

Health Letter

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Safety Alert!

It Is Better to Curse the Darkness Than to Light This Kind of Candle

More than 25 years ago, Public Citizen's Health Research Group (HRG) petitioned the government's Consumer Product Safety Commission (CPSC) to protect children and fetuses from brain damage caused by toxic emissions from candles with wicks containing lead. But in 1974, despite strong evidence of this danger disclosed by research from the same government's Environmental Protection Agency (EPA), the candle industry and CPSC arrived at a voluntary agreement to stop making these candles, thus supposedly making any federal ruling unnecessary. Since that time, however, evidence of the toxic effects of lead at progressively lower levels has mounted. Consequently, lead was banned in gasoline and paint, drastically reducing the average U.S. blood lead levels.

Lead is known to cause prematurity, decreased intelligence, antisocial behavior, impaired development, and learning disabilities at levels that the federal Centers for Disease Control and Prevention (CDC) previously considered acceptable. Higher lead exposure can result in high blood pressure, digestive difficulties, memory and concentration problems, joint pain, pathological changes to the brain and nerves, and even death.

Lead being so toxic, one wonders why it is used in candle wicks. The answer is that lead stiffens the wick so that the flame won't be extin-

guished in the melted wax. It also makes the flame burn hotter and more slowly, causing the scented material in the wax to vaporize better, thus enhancing the aroma. But lead is not the only substance that will do these things; many alternatives exist, including paper- and cotton-core wicks, and prewaxing of wicks before candles are formed.

In February 2000, to determine whether the voluntary ban had been effective, Public Citizen's Health Research Group conducted a survey of

12 stores in the Baltimore-Washington area. Thirty percent of all candles examined had metallic wicks. Ten percent of these metal wicks (and 3 percent of all candles in the study) contained lead, always in very high quantities such that 33 to 85 percent by weight of the metallic core was lead. In an industry that manufactures about 1 billion candles annually, there are millions of candles sold each year that contain lead.

Our study determined that burn-
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St. John's Wort: A Growing List of Harmful Drug Interactions

Once again, the British government is doing a better job warning doctors and patients in that country about dangers concerning drugs than the Food and Drug Administration (FDA). Reprinted below is a letter sent to FDA Commissioner Dr. Jane Henney by *Health Letter* editor Dr. Sidney Wolfe urging that Americans be similarly warned about new information concerning interactions between the widely-sold St. John's Wort and a long list of commonly used prescription drugs.

British physicians and patients are now being forcefully warned—for many more drugs than American physicians or patients—about potentially serious, clinically important drug interactions be-

tween the unregulated herbal St. John's Wort (*Hypericum perforatum*) and a large number of prescription drugs. For 10 widely-used drugs or classes of drugs, the British government's Committee on the Safety of Medicines is warning doctors and patients to stop the use of St. John's Wort in people using any of these drugs and urging that patients be warned not to start the use of St. John's Wort if they are already using these prescription drugs. For some of these drugs, however, patients are urged to see their pharmacist or doctor before stopping St. John's Wort as the dose of the prescription medicine may need to be altered to prevent adverse effects.

The United Kingdom's Committee on Safety of Medicines warned on February

29, 2000 that St. John's Wort should not be used with the following list of widely used prescription drugs because of the possible serious consequences: carbamazepine (Tegretol); citalopram (Celexa); cyclosporin (Sandimmune, Neoral); digoxin (Lanoxin); fluoxetine (Prozac); fluvoxamine (Luvox); naratriptan (Amerge); oral contraceptives; paroxetine (Paxil); phenobarbital (Luminal); phenytoin (Dilantin); rizatriptan (Maxalt); sertraline (Zoloft); sumatriptan (Imitrex); theophylline (Theo-Dur and many others); warfarin (Coumadin); and zolmitriptan (Zomig).

We have reprinted, immediately following, the fact sheet for the public for your reference:

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CANDLES, *continued from page 1*

ing these candles for a few hours daily in a typical room would exceed EPA air lead regulations by at least 1.5 times, but the output of some candles could exceed the limit by 29 times. Even the lowest of these air-lead concentrations would likely raise a child's blood level above CDC safety recommendations. In fact, exposing a child for only forty-five minutes a day in a room where these candles are burned will raise a child's blood-lead level above what the CDC considers safe. Furthermore, children ingest and inhale vaporized lead that settles as house dust on food, floors and other surfaces.

