PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

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What Happened in U.S. Health Care in 2007?

Given the active and early election campaign and the emergence of health care as the No. 1 domestic issue, health-related topics grabbed many headlines over the past year. Recurring themes included health reform, changes in disease prevalence, and that perennial problem, drug safety. Here, in approximate chronological order, is a recap of the issues that got much ink and provided fodder for policy wonks and talking heads. (See the August 2007* Health Letter *for a glossary of frequently-used terms in the health care debate.)

"Health care reform is in the air," wrote Paul Krugman in *The New York Times* on January 1st. Indeed, the year began with stirrings that the push for universal health coverage would begin anew in 2007. Democrats began talking about extending coverage to all children, potential presidential candidates such as John Edwards and Hillary Clinton echoed the call for health reform, and newly-installed governors resolved to cover the uninsured in their respective states.

• Confronting increasing evidence of conflicts of interest, the Food and Drug Administration (FDA) restricted those who can serve on its advisory panels: the regulatory agency prohibited those who earn more than $50,000 per year from pharmaceutical and other enterprises regulated by the agency from serving as consultants and advisors to FDA staff members, with what they described as "rare exceptions."

• Breast cancer deaths dropped, the decline being attributed to increased screening and, more importantly, the reduction in the number of women on hormone-replacement therapy (HRT). The decline was 8.6 percent between 2001 and 2004; this drop meant that in 2003 and 2004 there were 30,000 fewer deaths than would have occurred if previous trends had continued unabated. Additional studies coming out in the course of the year confirmed both the decline and its likely association with the lower use of HRT.

• Data suggested that Baby Boomers could very well be the first generation whose health was worse than their parents'. This was explained by the increase in obesity and in sedentary lifestyles.

• The diabetes drug Avandia (rosiglitazone), for which 11.3 million prescriptions were filled in 2006, was found to increase the risk of heart attacks by 43 percent in a study published in the *New England Journal of Medicine*. The publication of this finding had numerous repercussions: sales of the drug plummeted, GlaxoSmithKline stock decreased precipitously, study subjects in ongoing trials of the drug dropped out, and the FDA called for a black box warning for both Avandia and similarly-acting Actos, indicating that both drugs were "associated with an increased risk" of heart failure. More recently, a tepid warning about increased risk of heart attacks with Avandia was ordered by the FDA. Still, the FDA's drug safety oversight board narrowly voted in favor of keeping the drug on

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the market; the final vote was eight to seven. (See article on page 3 of this issue about Avandia updates.)

• Michael Moore's movie "Sicko" furthered the debate on health reform in the U.S. While critics and policy analysts predictably differed on their appraisal of the film, most agreed that the movie raised important questions concerning our broken health system and who we are as a people.

• Alli (orlistat) became the first (and only) over-the-counter weight-loss drug available in the U.S., entering the market despite serious concerns about its efficacy, disturbing side effects and the fact that it has caused pre-cancerous changes in the colons of animals. Marketed together with a kit providing advice on exercise and healthy diets, the drug is aimed at those who are committed to following a reduced-calorie, low-fat diet in addition to taking the drug.

• On July 1, new legislation came into effect which required most Massachusetts residents to be insured or pay a penalty. Hailed as the triumph of caring consensus over partisan bickering, the bill creating the Massachusetts plan nevertheless had a number of undefined provisions that caused problems in implementation. The state ended up exempting 60,000 residents because they could not afford any of the offered health plans, thereby seriously undermining its hopes for universal coverage.

• The State Children's Health Insurance Program (SCHIP) came up for re-authorization, igniting a Congressional battle between those who wanted to extend coverage by raising the income threshold for eligibility and those who feared "crowd out" (i.e., beneficiaries foregoing private coverage to enroll in the public program). President Bush, squarely on the side of the latter, vetoed the legislation, only the fourth such action during his tenure. Overriding the veto would have required a two-thirds majority in both houses, which the bill's supporters were not able to muster.

• We have heard a lot about the "obesity epidemic" but the term acquired new meaning in 2007: it referred not to the rising prevalence of overweight people, but rather to the process by which they got there. The idea of obesity being "contagious" (i.e., spread like an epidemic among contiguous or affinity groups) entered the popular conscience and vocabulary. Researchers found that weight depends on behaviors of people that are up to three degrees removed in a social network, and that these networks amplify the behaviors with which they are seeded. The good news: weight reduction can spread through the same pathways, and the current epidemic can be controlled and even reversed through similar mechanisms.

• The FDA increased the fees it charges pharmaceutical and device companies to review their applications. While the Prescription Drug Users' Fee Act (PDUFA) was enacted in 1992, its reauthorization in September 2007 in effect strengthened the conflicts of interest inherent in a regulatory agency relying on those it regulates for part of its budget. Public Citizen's Health Research Group expressed its opposition to PDUFA early and forcefully, urging its repeal and underlining that the reauthorization bill "favors drug approval at the expense of drug safety." As of this year, the majority of funds to pay for the drug review process at the FDA comes directly from the industry.

