

# Health Letter

SIDNEY M. WOLFE, M.D., EDITOR

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## Medical Liability Reform? FDA Does Not Adequately Protect Consumers

*The following is taken from testimony given on Feb. 10, 2005 by Sidney M. Wolfe, M.D., before the Health Subcommittee of the House Energy and Commerce Committee regarding medical liability reform legislation.*

Chairman Deal and Members of the Subcommittee, thank you for the opportunity to testify today. Under the most perfect circumstances, if the FDA were actually doing as good a job as possible at preventing the approval of drugs and other medical products whose benefits are known to be outweighed by their risks and, as expeditiously as possible, removing such products when such risks are discovered after approval, this legislation would still unfairly punish patients and their families.

I will focus on substantial evidence, based on our more than 33 years of oversight over the agency, demonstrating that the FDA is far from doing an adequate job protecting the public from such products, making the impact of this legislation even more disastrous to potential victims.

### **HRG Medical Officer Survey / FDA Study / Inspector General Study**

In late 1998, prompted by many drugs with clear evidence of dangers not being adequately regulated, we surveyed FDA medical officers who

were the primary reviewers in the Center for Drug Evaluation and Research (CDER) for new drug applications. The responses, from 53 FDA physicians, included 27 instances cited in which the FDA medical officer thought a drug too dangerous to be approved but approval occurred over their objection. Seventeen medical officers described the current standards of FDA review for safety and efficacy as "lower" or "much lower" compared to those in existence prior to 1995. And several medical officers said they had been instructed by their superiors to censor their reports or presentations.

A study in 2001 by the FDA itself, precipitated by high turnover rates among scientists and physicians in the agency, showed that about one-third of medical officers did not feel comfortable expressing differing scientific opinions, and a similar number felt that decisions adverse to a drug were stigmatized within the agency. A number of reviewers said that deci-

sions should be based more on science and less on corporate wishes.

A subsequent study by the HHS Inspector General in 2003 confirmed that decisions concerning drug safety and effectiveness were being overturned. Eighteen percent of surveyed FDA physicians and scientists felt pressure to recommend that drugs be approved for sale despite their reservations about the drug's safety, efficacy or quality. The report concluded: "Overall, these findings present a significant warning signal."

### **Specific Examples of Dangerously Poor FDA Regulation**

#### **Rezulin (troglitazone-diabetes drug)**

- March 1997: U.S. Rezulin marketing begins
- December 1997: drug withdrawn in U.K. after 130 cases of liver damage including six deaths, mainly in the U.S.

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## LIABILITY REFORM, from page 1

- July 1998: Health Research Group petitions FDA to ban Rezulin after 560 cases of liver damage, including 26 liver deaths
- March 1999: FDA advisory committee meeting: now 43 liver deaths
- Early 2000: Some FDA physicians state drug should be banned
- March 2000: Rezulin is withdrawn in the U.S.; by then, 63 liver deaths, seven liver transplants

### **Trovan (trovafloxacin-antibiotic)**

Like two other drugs also approved in 1997, the painkiller Duract (bromfenac) and the diabetes drug Rezulin (troglitazone), (now both off the market), there was also clear evidence of liver damage caused by Trovan (in animals and in humans) before the drug was approved in December 1997. In one study prior to approval in which the drug was used to treat prostatitis, 10% of the men (14 out of 140) given the drug developed evidence of liver toxicity. With eight other drugs in the fluoroquinolone antibiotic family available in the U.S. as well as dozens of other safer and equally or more effective drugs for infections, the removal of Trovan from the market would not have deprived doctors or patients of a drug that could possibly be considered indispensable. Instead of banning Trovan as was done everywhere else in the world, the FDA chose to "limit" its use in the United States to patients who were either hospitalized or in nursing homes. At the time of our petition in 1999 to ban the drug, there were eight cases of liver failure, including five deaths and three liver transplants. There are now a total of 56 cases of liver failure, including 29 deaths and nine people requiring liver transplants.

**Baycol (cerivastatin-cholesterol lowering)** Approximately one year before Baycol was removed from the market in August 2001, its manufacturer Bayer, using FDA data on other statins, found that Baycol had 20 times more reports of rhabdomyolysis (an often-fatal destruction of muscle) per million prescriptions than Lipitor. An FDA official, feebly excusing FDA's belated ban, stated

that "We weren't aware at that point of the difference between Baycol, and the other similar [drugs]. Our expectation is when a company becomes aware of a specific problem with their drug, they come to us." By the time Baycol was banned, there were 1,899 cases of rhabdomyolysis, a significant number having occurred between the time there was unequivocal evidence that FDA should have banned the drug and when it was actually banned a year later.

**Crestor (rosuvastatin-cholesterol lowering)** Despite the Baycol disaster, and some chemical similarity between Baycol and Crestor, the FDA approved Crestor in August 2003, knowing that prior to approval there had already been 7 cases of rhabdomyolysis in clinical trials, compared to none in clinical trials prior to Baycol's approval (or that of any other statin). In addition to this risk, which AstraZeneca (Crestor's manufacturer) and the FDA wrote off as limited to the highest (80 mg) dose that was subsequently not approved, the drug also causes unique kidney toxicity, even in people who did not have rhabdomyolysis that can lead to secondary kidney damage. An FDA medical officer reviewing dozens of cases of blood and protein in the urine and several cases of renal insufficiency/renal failure in people using Crestor before approval said, "If they [these findings] are the signals for the potential progression to renal failure in a small number of patients, this may represent an unacceptable risk since currently approved statins do not have similar renal effects." Since Crestor came on the market, there have been more than 100 cases of rhabdomyolysis reported to the FDA, a rate per million prescriptions that is higher than any of the other statins still on the market. In addition, there have been approximately 40 cases of renal failure in people without rhabdomyolysis, a rate approximately 75 times higher per million prescriptions than that of the other statins combined.