On February 24, 2000, Public Citizen's Health Research Group petitioned the CPSC to ban and recall all domestic and imported candles that have wicks containing lead. At least one other country has already acted along these lines: last year the Australian Minister of Financial Services and Regulation ordered a ban on all candles with lead-containing wicks because of a preponderance of evidence that they are hazardous. This official, Joe Hockey, stated, "Pub-

lic health experts have confirmed that lead emissions from any source pose an unacceptable public health risk and can result in increased blood-lead levels in unborn babies, babies and young children. ... Public health experts have confirmed that the candles pose a risk to public health if burned in a confined space."

Although it is apparent that the Australian government protects its citizens better than its American counterpart does, both are decades late. In 1974, Russell Train, then Administrator of EPA, had already warned that "inhabitants of homes in which lead-wicked candles are burned could be exposed to substantial incremental quantities of lead which, if continued on a regular basis, would pose a significant risk to health especially among children with already elevated lead body burdens. In my opinion candles represent an unnecessary incremental source of lead that can readily be controlled."

All this being well documented history, what is the CPSC waiting for? Too many children have been exposed since Public Citizen first urged action.

What You Can Do

Don't buy any candles that have metallic wicks unless they are labeled as not containing lead. Return all such candles to the store of sale. To determine if a candle has a metallic wick, look at the very center of the candle. Metallic wicks will have a thin, shiny center or core. Visualizing this sometimes requires peeling back the wax and cotton that surround the core of the wick. Do not trust industry claims that you can distinguish leaded wicks from non-leaded wicks.

If you or your children have been exposed to candles that contain metallic wicks, tell your doctor and ask him or her for blood tests to determine blood-lead levels.

Demand that your store stop selling candles with metallic wicks unless they are labeled as not containing lead—or tell them you'll take all your business elsewhere.

Write the CPSC urging a ban and recall orders for all candles containing wicks with lead at U.S. Consumer Product Safety Commission, Washington, DC 20207, Phone 1-800-638-2772 or email a message from their web site at <http://www.cpsc.gov/incident.html>.

FACT SHEET FOR THE PUBLIC

Important safety information for people taking St John's Wort preparations

St John's Wort (SJW) preparations are unlicensed herbal remedies. Their levels of active ingredients can vary from one preparation to another. They are widely used in the UK being available from pharmacies, health food shops and herbal practitioners. St John's Wort preparations may interfere (interact) with medicines, stopping them from working properly. If you are taking medicine, it may not be safe for you to take St John's Wort preparations. The advice in the box is provided below to help you understand how this may affect you.

I am currently taking a St John's Wort preparation, and I am not taking any medicine(s).

Advice: If you buy a medicine from a pharmacy or are prescribed a medicine by your doctor you must tell your pharmacist or doctor about the St John's Wort preparation.

I am already taking medicine(s) but I would like to start taking a St John's Wort preparation.

Advice: You must not take a St John's Wort preparation until you have checked with your pharmacist or doctor that it is safe for you to do so.

Epilepsy or fits: I am on tablets for epilepsy/fits and I am also taking a St John's Wort preparation.

Transplant: I am on tablets following a transplant and I am also taking a St John's Wort preparation.

Asthma or chronic bronchitis: I am on theophylline tablets for my chest and I am also taking a St John's Wort preparation.

Heart condition: I am taking digoxin for a heart condition and I am also taking a St John's Wort preparation.

Blood clots: I am taking warfarin to thin my blood and I am also taking a St John's Wort preparation.

Advice for patients with any of these conditions: You will need to stop taking the St John's Wort preparation as it may stop your medicine from working properly. However, you should see your pharmacist or doctor before stopping the St John's Wort preparation as the dose of your medicine may need to be altered to prevent side effects.

Contraceptive pill: I am on the pill and I am also taking a St John's Wort preparation.

Advice: You should stop taking the St John's Wort preparation as it may stop your pill from working. Continue to take your contraceptive pill as normal. There is no need to see your pharmacist or doctor urgently, however, mention it when you next consult your doctor or are dispensed a medicine.