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• Facing imminent action by the FDA, a number of drug manufacturers voluntarily recalled a small number of infant cough and cold medicines. The recall included medications produced under the brand names of Dimetapp, Little Colds, Pediacare, Robitussin, Triaminic and Tylenol. Between 1969 and 2006, there were 54 reported deaths associated with the use of decongestants, and 69 associated with the use of antihistamines. Citing studies showing that the remedies were not only unsafe but also no better than a placebo, an FDA advisory panel voted to ban over-the-counter cough and cold medicines for children younger than 6. The ban applies to medicines containing at least one of the following: decongestants, expectorants, antihistamines and antitussives. Public Citizen's Health Research Group recommends that no cough and cold medicines be given to children under 12, citing evidence that the remedies are of no benefit to older children either.

• Methicillin-resistant staphylococcus aureus (MRSA) emerged again as a deadly "superbug," responsible for more than 94,000 serious infections and nearly 19,000 deaths each year. The pathogen, which thrives in hospitals, clinics and dialysis centers, has elicited concern intermittently. It was recognized as a major threat only after researchers assessed its actual toll, publishing their results in the *Journal of the American Medical Association.*

• In a $4.85 billion settlement, Merck agreed to pay 47,000 plaintiffs who used the painkiller Vioxx (rofecoxib), which was withdrawn from the market because it caused heart attacks and strokes. The settlement was widely seen as a victory for the company, which cut its losses and ended the public relations nightmare resulting from individual lawsuits. Company shares rose 2.1 percent following the settlement. Public Citizen attacked the settlement as being too small and thus unfavorable to too many injured patients.

• Not satisfied with the two basic classes of pharmaceuticals – prescription and over-the-counter – the FDA proposed a "behind the counter" category for drugs that would require

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Update on Rosiglitazone (Avandia)
More Strikes Against the Drug

In May, a study in the *New England Journal of Medicine* linked the diabetes drug rosiglitazone (Avandia, Avandamet and Avandaryl) to heart attacks and heart-related deaths. But the heart risks of this drug should not have been a surprise.

Public Citizen has long warned about the dangers of using the glitazone class of diabetes drugs, beginning with our petition to the Food and Drug Administration (FDA) in 2000 for better warnings. We have classified rosiglitazone as a Do Not Use drug for the past three years.

Since the release of the *New England Journal of Medicine* study, the following actions have been taken:

1. In October, the Department of Veterans Affairs, after conducting its own review, removed rosiglitazone from its formulary (the drugs that its doctors may prescribe), concluding that, "for some patients, rosiglitazone may not afford the same margin of safety as alternative drug therapies."

2. On November 6, 2007, Health Canada, the Canadian equivalent of the U.S. FDA, issued broad new restrictions on the use of rosiglitazone.

In Canada, rosiglitazone is now no longer approved either as a single treatment for diabetes (except for patients unable to take metformin), or for use in combination with a sulfonylurea* except when patients are unable to take metformin.

Furthermore, Health Canada warns that rosiglitazone should not be used in any of these situations: in patients taking insulin, in combination with metformin and a sulfonylurea drug, or in patients diagnosed with any degree of heart failure, either past or current, even that which is very mild (NYHA Classes I, II, III or IV).

Public Citizen has long warned about the dangers of using the glitazone class of diabetes drugs, beginning with our petition to the Food and Drug Administration in 2000 for better warnings.

Health Canada advises patients to talk to their doctors about the benefits and risks of continuing therapy, especially those with heart disease or at a high risk for a heart attack or heart failure.

3. Shortly after the Canadian warning, on November 14, the FDA modified its black box warning for rosiglitazone concerning heart attacks, but in a most confusing fashion: it cites four analyses. One of the four is a meta-analysis of 42 studies which showed an increased risk of heart attacks; the results of the three others "have not confirmed or excluded this risk," according to the FDA. This is inaccurate and provides no useful guidance to patients or their physicians.

The FDA needs to immediately publish an alert similar to that of Health Canada to warn U.S. citizens who are at increased risk from heart attacks and heart failure not to take rosiglitazone. Until then, Health Canada remains the sole source of this vital information.

We continue to label Avandia as a Do Not Use drug. ■

* Examples of sulfonylurea drugs are glyburide, glimepiride, and tolbutamide. Ask your doctor if you are taking these or any other drugs in this class.

