers nationwide, Oct 2004-Aug 2005; DOLMAR Power Products, of Duluth, Ga.; (888) 673-7278 or www.dolmarusa.com; Makita U.S.A. Inc., of La Mirada, Calif.; (866) 714-3860, Ext.232 or www.makitatools.com.
Children's sunglasses. The lens in the sunglasses can separate from frames, posing a choking hazard to young children.	Sesame Street Toy Sunglasses; about 120,000 sold at discount, toy, drug, grocery, party and specialty/gift stores nationwide, Dec 2003-Aug 2005; American Greetings Corp., of Cleveland, Ohio; (800) 777-4891 or http://www.ag.com.
Children's sunglasses. The paint on the red sunglasses contains high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects.	Red Sunglasses/Toddler Cap Set; about 12,900 sold at The Disneyland Resort in California, The Walt Disney World Resort in Florida, Disney's Vero Beach Resort in Florida, and the Disney Cruise Line based in Florida, Nov 2004-Jun 2005; Walt Disney Parks and Resorts, LLC of Lake Buena Vista, Fla.; 866-802-2782 or www.disneyworld.com.
Costume jewelry. The recalled jewelry contains high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects.	Necklace and Earring Sets; about 455,000 sold at Dollar General Stores nationwide from May-Aug 2005; Dollar General Corp., of Goodlettsville, Tenn.; (800) 678-9258 or www.dollargeneral.com.
Cribs. The spindles on the crib's front rail can loosen and detach from the rail. This can allow the child to fall from the crib and poses a risk of entrapment.	Spindle Crib; about 7,600 sold at Pottery Barn Kids retail stores, the Pottery Barn Kids catalog and PotteryBarnKids.com nationwide, Jan 2004-Jul 2005; Pottery Barn Kids, of San Francisco, Calif.; (800) 330-6905 or www.potterybarnkids.com.
Floor mat map game. The orange paint on the floor mat maps contains excess levels of lead. Lead poisoning is a serious hazard to children and is associated with behavioral problems, learning disabilities, hearing problems and growth retardation.	Maptangle™ World Edition Floor Mat Map Games; about 140 distributed nationwide by educational, book, museum and specialty toy stores, Feb-Jun 2005; Hidden Hills Productions Inc., of Westlake Village, Calif.; (800) 641-9996 or http://www.borderlinegames.com.
Food processor. The interlocking lid assembly on the appliance can malfunction, allowing the food processor to be operated when the lid is off. This can result in a laceration or finger tip amputation hazard if consumers insert their hands into the food processor.	Ultimate Chopper™ food processor; about 1.5 million distributed through television infomercial sales, the firm's Web site, and various retailers nationwide, Mar 2002-Jul 2005; Ultimate Chopper LLC, of Los Angeles, Calif.; (800) 819-6297 or www.ultimatechopper.com.
Gas control valves. Screws on some water heater valves could break. If this happens, gas could leak from the valve, which poses a risk of gas explosion and fire.	Robertshaw R110 Series Gas Control Valves; about 178,000 sold on water heaters by gas appliance distributors and retailers, including Home Depot and Lowe's, and separately through gas appliance service providers, Jul-Sept 2005; Robertshaw Controls Co., of Long Beach, Calif.; (888) 225-1071 or www.robertshaw.com.
Gas grills and patio heaters. The regulators on these products can leak propane when the propane cylinder is turned on and the product is not in use. This can pose a fire or explosion hazard.	Coleman(r) Gas Grills and Patio Heaters; about 124,000 grills and about 6,200 heaters sold at Lowes, Expo Design Centers and various pool and patio retailers nationwide. Grills sold Jan 2004-July 2005; heaters sold Jun 2004-Jul 2005; (866) 584-8587 or www.coleman.com.