Migraine: I take treatment for migraine and I am also taking a St John's Wort preparation.

Depression: I am on treatment for depression and I am also taking a St John's Wort preparation.

Advice: You should stop taking the St John's Wort preparation as it may stop your medicine from working. There is no need to see your pharmacist or doctor urgently, however, mention it when you next consult your doctor or are dispensed a medicine.

HIV: I am HIV positive and on treatment and I am also taking a St John's Wort preparation.

Advice: You should stop taking the St John's Wort preparation and see your doctor who may suggest you have your HIV viral load checked.

Advice: I am currently taking both a St John's Wort preparation and a prescribed medicine not mentioned above.

Advice: Tell your pharmacist or doctor that you are taking a St John's Wort preparation when you are next dispensed a medicine or consult your doctor.

- It is important to always tell your pharmacist or doctor about any herbal remedy or over the counter medicine you are taking.
- For further information call NHS Direct on 08 45 46 47.

Medicare: Few Beneficiaries Use Colorectal Cancer Screening and Diagnostic Services

A Report by the U.S. GAO

The information below is excerpted from a March 2000 report by the General Accounting Office (GAO) which finds that despite the relatively new Medicare benefits for colorectal cancer screening, an alarmingly large proportion of older adults are not using these life-saving tests. Although the GAO study focuses on the Medicare population, the issue is relevant to anyone over the age of 50 or even many younger than 50 who have risk factors for colon or rectal cancer. Most of us know one or more people, often under 60, who have died of colon cancer. Most of these deaths were avoidable.

Colorectal cancer is the second leading cause of cancer death in the United States. Currently, only about one-third of all colorectal cancers are diagnosed at an early stage. Widespread screening aims to detect the disease early, and in many cases, the detection and removal of precancerous growths may actually prevent colorectal cancer. The Balanced Budget Act of 1997 expanded Medicare coverage to include colorectal cancer

screening services. The Congress' decision to include colorectal cancer screening as a Medicare benefit reflected an awareness that early screening and detection are important to maintaining beneficiaries' health.

GAO examined the extent to which this new preventive health service has been used since its addition to the Medicare benefit package and focused on (1) the extent to which Medicare beneficiaries (both aged and disabled) are using colorectal cancer screening and diagnostic services and (2) efforts to address barriers identified as limiting use. To do this analysis, patient use rates were determined from Medicare claims data from 1995 through June 1999. Use rates for screening services alone could not be measured because of coding and other technical issues.

In brief, the use of colorectal cancer screening and diagnostic services by Medicare beneficiaries is very low relative to recommended use rates and has remained almost unchanged over the past five years. Although guidelines recommend annual fecal occult blood

testing for all people aged 50 and older, only 9 percent of fee-for-service beneficiaries received that test each year. Use rates for flexible sigmoidoscopy are significantly lower and have also remained constant at about 2 percent of beneficiaries. Women's use of some colorectal cancer screening and diagnostic services was slightly higher than men's, and white beneficiaries received the services at somewhat higher rates than African Americans, Asians, and Hispanics. Although use data are not available for Medicare beneficiaries in HMOs, research suggests that enrollees in managed care plans are at least as likely to have colorectal cancer screening as those in fee-for-service Medicare. Various factors contribute to the low use of screening and diagnostic services, some of which are beginning to be addressed by public health agencies and private organizations. Key among these is poor patient awareness of recommendations and coverage for screening, physician reluctance to perform the procedures because of the time and complexity involved, and lack of moni-

ST. JOHN'S WORT, from page 2

We are aware from the FDA's February 10, 2000 Public Health Advisory that the agency has contacted manufacturers to add warnings to the professional product labeling of indinavir (Crixivan) and other antiretroviral drugs used to treat AIDS that when these drugs are used in combination with St. John's Wort the blood concentrations of the AIDS drugs may be significantly decreased. In the same letter, in a short paragraph entitled "Other Drugs", FDA mentioned categories of drugs, but not specific drugs which could have harmful interactions with St. John's Wort:

Other drugs

Based on this study and reports in the medical literature, St. John's Wort appears to be an inducer of an im-

portant metabolic pathway, cytochrome P450. As many prescription drugs used to treat conditions such as heart disease, depression, seizures, certain cancers or to prevent conditions such as transplant rejection or pregnancy (oral contraceptives) are metabolized via this pathway, health care providers should alert patients about these potential drug interactions to prevent loss of therapeutic effect of any drug metabolized via the cytochrome P450 pathway.