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the advice of a pharmacist but no medical prescription. (At present, only the emergency contraceptive Plan B is sold "behind the counter," but this is only to check the age of the person to make sure that they are 18 or older, not to involve a pharmacist, and is a measure taken for political rather than medical reasons). The proposal was supported by pharmacists who saw this as a way to safeguard patient safety and bolster their professional status. It was opposed by the over-the-counter industry, which does not want access to its products curtailed in any way. Public Citizen testified against the adoption of the new class on other grounds. Citing a GAO study of 10 countries that have a behind-the-counter provision, Dr. Sidney Wolfe called the proposal "neither new nor good": the experience in the countries that have the proposed class showed that it did not increase the public's access to drugs, and had no effect on costs. Moreover, counseling by pharmacists was infrequent and incomplete, which is not surprising given their limited time and lack of reimbursement. ■

Product Recalls

October 20, 2007 — November 14, 2007

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. 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*. Visit *www.recalls.gov* for information about FDA recalls and recalls issued by other government agencies.

Recalls and Field Corrections: Drugs — CLASS I

Indicates a problem that may cause serious injury or death

Name of Drug or Supplement; Problem; Recall Information

Metaboslim All Natural Fat Eater Apple Cider Vinegar Dietary Supplement, 60-capsule bottles, 4,180 bottles; Product was found to contain undeclared sibutramine, an active pharmaceutical ingredient used for weight loss in treatment of obesity. Lot # 3001006, exp. date 10/2009; Island Vitamins Inc.

Recalls and Field Corrections: Drugs — CLASS II

Indicates a problem that may cause temporary or reversible health effects; unlikely to cause serious injury or death

Name of Drug or Supplement; Problem; Recall Information

Ethyl Alcohol, USP, 190 Proof, in plastic bottles, 4,548 bottles; Product may not meet USP specifications for UV absorbance. Lot #s 7120, 7065, 07A1209AN, 06L1203LP, 06L1203LP, 06110829KI, 06H03WB, 06G17WB, 06E30WB, 06E17GB, 06C08GB, 06D26WB, 06E10WB, 06D17GB, 06D06WD, 06K2103K, 06F27WB, 06F13WB, 06F06GB, 06E02WB, 06D17GD, 06C23GB, 06C20WB, 06B14WB, 06B01GB, 06A24WB, 06A186B; 06A03WB, 06G17GB, 05H25WB, 05L15GB, 05J19GB, 05J05WB, 05126GB, 05H15GB, 05G27WB, 05G25PB, 05L12WB, 05L19PB, 05K23WB, 05K08GB, 05K02WB, 05E25GB; EMD Chemicals Inc.

Ethyl Alcohol, USP, 200 Proof, 18,318 bottles; Product may not meet USP specifications for UV absorbance. Lot #s 7179, 7121, 7070, 07A0523; 07B0823, 07A1283, 07A1284, 06H17WA, 06K2823, 06G24GA, 06H07GA; 06F28GA; 06F07GA; 06E09GA, 06C13GA, 06D27GA; 06D05WA, 06D19GA, 06C02GA; 06B13GA, 06B02GA; 06A19GA, 06K1523; 06K0823; 06J05GA; 06J30WA, 06J23GA; 06I06GA, 06A26GA; 05G19QA; 05K03GA; 05K28GA; 05K16PA; 05L28GA; 05L20GA; 05L06WA, 05J10GA; 05J04GA; 05G16QA; 05J13GA; 05H23QA; 05H24GA; 05H08GA; 05G26GA; 05F29GA; 05L06WA, 05G14GA; 05K14GA; EMD Chemicals Inc.

BETCO WINNING HANDS ULTRA MILD ANTIBACTERIAL SKIN CLEANSER, Triclosan 0.30%, NET CONTENTS 30.4 fl. oz. (900 mL) bag in box, 37.2 fl. oz. (1100 mL) bag in box, 67.7 fl. oz. (2000 mL) bag in box, 1 Gallon (3.78L) bottles, 1,212 gallons; Microbial contamination of Non Sterile Product; the product is contaminated with Pseudomonas aeruginosa. 1 Gallon Bottle (4-1 Gallon Containers per case) Lots 1088639, 1089891, 1087387 – 900 mL BAG IN BOX (12-900 mL per case) Lot 1088201 – 1100 mL BAG IN BOX (10-1100 mL per case) Lot 1088201 – 2000 mL BAG IN BOX (4 - 2000 ml per case) Lot 1090335; Betco Corp.

Top Care brand Tussin DM, cough suppressant expectorant for children and adults, alcohol free, active ingredients (in each 5 mL teaspoonful): Dextromethorphan HBr 10 mg and Guaifenesin 100 mg, 8 fl. oz. bottles, OTC, 23,664 bottles; Some dosing cups packaged with product lack the 1/2 teaspoon mark for dosing children 2 to 6 years of age which could result in administration of twice the recommended dose of dextromethorphan. Lot # 7HK0118, exp. date 06/2009; L. Perrigo, Co.