**Vioxx (rofecoxib-NSAID)** A study published more than four years ago showed a four- to five-fold

increase in heart attacks in people using Vioxx compared to those using naproxen. As a result, we asked FDA for a black box warning four years ago. Although such a warning would have greatly reduced the toll of tens of thousands of heart attacks occurring between then and Vioxx's withdrawal, the agency, to the pleasure of Merck, rejected a black box and chose not to adequately warn the public. Many lives were thus lost.

**Bextra (valdecoxib-NSAID)** When we learned almost two years ago that FDA had rejected Pfizer's application for a new pain indication for Bextra, the agency, in collaboration with Pfizer, denied our freedom of information request for the FDA review as to why the application had been rejected. We thus had to sue the FDA to obtain these data. The medical officer who reviewed the study stated that "the excess of serious cardiovascular thromboembolic [blood clots] in the valdecoxib arm of the CABG [Coronary Artery Bypass Graft] trial is of note as the entire study population received prophylactic low dose aspirin as part of the standard of care in this setting to minimize just such events. Given the emerging concern over a possible pro-thrombotic action of certain agents in the COX2 class, these data are of concern."

**Meridia (sibutramine-weight reduction)** Both the FDA medical officer who reviewed the new drug application for the amphetamine-like weight reduction drug Meridia and the FDA advisory committee were opposed to the drug's approval because of safety concerns such as increased blood pressure. Since approval, there have been reports of a total of 56 cardiovascular deaths in people using Meridia, a large proportion of whom were under the age of 50.

If this legislation is enacted, it will represent the third prong of a three-pronged attack on patients' safety involving the FDA and the drug and device industries:

The two prongs involving the FDA are, as discussed in the above examples, inadequate regulation over the introduction and market removal of unsafe drugs and a sharp (85%) decrease from 1998 through 2004 in



FDA enforcement actions concerning illegal prescription drug ads — distorting the power of information into misleading doctors and patients about risks and benefits of drugs. The third prong, reducing the “regulation” of drug and device companies by lessening their liability for injuries and deaths to patients, is all the more onerous in the face of such lax FDA activities. Unless all three forms of “regulation” are allowed to operate in a maximal way, patients will not be adequately protected.

In addition to the four drugs discussed above that are still on the market in this country, all of which we have petitioned the FDA to ban, the newly published edition of our book, *Worst Pills, Best Pills*, and our Web site, [worstpills.org](http://worstpills.org) both list 176 other prescription drugs that we and our consultants urge that people DO NOT USE and discuss safer alternatives to each of these.

Ensuring safe drugs for America’s consumers is not just predicated on a strong regulatory system at the FDA. The role of the civil justice system is equally important. Without strong state laws that enable patients and consumers to hold medical providers accountable for negligence or errors, the medical industry — including the drug companies — will have much more incentive to cut corners in pursuit of profits and will have much less incentive to be vigilant about patient safety.

For this reason, Public Citizen strongly objected to the two identical omnibus medical malpractice bills

voted approved by the House last Congress (H.R. 5 and H.R. 4280). As it is likely that the same legislation will soon be before this committee and the entire House, I would like to provide our perspective on how inadvisable it is.

The cumulative effect would be to limit the ability of patients to recover for serious injuries and also to limit the ability of patients to find lawyers willing to take their cases. As a result, drug and device companies would have less incentive to ensure that their products are as safe as possible and that adverse effects are known *before* the products are marketed — a consequence that will threaten the health and well-being of us all.

The two bills introduced in the last Congress proposed to cap non-economic damages at \$250,000. Non-economic damages compensate people for pain and suffering — sometimes a lifetime’s worth — resulting from permanent and significant injury such as brain damage, paralysis, disfigurement, or lost childbearing ability.

Last year’s legislation would have eliminated punitive damages *entirely* in cases against drug and medical device companies or restricted them to instances in which the plaintiff could show that the company had marketed the product without FDA approval or that it had committed fraud to get FDA approval. Because prescription drugs and medical devices cannot be sold legally without FDA approval, this latter proposal effectively bans punitives.

Litigation against Merck is still in its early stages, but it may unearth very incriminating documents showing that the company knew Vioxx posed a serious danger to a significant number of patients, that the company knew that Vioxx had limited, if any, improved efficacy over ibuprofen, but that, to protect the company’s investment, the company engaged in a cover-up of information that would have saved lives. If what I have posited about Merck is true, would the American public support sparing a company that engages in such unethical conduct from punitive damages? I can’t imagine it.

The proposal to apply a one-year statute of limitations, running from discovery of the injury, will provide another hurdle to the ability of injured consumers to bring suit. The law in most states starts the limitation period running from the discovery of the *malpractice*, not discovery of the *injury*. This distinction is important because an injury will frequently manifest itself well before its cause is known. For example, the association between the anti-depressant Serzone and liver toxicity was not widely known until 2002, years after the drug came on the market in 1995. The injured party should not have to twice bear the cost of this defective product.