continued on page 8

Type of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Gas grills. The regulators on these gas grills, the component that controls the amount of gas released to the burner, could leak gas when attached to certain liquid propane tanks. This poses a risk of fire and burn injuries.	Brinkmann-brand and Charmglow-brand Gas Grills manufactured by Brinkmann; about 130,000 sold at home centers, sporting goods and hardware stores nationwide, Jan-Sept 2005; The Brinkmann Corporation, of Dallas, Texas; (800) 675-5301 or www.brinkmann.net.
Gas grills. A hose connecting the natural gas source to the grill's main manifold may not have been supplied with these grills. Without this hose, the gas would be emitted into the air, creating a potential fire hazard. Consumers should not use the grill until the main burner hose is provided.	Jenn-Air Model 720-0100 Natural Gas Outdoor Gas Grills; 644 units sold at Lowes Stores nationwide, April-May 2004; Nexgrill Industries Inc., of City of Industry, Calif.; (800) 554-5799 or Jahose@nexgrill.com.
Gas grills. The hose connecting the propane tank with the manifold can run up too close to the firebox. The heat from the firebox can damage the hose, causing it to leak gas. The release of gas creates a fire risk that could cause injury and property damage.	Charmglow® Gas Grills; about 86,000 sold at Home Depot stores nationwide, Nov 2004-Jun 2005; Nexgrill Industries Inc., of City of Industry, Calif.; (888) 568-9888 or http://0036.serorder.com.
Glass candle holders. The candle holder can unexpectedly break, posing a laceration hazard to consumers.	Glass Candle Holders; about 10,000 sold at Pier 1 Stores nationwide, Feb-Aug 2005; Pier 1 Imports, of Fort Worth, Texas; (800) 245-4595 or www.pier1.com.
Golf cars. High engine temperatures can permit fuel to get into the air filter box, posing a risk of fire.	E-Z-GO 2002-2005 gasoline-powered Fleet and Freedom Golf Cars, and Shuttle 2+2 Personnel Carriers; about 60,000 sold at E-Z-GO and independent dealers, January 2002-August 2005; E-Z-GO, of Augusta, Ga. — A Textron Company; (800) 241-5855 Ext. 4558 or www.ezgo.com.
Grout sealer. The product's odor is not chemically pungent enough to force consumers to minimize their exposure to the fumes. Consumers overexposed to these fumes can experience respiratory-related illness.	Stand'n Seal "Spray-On" Grout Sealer; about 300,000 cans sold at Home Depot Stores, Apr-Jun 2005; Tile Perfect, a division of Roanoke Companies Group Inc., of Aurora, Ill.; (800) 552-6225 Ext. 2572 or www.standandseal.com.
Infant carriers. The stitching that attaches the webbing to the carrier/sling can break, posing a fall hazard to young children.	ZoloWear Infant Carriers/Slings; about 165 sold by the ZoloWear.com Web site, individual distributors, and children's boutiques in California, Hawaii and Texas, May-August 2005; ZoloWear Inc., of Austin, Texas; (888) 285-0044, recall@zolowear.com, or www.zolowear.com/recall.
Inflatable arm bands. The seams of the inflatable arm bands can tear, causing them to deflate. This poses a drowning hazard to young children.	Surf Club™ Arm Bands; about 480,000 pairs sold at CVS stores nationwide, Apr 2003-Aug 2005; Atico International USA, Inc., of Fort Lauderdale, Fla.; (877) 546-4835 or www.aticousa.com.
Menorahs. The cup holding the candles on these menorahs are not constructed of the correct material and could ignite, posing a fire hazard.	Cat and Dog Menorah; about 480 sold at specialty stores nationwide, Jul-Aug 2005; Continental Creations Inc., of New Bedford, Mass.; (800) 927-1515.
Off-highway utility vehicles. The brakes on these vehicles can fail.	Arctic Cat Prowler XT Off-Highway Utility Vehicle; about 700 units sold at Arctic Cat dealerships, Jul-Sept 2005; Arctic Cat Inc., of Thief River Falls, Minn.; (800) 279-6851 or www.arctic-cat.com.
Plush toy. Beads of glitter glue on the colored ribbons could detach and pose an aspiration hazard to young children.	Sparkle Horse Toys; about 1,100 sold at specialty toy and gift stores nationwide, Jul-Aug 2005; Douglas Company, of Keene, N.H.; (800) 992-9002 or www.douglascuddletoy.com.

Three Misleading Direct-to-Consumer Ad Campaigns

On September 29th, Peter Lurie, the Deputy Director of Public Citizen's Health Research Group, testified before the Senate Committee on Aging regarding the pitfalls of direct-to-consumer advertising. Among other issues, he highlighted one instance of direct-to-consumer advertising that encourages teens to ask for a particular prescription acne treatment by offering free music. It's illegal to bribe doctors — but not patients, it seems. Excerpts from his testimony and the offending ad follow.