Recalls and Field Corrections: Drugs — CLASS II *cont'd.*

Name of Drug or Supplement; Problem; Recall Information

Good Neighbor Pharmacy brand Tussin DM, cough suppressant expectorant for children and adults, alcohol and sugar free, active ingredients (in each 5 mL teaspoonful): Dextromethorphan HBr 10 mg and Guaifenesin 100 mg, 4 fl. oz. bottles, OTC, 23,664 bottles; Some dosing cups packaged with product lack the 1/2 teaspoon mark for dosing children 2 to 6 years of age which could result in administration of twice the recommended dose of dextromethorphan. Lot# 7HK0044, exp. date 06/2009; L. Perrigo, Co.

Sunburst CHOLESTRIX Red Rice Yeast Extract, Standardized to contain 1.35% Lovastatin, A Dietary Supplement, 90 Vegetable Capsules, 488 bottles (90 capsules per bottle); Unapproved new drug marketed without an approved NDA/ANDA containing Lovastatin, the active pharmaceutical ingredient in Mevacor. Lot # 5142, exp. date 08/2011; Bactolac Pharmaceutical, Inc.

IPN Therapy, Intraperitoneal Nutrition Solution in dialysate bags, 1 to 3 liter volumes, 27,000 bags; Increased incidence of fungal peritonitis. Prescriptions filled on or before 9/21/07; Pentec Health Inc.

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*. Visit *www.recalls.gov* for information about FDA recalls and recalls issued by other government agencies.

Name of Product; Problem; Manufacturer and Contact Information

AC Power Adaptors. The housing of the Yamaha AC Power Adaptors can separate, posing an electric shock hazard to consumers. Yamaha Corporation of America, (866) 509-0320 or www.yamaha.com/warranty_safety.asp.

Air Conditioners and Heaters. An electric heater in the Packaged Terminal Air Conditioners (PTAC) and Heat Pumps (PTHP) can break, posing a fire hazard to consumers. Carrier Corp., (800) 761-8492 or www.carrierptacrecall.com.

Aqua Dots Beads. The coating on the Aqua Dots beads that causes the beads to stick to each other when water is added contains a chemical that can turn toxic when many are ingested. Children who swallow the beads can become comatose, develop respiratory depression, or have seizures. Spin Master, (800) 622-8339 or www.aquadotsrecall.com.

ATVs. The rear brake caliper support can crack; this could result in the potential for a loss of the use of the rear brake and subsequently lead to an accident. KTM North America Inc., (888) 985-6090 or www.ktmnorthamerica.com.

Baby Chairs. If the Bumbo "Baby Sitter" Seat is placed on a table, countertop, chair, or other elevated surface, young children can arch their backs, flip out of the Bumbo seat, and fall onto the floor, posing a risk of serious head injuries. Bumbo International, (877) 932-8626 or www.bumbosafety.com.

Bicycle Forks. Reynolds UL Bicycle Fork tips could separate from the fork legs, causing the wheel to come loose from the fork while riding. This could pose a serious fall hazard to riders. MacLean Quality Composites, d.b.a. Reynolds, (866) 798-3040 or www.reynoldscycling.com/recall.

Candles. The bark wrapping of the Birch Bark Wrapped Candles can ignite when the candle burns down, posing a fire hazard. Gate Five Group LLC, d.b.a. Roost, (415) 339-9500 ext. 212 or www.roostco.com.

Children's Bathrobes. The Girls and Boys Bath Robes fail to meet the children's sleepwear flammability standard, posing a risk of burn injuries to children if the robe caught fire. The Bon-Ton Department Stores Inc., (866) 798-2875 or www.bonton.com.

Children's Jewelry. Beary Cute, Expressions, and Sassy & Chic Children's Metal Jewelry contains high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. Dollar Tree Stores, (800) 876-8077 or www.dollartree.com (pdf).

Children's Jewelry. WeGlow Children's Metal Jewelry contains high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. WeGlow International, (866) 934-5692 or www.weglow.com.

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Name of Product; Problem; Manufacturer and Contact Information

Children's Kitchen Toys. Pieces of the faucet or the clock hands of the Laugh & Learn™ Learning Kitchen™ Toys can detach, posing a choking hazard to young children. Fisher-Price Inc., (888) 812-7187 or www.service.mattel.com.

Children's Sunglasses. The yellow surface paint on the Children's Fashion Sunglasses may contain excessive levels of lead, violating the federal lead paint standard. Dolgencorp Inc., (800) 678-9258 or www.dollargeneral.com.

Children's Toy Gardening Tools. Surface paint on the handle of the Children's Toy Gardening Tools can contain excessive levels of lead paint, violating the federal lead paint standard. Jo-Ann Stores Inc., (888) 739-4120 or www.joann.com.