Medical malpractice and product liability cases are very risky for plaintiffs’ attorneys for three reasons: the costs are especially high, the likelihood of prevailing is quite low

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THE PUBLIC CITIZEN HEALTH RESEARCH GROUP

## Health Letter

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# Illness and Medical Bills Cause Half of All Bankruptcies

*The following discusses the important points of a recently released study by Harvard researchers David Himmelstein, M.D., Steffie Woolhandler, M.D. and other researchers from Harvard Medical School and Harvard Law School.*

Medical problems contributed to about half of all bankruptcies, involving 700,000 households in 2001, according to a story published as a Web exclusive by the journal *Health Affairs*. Families with children were especially hard hit — about 700,000 children lived in families that declared bankruptcy in the aftermath of serious medical problems. Another 600,000 spouses, elderly parents and other dependents brought the total number of people directly affected by medical bankruptcies to more than two million annually.

Surprisingly, most of those bankrupted by medical problems had health insurance. More than three-quarters were insured at the start of the bankrupting illness. Among those with private insurance, however, one-third had lost coverage at least temporarily by the time they filed for bankruptcy. Often illness led to job loss, and with it the loss of health insurance. Out-of-pocket medical costs (for co-payments, deductibles and uncovered services) averaged \$13,460 for those with private insurance at the onset of their illness, vs. \$10,893 for the uninsured. The highest costs — averaging \$18,005 — were incurred by those who initially

had private coverage but lost it in the course of their illness. Many families were bankrupted by medical expenses well below the catastrophic thresholds of high deductible plans that are increasingly popular with employers. The authors comment that even their own coverage from Harvard leaves them at risk for out-of-pocket costs above levels that often led to medical bankruptcy.

In many cases, high medical bills coincided with a loss of income as illness forced breadwinners to lose time from work.

The research, carried out jointly by researchers at Harvard Law School and Harvard Medical School, and supported by a grant from the Robert Wood Johnson Foundation, is the first in-depth study of medical causes of bankruptcy. With the cooperation of bankruptcy judges in five Federal districts (in California, Illinois, Pennsylvania, Tennessee and Texas) they administered questionnaires to 1,771 bankruptcy filers and reviewed their court records. 931 of the filers subsequently underwent more detailed interviews about their financial and medical circumstances. The researchers found that illness and medical bills contributed to at least 46.2%, and as many as 54.5% of all bankruptcy filings.

Dr. David Himmelstein, the lead author of the study and an Associate Professor of Medicine at Harvard, commented: "Our study is frightening. Unless you're Bill Gates, you're just one serious illness away from bankruptcy. Most of the medically bankrupt were average Americans who happened to get sick. Health insurance offered little protection. Families with coverage faced unaffordable co-payments, deductibles and bills for uncovered items like physical therapy, psychiatric care and prescription drugs. And even the best job-based health insurance often vanished when prolonged illness caused job loss — precisely when families needed it most. Too often, private health insurance is an umbrella that melts in the rain."

"When medical debts and lost income from illnesses leave families facing a mountain of bills, bankruptcy is their last chance to stop the collection calls and try to put their lives back on track," noted Elizabeth Warren, Leo Gottlieb Professor of Law at Harvard and a study co-author. Professor Warren, a leading expert on personal bankruptcy, went on: "Bankruptcy costs these families substantial assets and deep personal shame. A person may recover physically from a medical problem, but millions of Americans will never recover financially from their encounters with the health care system."

According to study co-author Dr. Steffie Woolhandler, an Associate Professor of Medicine at Harvard and primary care physician in Cambridge, Mass.: "We need to rethink health reform. Covering the uninsured isn't enough. We must also upgrade and guarantee continuous coverage for those who have insurance. Only national health insurance can do that. But we're headed in the wrong direction. An increasing number of employers and politicians are peddling phony insurance — stripped-down plans so riddled with co-payments, deductibles and exclusions that serious illness leads straight to bankruptcy. We need real health security, not counterfeit coverage."

Copies of the article are available at: <http://content.healthaffairs.org/webexclusives/index.dtl?year=2005>

## FACT SHEET

- 1.458 million individuals or couples filed for bankruptcy in 2001. These bankruptcies involved 1.925 million debtors and 1.939 million dependents — a total of 3.864 million people.
- Between 46.2% and 54.5% of all bankruptcies (midpoint estimate 50.35%) were caused, at least in part, by illness or medical debts. Thus, medical bankruptcy involved between 1,850,098 and 2,227,000

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## LIABILITY REFORM, from page 3

compared with other types of tort actions, and the lawyers do not get paid unless they win. But limiting plaintiffs' attorney fees will create an enormous imbalance in favor of the defendant. While we may disagree on the need for damage caps, we should all be able to agree that our legal system should remain a fair and balanced forum accessible to all Americans. ■



# Product Recalls

January 13 — February 16, 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](http://www.fda.gov).