Distinctly uncool: acne drug maker manipulates teens

In the eight years since the FDA opened the floodgates to broadcast DTC advertising [by deregulating such ads], numerous inappropriate advertisements have appeared. The most widely discussed have been the massive DTC campaigns waged by the manufacturers of the Cox-2 inhibitors. Importantly, these drugs were never proved to be more effective pain relievers than many drugs available over-the-counter. For most patients the purported stomach protection offered by these drugs (a claim that the FDA permitted only for Vioxx, but through industry promotional efforts came to be associated with the other Cox-2 inhibitors as well) was irrelevant as those patients tolerated conventional pain relievers without stomach upset. Nonetheless, an estimated two-thirds of the growth in Cox-2 use between 1999 and 2000 was among such patients. In 2000, Vioxx was the number one DTC-advertised drug — at $160 million, larger than the campaigns that year for Pepsi and Budweiser — and retail sales quadrupled. With as many as 140,000 serious cardiovascular events due to Vioxx alone, the dangers of such promotions are now increasingly apparent. Other drugs that have been transformed from pedestrian to blockbuster in part by DTC advertising are Claritin for allergies and Singulair for asthma.

One of the more astounding DTC advertisements we have seen is still running. Produced by Galderma Laboratories, the makers of the prescription acne medication Differin (adapalene), and broadcast both on the Internet and on MTV, the advertisements direct teenage viewers to a portion of the Differin website to receive free music downloads. The advertisements are clearly directed at teenagers: the viewer is exhorted to obtain a Teen Survival Handbook and to take a self-test on acne called Zit

continued on page 10

CONSUMER PRODUCTS *cont.*

Type of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Thermos bottles. The handle on the thermos bottles can break, causing the vacuum seal to fail and release organic, non-toxic charcoal powder insulation into the air. This can cause consumers to suffer short-term vision problems and temporary breathing problems when they inhale the powder.	Stanley thermos bottles; about 45,000 sold at Wal-Mart, Kmart, Target and other discount department stores nationwide, Oct 2002-Feb 2003; PMI, of Seattle, Wash.; (800) 919-6330 or www.Stanley-pmi.com.
Water kettles. The handle can detach from the glass carafe, spilling hot water and causing severe burn injuries.	Capresso Water Kettles; about 15,000 sold at specialty kitchen stores nationwide, mail order gourmet catalogs, Capresso.com and other Web site retailers such as Amazon.com, Aug 2004-May 2005; (800) 767-3554 or www.capresso.com.
Water scooters. Hydrogen gas can build up in the battery compartment and cause the battery cover and the battery package to forcefully expel from the product, posing a risk of injury to the user or bystanders.	Aqua Scout Water Scooters; About 475 sold online at the Aqua Scout Web site and through eBay, May-July 2005; MyDigitalDiscount.com Inc. / Aqua Scout, of Minetto, N.Y.; matchoo5050@yahoo.com, www.aquascout.us.

Insurers Have it Wrong on Malpractice — Again

Following a misleading advertising campaign in Washington, D.C. this spring, a health insurance industry group, America's Health Insurance Plans, is back with a second effort that once again sensationally overstates the cost of the medical liability system.

Two new ads appearing in local publications and the District of Columbia's public transportation system claim that "with the money D.C. residents will spend this year on the medical liability crisis," the city could hire 4,728 new teachers or 3,463 new police officers. "These numbers are so fraudulent the purveyors should be prosecuted for false advertising," said Frank Clemente, director of Public Citizen's Congress Watch.

In fact, as Public Citizen found in a recent report, malpractice litigation and awards are on the decline in the District, and there is no evidence that lawsuits are responsible for higher malpractice insurance premiums faced by some doctors in the city.

America's Health Insurance Plans claims that the annual cost of the medical liability system nationally is $134.5 billion, with the District of Columbia's share, based on population, at $255.6 million. But those numbers are bogus.

About 80 percent of the cost, the group claims, is attributable to unnecessary tests and procedures done as "defensive" medicine aimed not at better patient care but at heading off lawsuits. The group cites a 2002 report from the Bush administration's Department of Health and Human Services (HHS). But two leading nonpartisan federal investigative agencies — the Government Accountability Office (GAO) and the Congressional Budget Office (CBO) — have rejected the defensive medicine theory in reports issued in 2002 and 2004 respectively.

The remaining 20 percent of the cost is attributed to medical liability expenses as described in a Towers Perrin report on U.S. tort expenditures. But half the "costs" reported are compensation to victims for injuries suffered. Also among these other costs are insurance company marketing, overhead and profits.