Circuit Breakers. Counterfeit "Square D" Circuit Breakers are counterfeit and could fail to trip when they are required to, posing a fire hazard to consumers. Connecticut Electric & Switch Mfg. Co. (Connecticut Electric), (866) 264-3702 or www.connecticut-electric.com.

Concrete Grinders. The flexible coupler on the Blastrac BG 250 Series Concrete Grinders with round flexible couplers can break during use allowing the internal parts, including the tooling plate and grinding disc, to be forcefully ejected from the grinder. This can pose a risk of injury from projectiles to the user and those nearby. Blastrac N.A., (800) 256-3440 or www.blastrac.com.

Costume Teeth. The surface paint on the "Ugly Teeth" Party Favors contains excessive levels of lead, violating the federal lead paint standard. Amscan Inc., (800) 335-7585 or www.amscan.com.

Cribs. The bolts connecting the top corners of the Wendy Bellissimo Collection Convertible Cribs can come loose, creating a gap and posing a serious entrapment and strangulation hazard. Bassettbaby, (888) 897-4689 or www.bassettbaby.com.

Curious George Plush Dolls. Surface paint on the Curious George Plush Doll's plastic face and construction hat contain excessive levels of lead, which violates the federal lead paint standard. Marvel Toys, (800) 352-2064 or www.regcen.com/curiousgeorge.

Digital Color Printers. The C9600 Series Digital Color Printers have an internal electrical problem that could result in electrical shock to consumers. Oki Data Americas, (877) 654-6364 or www.okidata.com.

Dizzy Duck Music Boxes. Surface paints on the wooden base of the Dizzy Ducks Music Box contain excessive levels of lead, which violates the federal lead paint standard. Schylling Associates Inc., (800) 767-8697 or www.schylling.com.

Folding Chairs. The Plastic Folding Chairs can collapse during use, posing a fall hazard to consumers. Iceberg Enterprises LLC, (800) 580-1310 or chairrecall@icebergenterprises.com.

Football Bobble-Head Cake Decorations. Surface paint on the body of the Football Bobble Head Cake Decorations contains lead in excess of the federal lead paint standard. DecoPac Inc., (800) 536-6558 or www.decopacproductsafety.com.

Football Helmet Chin Straps. The Football Helmet Chin Strap's plastic cup can break as a result of contact, exposing the player to facial or head injuries. Nike Inc., (888) 583-6453 or www.nikebiz.com.

Galaxy Warrior Toy Figures. Surface paints on the "Galaxy Warriors" Toy Figures contain excessive levels of lead, violating the federal lead paint standard. Henry Gordy International Inc., (888) 790-2700.

Game Pieces. Magnetic Game Pieces sold with *"Cars"* Themed Backpacks can fall out of their plastic enclosure. Magnets found by young children can be swallowed or aspirated. If more than one magnet is swallowed, the magnets can attract each other and cause intestinal perforation or blockage, which can be fatal. Global Design Concepts Inc., (877) 848-4070 or www.carsbackpackrecall.com.

Girls' Gift Sets. The surface coating of Decorative Packaging Pearl-like Bead Attachments sold with Girl's Gift Sets contains excessive levels of lead, violating the federal lead paint standard. Tween Brands Inc., (800) 934-4497 or www.limitedtoo.com.

Go Diego Go Toy Boats. Surface paints on the Go Diego Go Animal Rescue Boats contain excessive levels of lead, which violates the federal standard prohibiting lead paint on children's toys. Fisher-Price Inc., (888) 299-0579 or www.service.mattel.com.

Halloween Pails. The green paint on the Purple Halloween Pails with Witch Decorations contains excessive levels of lead, violating the federal lead paint standard. Family Dollar Stores, (800) 547-0359 or www.familydollar.com.

Name of Product; Problem; Manufacturer and Contact Information

Home Patio Sets. The chair of Home Patio Sets can collapse when weight is applied to the front end of the arm rests, posing a fall hazard to consumers. Target, (800) 440-0680 or www.target.com.

Humidifiers. Water used in the Warm Mist Carefree Humidifier can leak into the unit's electrical compartment, posing a fire hazard. Hunter Fan Co., (877) 288-1145 or www.hunterfan.com.

Lawn Mowers. Due to a manufacturing defect, a crack can occur in the fuel tank of the Honda HRX217KHXA and HRX217KHMA Lawn Mowers causing a fuel leak. If gasoline leaking from the fuel tank is ignited, a fire or explosion can occur. American Honda Motor Corp., (800) 426-7701 or www.hondapowerequipment.com.

Pool Toys. The elastic tongue of the "Skippy" Pool Toys can break and forcefully come out and cut the users' hands during launching of the toy. Swimways Corp., (888) 559-4653 or www.swimways.com.