Name of Drug or Supplement; Class of Recall; Problem	Lot #: Quantity and Distribution; Manufacturer
<b>Biosilk Dandruff Control Conditioner</b> 11.6 oz and 34 oz., Class III, cGMP deficiencies.	Product Numbers BI9111 and BI9134, all lots remaining on the market; 1,413 units distributed nationwide; Farouk Systems, Inc.; Houston, TX.
<b>Crest Spinbrush Pro-Whitening Toothbrush and Refill Heads</b> , Extra Soft and Medium, Class II. Quality issue.	Market withdrawal, all lots; 7.5 million units distributed nationwide; Procter & Gamble, Co., Cincinnati, OH.
<b>Desyrel Dividose Tablets</b> (trazodone HCL) 150 mg, 100 count bottle, Rx only, Class III, Good Manufacturing Practice Deviation.	Lot # 4F83245, exp. date 6/30/07; 242 bottles distributed nationwide; Bristol-Myers Squibb Manufacturing Co, Mayaguez, PR.
<b>E'OLA Ultra-S, Super Strength, 8 oz liquid</b> . Ultra S SUPER STRENGTH DIETARY SUPPLEMENT Purified Silver in Solution, Class II, Product makes drug claims.	Item codes 11365 and 11363; 6,397 units distributed nationwide; Biogenics, Inc.; Saint George, UT.
<b>Metoclopramide Tablets</b> , USP, 5 mg tablets, Rx only, packaged in 30 and 31 count grid cards, and Folic Acid Tablets, USP, 1 mg, Rx only, packaged in 30 and 31 count grid cards, Class II, Mislabeling.	Lot 3546-4009, exp. date 10/31/05, Lot 0664-4010, exp. date 10/31/05; 38,354 packages distributed nationwide.

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### MEDICAL BILLS, from page 4

Americans in 2001 (midpoint estimate = 2,038,549).

- The number of medical bankruptcies increased approximately 2200% between 1981 and 2001.
- Most medical debtors had some health insurance, but many suffered gaps in coverage:

- 75.7% had health insurance at the onset of the bankrupting illness
- 68% had coverage at the time of their bankruptcy filing
- 62% had continuous coverage
- 1/3 of those with private coverage at onset lost it during the course of illness
- Only 2.9% of the uninsured

went without coverage voluntarily — most others couldn't afford it

- High medical bills contributed to 60% of medical bankruptcies, with drug costs contributing to 48%. (Drug costs were the major problem for most Medicare-insured debtors, and many of those with psychiatric disorders). In 35% of cases, lost income due to illness was a factor.
- Out-of-pocket medical costs since the onset of illness averaged \$11,854:
- The privately-insured had the highest costs — \$13,460 — due to the very high costs incurred by those who initially had private coverage but then lost it

- Cancer patients' costs averaged \$35,878

- Families in medical bankruptcy suffered many privations. In the 2 years before filing for bankruptcy:

- 22% went without food
- 30% had a utility shut off
- 61% went without needed medical care
- 50% failed to fill a doctor's prescription

- Only between 7.1% and 14.3% of Canadian bankruptcies are due to "health/misfortune" (a category that includes some non-medical problems) according to previous studies. ■

## DRUGS AND DIETARY SUPPLEMENTS *cont.*

### *Name of Drug or Supplement; Class of Recall; Problem*

a) **MYO MAX**, Scitec Nutrition the ultimate engineered anabolic MRP formula; b) **MYO MAX Gain + Ultrapure Aminogen**, High Protein performance support formula; c) **His and Her Low-Calorie High-Protein formula**, Class II, Dietary Supplements/meal replacements are subpotent.

**Paxil Tablets (paroxetine hydrochloride)**, 10mg scored tablets, 30 count bottles, Rx only, Class II, Subpotent (3-month stability).

**Premarin (conjugated estrogens) tablets** USP, 0.625 mg, 100 count tablet bottles, Class III, Dissolution failure.

**Power Plus Energy Supplement N-3, 4 oz, Power Plus Energy Supplement C-3, 4 oz, Power Plus Normal Kit**, and **Power Plus Chemically Treated Kit**, Class II, Unapproved new drug, hair regrowth claims, contains minoxidil.

**USEpt Tablets**, Urinary Antiseptic Antibacterial/Analgesic, Rx only, 100 count tablets, Class III, Presence of foreign substance.

### *Lot #: Quantity and Distribution; Manufacturer*

Lots beginning with 0309, 0310, 0311, 0312, 0401, 0402, and 0403; 16,429 bottles distributed nationwide; Advanced Nutritional Biosystems, Inc., Orlando, FL.

Lot F61-4B10, exp. date 07/31/06; 78,000 bottles distributed nationwide; Sb Pharmco Puerto Rico Inc., Cidra, PR.

Lots 034039 and 040349; 48,883 bottles distributed nationwide; Amerisource Health Services Corp., Columbus, OH.

All lots remaining on market; 17,140 units distributed nationwide and internationally; Farouk Systems, Inc.; Houston, TX.

Lots S04C01 and S04E05, exp. date 5/07; S04F03 exp. date 6/07; 29,659 bottles distributed nationwide; Syntho Pharmaceuticals, Inc., Farmingdale, NY.

## 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](http://www.cpsc.gov).

### *Name of Product; Problem*

**Air cleaners.** The air cleaner's plastic inner housing and filter are not flame-resistant. If electrical arcing occurs in the cleaner, a fire can develop. This poses a risk of burn injuries and property damage.