Seeking labeling changes only for the antiretroviral drugs as indicated in FDA's February 10th Advisory is an insufficient response to a serious public health hazard. We strongly urge the FDA to immediately issue a warning to American physicians and patients about

all of these drugs and require warnings be included in the labeling for the above listed drugs about the potentially serious consequences that can result when St. John's Wort is used in combination with any of the drugs listed above.

Once viewed as the gold standard for drug regulation, FDA's image and reality have been not only tarnished but corroded. It is the United Kingdom, but not the United States, which has taken Rezulin and Halcion off the market and which now moves more swiftly and definitively concerning the harmful or potentially harmful effects of interactions between St. John's Wort and the large number of drugs listed above.

We hope for an immediate response to this urgent situation.

toring systems to encourage greater use.

Colorectal cancer is the third most commonly diagnosed cancer for both men and women in the United States. An estimated 129,400 new cases and 56,600 deaths from colorectal cancer were expected in 1999. Among the general population, the colorectal cancer mortality rate in 1997 was 21.6 per 100,000 individuals. Broken down into demographic groups, mortality rates were 28.8 for blacks, 21.1 for whites, 14.5 for Native Americans, 13.5 for Asians, 12.8 for Hispanics, 26.0 for men, and 18.4 for women.

According to medical experts, the risk factors for colorectal cancer include older age, family history, certain hereditary conditions, a diet high in saturated fat and low in fiber, excessive alcohol, and a sedentary life style. Research shows that the number of people developing and dying of colorectal cancer could be reduced through screening (identifying people with precursors to or early signs of the disease) and surveillance (monitoring people with previously diagnosed colorectal disease). Studies have shown that in the majority of colorectal cancers, noncancerous polyps grow slowly for 10 years or longer in the colon in a benign state before becoming cancerous. Identification and removal of the polyps during that time can prevent colorectal cancer from developing.

In 1997, a consortium led by the American Gastroenterological Association produced clinical practice guidelines to address uncertainty about the choice and frequency of screening tests

for different groups of patients.

For people at average risk of developing colorectal cancer, the practice guidelines recommend that people aged 50 and older have a fecal occult blood test annually, a flexible sigmoidoscopy every 5 years, an optional double-contrast barium enema every 5 to 10 years, and a colonoscopy every 10 years. For groups at high risk, experts recommend more frequent screening through colonoscopy.

The Medicare benefit for colorectal cancer screening addresses several of the clinical practice recommendations. Before January 1, 1998, Medicare covered the fecal occult blood test, sigmoidoscopy, colonoscopy, and barium enema only for diagnosis and treatment, such as for evaluating a specific complaint or monitoring an existing medical condition. The Balanced Budget Act of 1997 extended coverage of these services for screening purposes, with no coinsurance and deductible for the fecal occult blood test. For all other tests, the cost sharing is the same as for treatment services, which is payment of 20 percent of the Medicare approved amount after the yearly deductible. For people at average risk for colorectal cancer (those with no predisposing factors), Medicare now pays for a screening fecal occult blood test every year and a screening sigmoidoscopy every 4 years for beneficiaries aged 50 and older. In addition, for individuals at high risk, Medicare covers a screening colonoscopy every 2 years. For both risk groups, a double-contrast barium enema may be substituted at the same frequency as the sigmoidoscopy or the colonoscopy, if the physician be-

lieves that it is appropriate.

Despite the fact that nearly all older Americans report having a regular source of health care and a large majority report receiving routine checkups, Medicare beneficiaries' use of colorectal cancer services falls far short of recommended levels. In 1999, 14.1 percent of beneficiaries had one or more of the covered services (fecal occult blood test, flexible sigmoidoscopy, colonoscopy, or double-contrast barium enema) for screening or diagnostic purposes. Overall use is roughly equivalent to rates in 1995, when 13.6 percent of beneficiaries used any of these services.