Portable CD/DVD/MP3 Players. The Portable DVD/CD/MP3 Players can overheat, posing a fire hazard. Coby Electronics Corp., (877) 231-9240 or www.cobyusa.com.

Power Packs. Charging the battery inside the box of the Power Packs for Portable Team Hydration Units can result in excessive gas buildup which can burst the lid of the power pack box off or rupture the box. This poses an injury hazard to bystanders. Collegiate Pacific, (800) 243-5133 or http://www.BSNCP.com/recall.

Power Tool Battery Chargers. When used with an incompatible charger, Battery Chargers supplied with certain Kawasaki branded Power Tool Kits can overheat and melt during charging, or can explode during use, posing burn, laceration and bruise hazards to consumers. Alltrade Tools LLC, (877) 231-9239 or www.alltradetools.com (pdf).

Ribbit Board Games. Surface paint on the five frog-shaped wooden pieces of Ribbit Board Games contain excess levels of lead, violating the federal lead paint standard. SimplyFun LLC, (877) 557-7767 or www.simplyfun.com.

Ski Boards. Screws installed improperly can cause the bindings to come loose or pull off the 2006 Line X-Fly and Line Pro Ski Boards during use, causing the skier to lose control or fall and suffer injuries. Line Skis, (800) 987-2576 or www.lineskis.com.

Snowmobiles. Ski-Doo Model Year 2008 Snowmobiles' fuel tanks can crack allowing liquid fuel and fuel vapor to leak, posing a fire and burn hazard to consumers. In addition, a problem with the throttle cable can lead to loss of speed control, posing a crash hazard. Bombardier Recreational Products Inc. (BRP), (888) 638-5397 or www.ski-doo.com.

Snowmobiles. Snowmobiles' fuel tank filler neck can crack and separate allowing fuel or fuel vapors to leak from the fuel tank. This poses a fire hazard to consumers. Polaris Industries Inc., (888) 704-5290 or www.polarisindustries.com.

Spinning Tops. Surface paint on the wooden handle of the Winnie-the-Pooh Spinning Top contains excessive levels of lead, violating the federal lead paint standard. Schylling Associates Inc., (800) 767-8697 or www.schylling.com.

Toy Cars. Surface paint on the wheels and engine of the Dragster and Funny Car toys contains excessive levels of lead, violating the federal lead paint standard. International Sourcing Ltd (ISL), (877) 404-1584 or www.islpromotions.com.

Toy Cars. Surface paint on the Pull-Back Action Toy Cars contains excessive levels of lead, violating the federal lead paint standard. Dollar General Merchandising Inc., (800) 678-9258 or www.dollargeneral.com.

Toy Duck Families. Surface paints on the Duck Family Collectable Wind-Up Toys contain excessive levels of lead, which violates the federal lead paint standard. Schylling Associates Inc., (800) 767-8697 or www.schylling.com.

Toy Robots. Surface paints on the "Robot 2000" collectable tin robots contain excessive levels of lead, which violates the federal lead paint standard. Schylling Associates Inc., (800) 767-8697 or www.schylling.com.

Toy Soldiers. Surface coatings on the Elite Operations Toys contain excessive levels of lead, violating the federal lead paint standard. Toys "R" Us Inc., (800) 869-7787 or www.toysrus.com.

Treadmills. During repairs associated with the October 8, 2003 recall of Cybex or Trotter Treadmills, wire nuts were installed improperly, causing the treadmills to overheat and posing a fire hazard to consumers. Cybex International, Inc., (888) 678-3846 or www.cybexintl.com/retro.

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Reporting Adverse Events From Drugs and Medical Devices to the Food and Drug Administration

Consumers can play an important role in protecting the public health by reporting to the Food and Drug Administration (FDA) the serious health problems they experience while taking prescription drugs and dietary and herbal supplements or while using medical devices.

Consumers should consider reporting serious reactions and problems to the FDA when the outcome is:

Death: Report if the patient's death is suspected as being a direct outcome of the use of the drug, supplement or medical device.

Life-Threatening: Report if the patient was at substantial risk of dying from the adverse reaction or it is suspected that the use or continued use of the product would result in the patient's death. Life-threatening examples include pacemaker failure, gastrointestinal hemorrhage (stomach or intestines) and inability to produce new blood cells. Another life-threatening reaction could result from infusion pump failure, which permits uncontrolled free flow of the drug into the blood stream and can result in excessive dosing.

Hospitalization (initial or prolonged): Report if admission to the hospital or a prolonged hospital stay results from the use of the drug, supplement or device. Examples include a severe allergic reaction, acute inflammation of the colon (which is usually induced by antibiotics) and bleeding.

Disability: Report if the adverse event resulted in a significant, persistent or permanent change in the patient's body function/structure, physical activities or quality of life. Examples include a stroke due to either a drug-induced increase in the tendency for the blood to clot and drug-induced bleeding and peripheral neuropathy (nerve problems).