The best way to gauge the impact of medical malpractice is from the standpoint of those whom the system is supposed to serve — patients. In 2004, the amount of damages paid on behalf of District doctors to their patients totaled $19 million, according to a Public Citizen examination of malpractice payments. The total is only 7 percent of the amount claimed by the insurers group.

Legislation limiting awards is under consideration in the current session of Congress and is being pushed by Mayor Anthony Williams. But Public Citizen has found that such targeting of the legal system is off the mark. In a May report on malpractice in the District, Public Citizen found that:

- The value of medical malpractice payments to victims made on behalf of District doctors has declined 52.5 percent from 1991 to 2004 when adjusted for medical inflation. The decline was 64 percent from 2001 to 2004 — the peak years of the "crisis."
- The annual number of malpractice payments has declined 14.5 percent from 1991 to 2004, dropping from 55 to 47. Moreover, total payments have dropped 35.6 percent from 2001 to 2004, from 73 to 47, when warnings about the "crisis" began.

Additionally, the number of medical malpractice case filings is down 31 percent in the past decade, from a peak of 213 in 1997 to 148 in 2004.

"This latest campaign from the insurers is just another effort to ignore the facts and, through exaggeration and distortion, try to scare lawmakers into approving legislation that would produce windfall profits," said Clemente.

For more information, visit http://www.citizen.org/civjus/medmal/. ■

DIFFERIN AD, *from page 9*

101, a course on offer at Acne High. The advertisement plays to teenage fears ("Remember: There are thousands of pores on your face, which means your skin has the potential to 'give birth to' thousands of microcomedones.") and notions of empowerment ("Fight Acne with Free Music. How Cool is That?"). Realizing that many teens will visit physicians only with their parents, the website has an entire section on "Talking to Parents About Acne." If you can convince your parent to help you secure a prescription for Differin, the benefits multiply: the "3 levels of cool" are Level 1: sign up (two free music downloads); Level 2: get and fill Differin prescription (seven free downloads); and Level 3: refill Differin prescription (ten free downloads). Bribing physicians to prescribe medications has long been held to be illegal. This advertisement essentially pays teenagers to convince adults to procure this drug for them, with the size of the payment in proportion to the amount of drug prescribed. Incidentally, a previous Differin DTC advertisement has already been the subject of an FDA regulatory letter.

An improbable new low in inappropriate DTC advertising was reached in a November 2004 advertisement by AstraZeneca on its website and in print that actually had the audacity to mislead the public by misrepresenting the FDA. In an advertisement for the cholesterol-lowering drug Crestor, a drug associated with muscle and kidney damage, AstraZeneca claimed that "We have been assured today at senior levels in the FDA that there is no concern in relation to CRESTOR's safety." Public Citizen wrote to the FDA pointing out that the agency was actually on record stating that "[the Agency] has been very concerned about Crestor since the day it was approved, and we've been watching it very carefully." The agency forced the company to terminate its campaign. ■

Industry Drug Guidelines Will Do Little to Prevent Misleading Ads

Recently, in response to increasing pressure and calls for expanded regulation of direct-to-consumer advertising of prescription drugs by lawmakers from both political parties, the Pharmaceutical Research and Manufacturers of America (PhRMA) issued guidelines to its members on drug advertising. Dr. Sidney Wolfe's response is below.

Like many misleading direct-to-consumer (DTC) ads, the new PhRMA guidelines attempt to fool people into believing the guidelines are stronger than they really are.

Since the fundamental purpose of DTC advertising is to sell drugs, the best way to do so is to overstate the benefits and understate the risks. The 85% decrease in FDA actions to stop illegal prescription drug ads from 1998 (157 illegal ads stopped) to 2004 (only 24 illegal ads stopped) all but encourages the pharmaceutical industry to persist in its illegal, but successful drug ad campaigns.

The reason the FDA has had the authority to regulate prescription drug ads for more than 40 years is because of failed drug industry self-regulation. PhRMA's latest campaign of industry self-regulation via the guidelines announced today is both dangerous and, like previous industry efforts, doomed to failure since selling drugs will always trump obeying the law.

Three essential changes that, unlike the PhRMA guidelines, would actually make a difference in this serious problem of misleading drug ads include:

1) A significant increase in FDA law enforcement actions concerning illegal ads
2) Congressional authorization to impose large fines on companies for violation of the law and regulations
3) Legal authority to require all TV ads to be approved by the FDA before they air ■

For examples of over-the-top drug advertising, see page 9.

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