**Baby walker.** The walkers fit through a standard doorway and are not designed to stop at the edge of a step. Additionally, these walkers can tip-over. Babies using these walkers can be seriously injured or killed.

**Barbecue lighters.** The lighters lack child-resistant mechanisms that meet federal safety standards. Young children could operate these lighters, which poses a fire hazard.

**Bicycle brake cable.** The bicycle brake cable can detach during braking, causing the rider to lose control and fall.

**Candleholder.** The hook or handle of the candleholder can overheat and break, causing the lit candle to fall out and pose a fire hazard.

### *Lot #: Quantity and Distribution; Manufacturer*

Aprilaire Model 5000 Electronic Air Cleaners; about 67,000 sold by independent HVAC dealers from June 2000-December 2004; Research Products Corp.; Madison, WI; (888) 742-2401; [www.aprilaire.com](http://www.aprilaire.com).

Big Save baby walkers; model numbers 9026, 9028, 9090, 90110 and 90111; about 12,000 units sold at toy and juvenile product stores nationwide; model 9026 walkers sold from June 1998-December 2002, other models sold from December 2003-December 2004; Big Save International Corp.; Los Angeles, CA; (800) 626-9393.

Kitchen Works barbecue lighters; about 2 million sold at dollar stores nationwide from January 2001-July 2004; Arett Sales Corporation (ASC); Cherry Hill, NJ; (800) 431-1212.

Shimano Road Racing Bicycle Brake Inner Cables; Shimano 1.6 mm X 1,700 mm brake inner cables for ATB and road racing bicycles. Part numbers: Y80098400/Z80098400, Y80098110/Z80098110, Y80098300/Z80098300; about 13,630 sold at sporting goods and bicycle specialty stores nationwide from April 2003-October 2004; Shimano American Corp.; Irvine, CA; (800) 353-4719; [www.shimano.com](http://www.shimano.com).

Decorative Candleholder; about 48,000 sold at Deb Shops retail stores nationwide from November 2001-November 2004; Deb Shops Inc.; Philadelphia, PA; (800) 332-7467; [www.debshops.com/recall/candleholder](http://www.debshops.com/recall/candleholder).



***Type of Product; Problem***

**Carpet cleaners.** The carpet cleaner's metal upper handle can pose an electric shock hazard to consumers.

**Children's blankets.** The decorative stitching on the blanket's edge can come loose, allowing a child to become entangled in the yarn. This poses a strangulation hazard to young children.

**Children's drum set.** Small parts can break off during use, posing a choking hazard to young children.

**Computer temperature sensors.** When connected to a computer, a static discharge to the sensor can cause the sensor to draw too much current from the computer, causing the sensor to get hot. The sensor can get hot enough to cause a burn to the skin or damage objects in contact with it.

**Dining sets.** The wooden chairs can break, posing a fall hazard to consumers.

**Gas/electric heating and cooling units.** A gas leak can occur if there is a crack in the gas valve body near the inlet pipe connection. A build-up of gas in the burner compartment of the unit could occur, which could be ignited by an internal spark.

**Girl's sweaters.** The furry trim on the sweaters is dangerously flammable.

**Jumper set.** The paint on the buttons contains excessive lead levels, posing a lead poisoning hazard to young children.

**Lantern set.** The lantern can overheat and melt or ignite, posing a burn hazard to consumers.

***Lot #: Quantity and Distribution; Manufacturer***

BISSELL upright carpet deep cleaners; PowerLifter(r) Plus (model number 1620), PowerSteamer(r) ClearView(r) (model numbers 1692, 1692-1, 1692-R), Power Steamer(r) (model numbers 1685, 1693, 1693-R, 1693-W, 1694, 1694-1, 1694-R), Power Lifter(r) (model number 1694-3), and Rubbermaid X-tra-Lift(tm) (model 9E00); about 750,000 sold at major discount, appliance and department stores nationwide from January 2001-December 2004; BISSELL Homecare Inc.; Grand Rapids, MI; (866) 860-2392; [www.BISSELL.com](http://www.BISSELL.com).

Chamois Blankets; about 92,000 sold nationwide at Pottery Barn Kids' stores, through the Pottery Barn catalog, and PotteryBarnKids.com from December 2002-December 2004; Barn Kids; San Francisco, CA; (877) 800-9720; [www.potterybarnkids.com](http://www.potterybarnkids.com).

Fun Years Music Big Drum Musical Set; about 10,500 sold at Toys 'R Us stores nationwide from August-December 2004; Kids Station Inc.; Miami, FL; (800) 227-4772; [www2.toysrus.com](http://www2.toysrus.com)

Vernier's Go!(tm) Temp Temperature Sensors; serial numbers 0104XXXXXXX through 2004XXXXXXX; about 4,300 sold by Vernier Software & Technology and its resellers from February-December 2004; Vernier Software & Technology; Beaverton, OR; (888) 837-6437; [www.vernier.com/recall](http://www.vernier.com/recall).