Congenital Anomaly (Birth Defects): Report if there are suspicions that exposure to a medical product prior to conception or during pregnancy resulted in birth defects in the child. Examples include vaginal cancer in female offspring from use of the synthetic non-steroidal estrogen diethylstilbestrol (DES) during pregnancy and malformation in the offspring caused by the anti-nausea medication thalidomide.

Danger of Permanent Impairment or Damage: Report if you suspect that the use of a medical product may result in a condition that requires medical or surgical intervention to preclude permanent impairment or damage to a patient. This could be acetaminophen (Tylenol) overdose-induced liver damage requiring treatment with the drug acetylcysteine (ACC, Mucomyst, Acetadote, Fluimucil and Parvolex) to prevent permanent damage. Other examples include burns from radiation equipment requiring drug therapy and breakage of a screw used to aid in the healing of a fractured long bone requiring replacement of a medical device.

Product problems should also be reported to the FDA when there is a concern about the quality, authenticity, performance or safety of any drug or device.

Problems with product quality may occur during manufacturing, shipping or storage. They include:

- Suspected counterfeit products
- Product contamination
- Defective components
- Poor packaging or product mix-up
- Questionable stability
- Device malfunctions
- Labeling concerns

What You Can Do

Individuals can report their serious drug, supplement or device reactions and problems to FDA's MedWatch program.

The FDA offers several ways for consumers or health professionals to submit MedWatch reports:

- Go to the MedWatch Web site at www.fda.gov/medwatch/ and follow the instructions for submitting a report electronically.
- Fill out and mail the MedWatch form on the next page to the FDA:

MEDWATCH
The FDA Safety Information and Adverse Event Reporting Program
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852-9787

- Submit a completed form to MedWatch's fax at 1-800-332-0178.
- Call the FDA's toll-free reporting number at 1-800-FDA-1088. ■

CONSUMER PRODUCTS *cont.*

Name of Product; Problem; Manufacturer and Contact Information

Wireless Receivers. If the 64 Zone Wireless Receivers lose power, they could fail to receive the signal from transmitters monitoring for intrusion detection in a property and place the security of residents at risk. Home Automation Inc., (800) 229-7256 or www.homeauto.com (pdf).

Wagons. Surface paints on the "Big Red" Wagons wagon and handle contain excessive levels of lead, violating the federal lead paint standard. Northern Tool & Equipment Co., (800) 222-5381 or www.northerntool.com.

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events, product problems and product use errors

Page ____ of ____

Form Approved: OMB No. 0910-0291, Expires: 10/31/08
See OMB statement on reverse.

FDA USE ONLY

Triage unit sequence #

A. PATIENT INFORMATION

Patient Identifier / In confidence	2. Age at Time of Event, or Date of Birth:	3. Sex	4. Weight
		☐ Female ☐ Male	____ lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☐ **Adverse Event** ☐ **Product Problem** *(e.g., defects/malfunctions)*
   ☐ **Product Use Error** ☐ **Problem with Different Manufacturer of Same Medicine**

2. **Outcomes Attributed to Adverse Event** *(Check all that apply)*
   - ☐ Death: _____ *(mm/dd/yyyy)*
   - ☐ Life-threatening
   - ☐ Hospitalization - initial or prolonged
   - ☐ Disability or Permanent Damage
   - ☐ Congenital Anomaly/Birth Defect
   - ☐ Other Serious (Important Medical Events)
   - ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event *(mm/dd/yyyy)*	4. Date of this Report *(mm/dd/yyyy)*

5. **Describe Event, Problem or Product Use Error**

6. **Relevant Tests/Laboratory Data, Including Dates**

7. **Other Relevant History, Including Preexisting Medical Conditions** *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*

☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. **Name, Strength, Manufacturer** *(from product label)*
   #1
   #2

2.	Dose or Amount	Frequency	Route
#1			
#2			

3. **Dates of Use** *(If unknown, give duration) from/to (or best estimate)*
   #1
   #2

4. **Diagnosis or Reason for Use** *(Indication)*
   #1
   #2

6. Lot #	7. Expiration Date
#1	#1
#2	#2

5. **Event Abated After Use Stopped or Dose Reduced?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

8. **Event Reappeared After Reintroduction?**
   #1 ☐ Yes ☐ No ☐ Doesn't Apply
   #2 ☐ Yes ☐ No ☐ Doesn't Apply

9. **NDC # or Unique ID**

E. SUSPECT MEDICAL DEVICE

1. **Brand Name**
2. **Common Device Name**
3. **Manufacturer Name, City and State**

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mm/dd/yyyy)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mm/dd/yyyy)*	7. If Explanted, Give Date *(mm/dd/yyyy)*