HD Designs, 5-piece Dining Set; about 600 sets sold at Fred Meyer stores in Idaho, Washington, Oregon and Alaska, Fry's stores in Arizona, and Smith's Marketplace stores in Utah from April-October 2004; Commend Co. Ltd.; Fair Lawn, NJ; (800) 697-2448; [www.fredmeyer.com](http://www.fredmeyer.com)

Trane and American Standard Gas-Electric heating/cooling units; model numbers with YCP or YCX, serial numbers with 3383 through 4475; model numbers with YCY or YCZ, serial numbers with 4282 through 4475; 18,200 units sold by independent dealers and installers October 2003-December 2004; Trane and American Standard, divisions of American Standard Inc.; Tyler, TX; (888) 556-0125; [www.trane.com](http://www.trane.com); [www.americanstandardair.com](http://www.americanstandardair.com).

Dubbster Girls' Cardigan Sweaters with Faux Fur Trim; about 470 sold at H & M stores in the northeastern United States from November-December 2004; Dubbster (H & M private label), H & M; New York, NY; (877) 439-6261; [www.hm.com](http://www.hm.com).

Denim Jumper Set; style number 2814X, 2817X, and 2818X; about 6,700 sold exclusively at Kmart Stores nationwide from July 2004 to November 2004; HIS International; New York, NY; (888) 467-3990; [www.nokidding-HIS.com](http://www.nokidding-HIS.com).

Full Moon Lantern Set, Halloween themes: Model # XPM 012A, B and C; sold through on-line and print catalog from September 1-October 31, 2004; Martha Stewart Living Omnimedia, Inc.; (800) 950-7130; P.O. Box 11650, Pueblo, CO 21001-0650.

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***Type of Product; Problem***

**Leaf vacuum.** These leaf and lawn vacuums have a plastic elbow and blower exit adaptor that is connected to the top of the shredding chamber. The plastic can crack allowing stones, large sticks, and other material to puncture the plastic. This creates the possibility that pieces of plastic or other debris can fly upward toward bystanders or the operator. When this occurs, the potential for personal injury or property damage exists. This is more prone to occur when the outside temperatures are below 35 degrees.

**Light fixtures.** Due to a manufacturing defect in a component part, the light fixture could fall and strike a person beneath the light fixture. The fixture also poses a laceration risk if the lamp breaks.

**Log splitters.** The log splitter's hydraulic cylinders can have defective rod retention, causing the seals to leak and the rods to detach. This can result in serious injury to the operator, as the rod can rapidly and unexpectedly extend the splitting wedge.

**Motion lamp.** The lamp may shatter in use, causing a threat of serious injury from glass.

**Multi-task tool.** An internal clip may become dislodged and as a result, the clutch shoes could be projected from the clutch housing and strike consumers, posing the risk of injury.

**Oil-filled electric heaters.** Welds can rupture, expelling hot oil that can burn nearby consumers.

**Pacifier necklace.** The nipple can detach from the pacifier, posing a choking hazard to young children.

**Plate set with plastic fork.** The plastic fork prongs in the plate set can break posing a choking hazard to young children.

***Lot #: Quantity and Distribution; Manufacturer***

DR(r)Leaf and Lawn Vacuum; 1,071 sold nationwide through mail orders, internet, and retail stores from September-November 2004; Home Products, Inc.; Vergennes, VT; (877) 405-7464; [www.drpower.com/llvsafetynotice](http://www.drpower.com/llvsafetynotice).

Ceiling Light Fixtures; models 31021-794, 31022-794, 66022-794, 5217-02, 5217-746 and 5217-786; about 2,700 sold by home improvement outlets, lighting showrooms and contractors nationwide; 5217 model fixtures sold from October 2003-October 2004; 31021, 31022 and 66022 models sold from June 2004 through October 2004; Sea Gull Lighting Products Inc.; Riverside, NJ; (800) 347-5483; [www.seagulllighting.com](http://www.seagulllighting.com).

Log Splitter; Brave VH0234 Serial #S012368-S016976, Brave VH9926 Serial #S014226-S017534, Brave VH9922 Serial #S011460-S016862, Brave HB0115 Serial #S013853-S017534; about 4,000 sold at Ace, True Value, and Do It Best Hardware stores and independent power equipment dealers nationwide from June 2003-October 2004; Brave Products Inc.; Streator, IL; (800) 350-8739; P.O. Box 577, Streator, IL 61364-0577.

Metallic Motion Lamp; about 2,100 sold via Bits and Pieces catalog or [www.bitsandpieces.com](http://www.bitsandpieces.com) from October-December 2004; Superlines International; Taiwan R.O.C.; (800) 884-2637; [customerservice@bitsandpieces.com](mailto:customerservice@bitsandpieces.com).

KombiSystem Multi-Task Tool powerhead; Models KM55, KM55R, KM55RC, FS55T or FS55RT; about 45,000 sold by authorized Stihl dealers; FS models sold October 2001-October 2002, KM models sold September 2002-October 2004; Stihl Inc.; Virginia Beach, VA; (800) 610-6677; [www.stihlusa.com](http://www.stihlusa.com).

Model 5101 oil-filled electric radiator heaters; 70,000 sold by retailers nationwide, including Wal-Mart and Ace Hardware, from August-November 2004; Lakewood Engineering & Mfg. Co.; Chicago, IL; (888) 858-3506; [www.lakewoodeng.com](http://www.lakewoodeng.com).

Flashing Pacifier with Whistle Necklace and Flashing Pacifier Shock Baby Necklace; about 102,000 sold through Internet sales, distributors and small retail stores from January-November 2004; Todo Dollar Wholesale; Los Angeles, CA; (866) 325-4732.

Winnie the Pooh Plate Set with plastic fork and spoon; about 13,630 sold at school holiday shops; Giftco, Inc.; Vernon Hills, IL; 888-448-6728.



## C O N S U M E R   P R O D U C T S   *cont.*

### *Name of Product: Problem*

**Snowboard bindings.** The baseplate of the binding can break, resulting in loss of control and possible fall and injury to the snowboarder.

**Snowmobiles.** Inappropriate clutch ring gear installed on some units. This may cause ring gear fragmentation at high speeds and debris could act as projectiles. A projectile could cause serious injury or death.

**Subwoofers.** Electrical components in the subwoofer can overheat and fail, resulting in electrical arcing and smoke.

**Tea light.** During normal use, the decorative marshmallows or decorative campfire flames may catch fire.

**Toy cars.** Small parts can break off during use, posing a choking hazard to young children.

**Trampolines and ring enclosures.** Welds on the frame of these trampolines can break during use, resulting in falls and possible injuries. Additionally, the mounting brackets of the FunRing enclosures have sharp edges, which can cause lacerations.

**Trunks.** The lid can fall on a child who is looking or reaching inside entrapping the child at the neck, which poses a risk of strangulation. Also, the lid can close and self-fasten, entrapping the child inside the trunk, which poses a suffocation hazard.

**Vitamins.** The vitamins, which contain iron that can cause serious injury or death if ingested by children, do not have child-resistant packaging as required by the Poison Prevention Packaging Act.

### *Lot #: Quantity and Distribution; Manufacturer*

Rossignol and Dynastar Snowboard Bindings; Rossignol-brand HC 500, Zena, Unit Pack, HC Rental, and Unit Rental snowboard bindings; about 11,000 pairs sold at sporting goods stores and ski and snowboard rental shops nationwide from October-December 2003; Rossignol Ski Company, Inc. and Skis Dynastar, Inc.; Williston, VT; 877-677-6092; 800-992-3962.

2005 Mach Z(r) 995 and Summit(r) 995 Ski-Doo(r) Snowmobiles without functional electric starter; 2005 Mach Z Adrenaline, Summit Highmark CA5A / CA5B; Summit Highmark X CD5A / CD5B / CD5C; about 1,455 sold at Ski-Doo dealers nationwide from Sept. 2004-Jan. 2005; (888) 864-2002.

LSiW Powered Subwoofer; Polk Audio model LSiW subwoofers with part numbers AM8080-A and AM8083-A; serial number from AM808000100 to AM808000597 and AM808300100 to AM808300599; about 670 sold at stereo and electronics stores nationwide from June-August 2004; Polk Audio Inc.; Baltimore, MD; (800) 377-7655.

Roasting Marshmallow Tealight Candle Holder; Model numbers 4-01-427, 231279-4; about 5,000 sold nationwide at card stores from October 2004 through December 2004; Carlton Cards Retail, Inc.; Cleveland, OH; (800) 955-1244; <http://www.carltoncards.com>.

Toy Cars; about 1,200 sold at toy, department and discount stores nationwide from September-December 2004; New Star Toys & Gifts Inc.; Vernon, CA; (888) 647-0051.

Jumpking trampolines sold separately and with FunRing enclosures, 14-foot and 15-foot sizes; trampolines with enclosures were sold at discount, department and toy stores nationwide and in Canada from July 1999 through December 2003; trampolines without FunRing enclosures were sold from July 1999 through February 2004; Jumpking Inc.; Mesquite, TX; (866) 302-8669; [www.jumpking.com](http://www.jumpking.com).

Memory Trunks; about 1,600 sold by sales consultants at home events nationwide from November 2002 through October 2004; Once Upon a Family; Irvine, CA; (800) 377-6823; [www.onceuponafamily.net](http://www.onceuponafamily.net).

Long's Central-Vite Multivitamins; about 13,000 units sold Long's retail stores nationwide from March 2004 through December 2004; Leiner Health Products; Carson, CA; (800) 421-1168; [www.leiner.com](http://www.leiner.com).

## OUTRAGE, from page 12

exposures have been linked to intellectual impairment. Because of these risks, Congress and CPSC have long sought to protect children from lead exposure.

Two statutes govern the lead content of toys. Regulations implemented under the Consumer Product Safety Act ban paint containing greater than 0.06% lead. The Federal Hazardous Substance Act bans toys or articles that expose children to "hazardous substances" through routine handling or reasonably foreseeable use, including ingestion.

The responsibility for complying with these laws rests with manufacturers, which often hire private laboratories to conduct premarket testing. To help manufacturers and private laboratories implement the statutory standard for lead, CPSC in 1998 provided guidance on the importance of assessing the following factors:

the total amount of lead contained in a product, the bioavailability of the lead, the accessibility of the lead to children, the age and foreseeable behavior of the children exposed to the product, the foreseeable duration of the exposure, and the marketing, patterns of use, and life cycle of the product.

In the absence of a legal requirement to follow CPSC's lead testing standards, toy manufacturers can decide for themselves how to assess the safety of their toys. Companies that test to industry standards, however, do not perform the four CPSC tests.

Five recent recalls of millions of pieces of toy jewelry sold widely in vending machines raise serious questions about the adequacy of this voluntary industry testing.