8. **Is this a Single-use Device that was Reprocessed and Reused on a Patient?** ☐ Yes ☐ No
9. **If Yes to Item No. 8, Enter Name and Address of Reprocessor**

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates *(exclude treatment of event)*

G. REPORTER *(See confidentiality section on back)*

1. **Name and Address**

Phone #	E-mail

2. Health Professional?	3. Occupation	4. Also Reported to:
☐ Yes ☐ No		☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. **If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:** ☐

PLEASE TYPE OR USE BLACK INK

 Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

OUTRAGE, *from page 12*

An investigation by the Associated Press revealed that five makers of artificial joints paid more than $200 million in 2007 to U.S. doctors and hospitals, often the same doctors and hospitals who are deciding which company's joints to buy.

The fake consulting arrangements were a common practice by the companies from 2002 (and possibly earlier) through 2006. According to the Justice Department announcement, "Surgeons who had agreements with the companies were typically paid tens to hundreds of thousands of dollars per year for consulting contracts and were often lavished with trips and other expensive prerequisites."

The announcement also stated:

> Prior to our investigation, many orthopedic surgeons in this country made decisions predicated on how much money they could make – choosing which device to implant by going to the highest bidder. With these agreements in place, we expect doctors to make decisions based on what is in the best interests of their patients – not the best interests of their bank accounts.

Four companies were charged with criminal conspiracy to violate anti-kickback laws, and each of them settled out of court. They will not be criminally prosecuted if they follow new corporate compliance procedures and federal monitoring under 18-month agreements with the Department of Justice.

These companies have agreed to pay a total of $310 million in penalties to settle federal accusations that they used fake consulting agreements and other tactics to get surgeons to use their products in violation of the anti-kickback statute and the civil federal False Claims Act.

The four companies who made financial settlements with the government follow:

- Zimmer Inc., based in Warsaw, Ind., will pay $169.5 million.
- Depuy Orthopaedics, Inc., also based in Warsaw, Ind., a subsidiary of Johnson & Johnson Corp. of New Brunswick, N.J., will pay $84.7 million.
- Smith & Nephew Inc., of Memphis, Tenn., will pay $28.9 million.
- Biomet Orthopedics, Inc., also of Warsaw, Ind., will pay $26.9 million.

A fifth company, Stryker Orthopedics, Inc., of Mahwah New Jersey, voluntarily cooperated with the U.S. Attorney's Office before any other company. Due to its cooperation, Stryker executed a Non-Prosecution Agreement with the government, under which Stryker is required to implement all the reforms imposed on the other companies, including Federal monitoring.

Despite what appears at first glance to be a job-well-done by the Justice Department, there are two major flaws in the details of the settlements (in addition to the fact that none of the companies admitting any wrongdoing).

First, compared with the billions of annual collective profits of these companies, the total amount of the fines – $300 million – is a paltry sum. Confirming that this is so, there was an increase in the stock prices of the four companies that are publicly traded following the announcement of the settlements.

Second, although some sort of justice has been meted out to the bribing companies, none of those people who willingly accepted the bribes, the orthopedic surgeons, were cited in the settlements. Just as it "takes two to tango," it takes two parties to complete a successful bribe!

Public Citizen applauds the efforts of the Justice Department in reducing bribery and corruption in medical sales, but urges much stronger future actions on this issue. ■

THE PUBLIC CITIZEN HEALTH RESEARCH GROUP
Health Letter

The Health Research Group was co-founded in 1971 by Ralph Nader and Sidney Wolfe in Washington, D.C. to fight for the public's health, and to give consumers more control over decisions that affect their health.

Annual subscription price is $18.00 (12 issues). Mail subscriptions and address changes to *Health Letter*, Circulation Department, 1600 20th St., NW, Washington, D.C., 20009. Our Web site address is **www.citizen.org/hrg**.

Illegal Kickbacks from Artificial Knee and Hip Manufacturers to Orthopedic Surgeons

Patients facing knee or hip replacement surgery have more to worry about than just whether the surgeon is competent at doing the procedure; they must also be sure that the brand of device is chosen because it is the best available. Doctors are human too, and can sometimes be "bribed" by a kickback from the manufacturer to use Brand A instead of Brand B because the Brand A Company offered more than the Brand B Company, not because Brand A is better. This can have serious implications for a patient's health. Proven safety and effectiveness – *not* personal financial gain for doctors and hospitals – should always be the top priorities when choosing drugs and medical devices.

Proven safety and effectiveness - not personal financial gain for doctors and hospitals - should always be the top priorities when choosing drugs and medical devices.

On September 27, 2007, the U.S. Department of Justice announced that five companies, accounting for nearly 95 percent of the highly profitable market in hip and knee surgical implants, have avoided criminal prosecution over financial inducements paid to surgeons to use their products.

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