The first recall occurred in September 2003 and involved 1.4 million toy necklaces distributed by L.M. Becker & Company, incorporat-

ed, of Kimberly, Wisconsin. The necklaces came to CPSC's attention after a child swallowed a pendant and subsequently developed extremely high blood lead levels. This pendant did not appear to have any outer coating.

The second recall, in March 2004, involved one million toy rings manufactured by Brand Imports, LLC, of Scottsdale, Arizona. The rings contained lead and were covered in lead paint.

The third recall, in July 2004, affected an additional 147 million pieces of jewelry, made by L.M. Becker & Company, Brand Imports, A & A Global Industries, Incorporated, and Cardinal Distributing Company. Some of these pieces had a non-lead-containing metal plating that did not prevent exposure to underlying lead when mouthed, touched, or ingested.

The fourth and fifth recalls occurred even more recently. Last month, CPSC announced a recall of 155,000 pieces of metallic necklaces featuring frogs, dolphins, and a "sunshine smiley face" because of dangerous levels of lead. Just this week, CPSC announced a recall of 7,100 pieces of lead-containing metal costume jewelry that have heart, oval, and rectangular shaped charms. These products were sold at Bloomingdale's, Kohl's, and other major department stores.

These recalls reveal serious deficiencies in the current industry testing for lead. According to industry representatives, the manufacturers of most of toy jewelry involved in the recalls did conduct pre-market testing according to the ASTM standard. If true, this means that it is not the failure to test, but rather the presence of lead and inadequacies in the testing protocol that are exposing children to dangerous levels of lead.

Despite the problems demonstrated by the recalls, many industry representatives continue to resist removing lead from their products or testing their products according to

the CPSC recommended tests. Four major distributors of toy jewelry sold in vending machines have agreed in writing not to use any lead until further guidance is produced by the CPSC. However, other important sectors of the industry have not taken this step.

The current system is not working to protect children from lead hazards. We need a system that protects children from being exposed to lead in the first place, not one that relies on after-the-fact recalls. By their nature, recalls occur after children are already exposed. Also, they can be difficult to enforce.

Recent evidence indicates that there continues to be significant risk to children from lead in consumer products. Researchers at the University of North Carolina-Asheville recently tested bracelets, pins, earrings, toe rings, and other costume jewelry from major department stores in California and the South. They found that over 60% of 400 items tested contained dangerous levels of lead.

The ultimate answer to this threat is to ban lead in children's products. I urge you in the strongest possible terms to take this step as soon as possible. If CPSC cannot take this step on its own, I ask that you recommend legislation to Congress.

In the interim, CPSC should immediately strengthen its testing requirements. Despite repeated recalls of children's products with toxic levels of lead, CPSC has failed to take basic steps to ensure that its recommended tests are conducted appropriately. The agency has not sought to include its tests either in Federal regulations or in the next revision to the ASTM testing standards. CPSC has also not asked the American Association for Laboratory Accreditation to develop a testing module around its recommended tests. These steps should be taken without delay. ■



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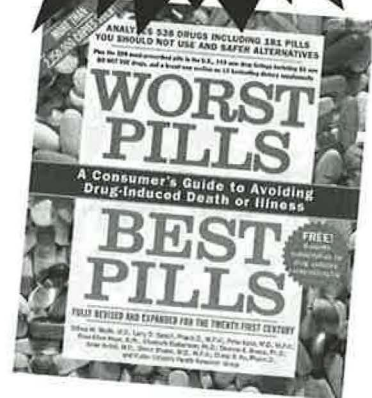
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# Get the Lead Out!

*This month's outrage is excerpted from a letter sent by Rep. Henry Waxman, D-Calif, to the Consumer Product Safety Commission on January 13, 2005. For recalls of lead-containing children's items, see our recalls section in this and previous issues of Health Letter or visit <http://www.cpsc.gov> for more information.*

From September 2003 through July 2004, the Consumer Product Safety Commission (CPSC) oversaw three recalls of nearly 150 million pieces of toy jewelry because of toxic levels of lead. Last month, and again this week, there have been more recalls involving an additional 162,000 pieces of lead-containing children's jewelry.

Yet despite these actions, children continue to be exposed to products

with dangerous lead levels. A recent study has found that 60% of more than 400 pieces of costume jewelry purchased at major department stores contain dangerous amounts of lead. I am writing to urge CPSC to solve the underlying problems that have led to the repeated marketing of these dangerous items.

These problems start with a basic disagreement between CPSC and manufacturers of children's products over which laboratory tests for lead should be conducted. CPSC recommends a series of tests to measure the accessibility of lead in a given product. The industry standard, however, is to test only the product's surface coating. Companies using this method can fail to detect major risks to children.

It is unacceptable that this situation has not been corrected. While four

companies have agreed temporarily not to use lead in toy jewelry, CPSC has not sought to include its recommended tests in federal regulations or industry standards applicable to a wide range of children's products. Nor has the agency worked to ensure that laboratories can be accredited in performing these tests correctly. These steps should be taken immediately.

More broadly, CPSC should address the question of why lead is permitted in toy jewelry and other children's products at all. To protect children, CPSC should ultimately ban the use of this toxic metal altogether. Acute lead toxicity can cause seizures, coma, and even death. Chronic lead toxicity is associated with attention problems, learning disabilities, mental retardation, and antisocial and delinquent behaviors. Even very low dose

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