Among the colorectal cancer screening and diagnostic services, the most common and least invasive is the fecal occult blood test. In 1999, the use rate for this service was 9.1 percent of beneficiaries, well below the recommended rate of once a year. In the same year, the use rate for flexible sigmoidoscopy, which is covered every 4 years, was 1.9 percent, while 3.8 percent of beneficiaries received a colonoscopy.

Similar data are not available on the use of colorectal cancer services by enrollees in the Medicare managed care program, called Medicare+Choice, because the Health Care Financing Administration (HCFA) does not require Medicare+Choice plans to report patient-specific data. However, evidence suggests that colorectal cancer screening rates among Medicare HMO beneficiaries may be similar to or higher than use rates among fee-for-service beneficiaries. In a recent synthesis of studies on

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What You Can Do

Public Citizen's Health Research Group Suggestions

We strongly support the screening guidelines mentioned above for anyone 50 or older or for younger people with risk factors. They include:

- For people at average risk of developing colorectal cancer, the practice guidelines recommend that people aged 50 and older have a fecal occult blood test annually, a flexible sigmoidoscopy every 5 years, an optional double-contrast barium enema every 5 to 10 years, and a colonoscopy every 10 years. For groups at high risk, experts recommend more frequent screening through colonoscopy.
- For people at average risk for colorectal cancer (those with no predisposing factors), Medicare now pays for a screening fecal occult blood test every year and a screening sigmoidoscopy every 4 years for beneficiaries aged 50 and older. In addition, for individuals at high risk, Medicare covers a screening colonoscopy every two years.
- For both risk groups, a double-contrast barium enema may be substituted at the same frequency as the sigmoidoscopy or the colonoscopy, if the physician believes that it is appropriate. *We strongly object to the idea that Medicare does not pay for screening colonoscopy and you should discuss this with your physician.*

Product Recalls

February 10—March 8, 2000

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

DRUGS & 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 reasonable 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 <http://www.fda.gov>.

Our listing of drug recalls this month includes a Class I recall of a topical antiseptic Techni-Care Surgical Scrub/Prep Broad-Spectrum Topical Antiseptic Microbicide. The wound care product was discovered to have microbial contamination.

Name of Drug or Supplement; Class of Recall; Problem	Lot #: Quantity and Distribution; Manufacturer
Levothyroxine Sodium , 25 mcg (0.025 mg) tablets, in 100 and 1,000 unit bottles, Rx used as a therapy in patients with hypothyroidism and as a pituitary TSH suppressant; Class II; Subpotency prior to labeled expiration date	All lot numbers; 5,400 bottles distributed nationwide; Science Enhancement Systems, Inc., Delray Beach, Florida
Naproxen Tablets , Rx 250 mg in 100, 500, 1,000-tablet bottles and 375 mg in 500-tablet bottles; Class II; Metal wire/particle contamination	Lot Numbers: 024107C, 113038A, 113038D, 071128A, 071128B, 071128C, 071128D; 12,468 bottles distributed in Alabama; Vintage Pharmaceuticals, Inc., Charlotte, North Carolina
Panadol (Extra Strength) PM Caplets , (500 mg Acetaminophen, 25 mg Diphenhydramine HCL), OTC, in bottles of 36 and 50 caplets and dispenser cartons of two caplets per pack; Class II; Glass particles were found in bulk diphenhydramine used in manufacturing	Lots: 106404 EXP 04/01, 106404, 106405, 106249 EXP 04/02, 107022, 107153 EXP 05/02, 107553 EXP 06/02; 12,010,500 tablets distributed nationwide; Geneva Pharmaceuticals, Inc., Broomfield, Colorado
Procanbld(tm) Extended-Release Tablets (Procainamide HCL), 500 mg, in 60 tablet bottles, Rx for use as an anti-arrhythmic; Class III; Dissolution failure (2 hour time point)	Lot Numbers: PA033SH1, PA033SH2, PA027SJ2, PA083SH1, PA034SH1, PA035SH1, PA098SH1, PA036SH1, PA032SH1, PA027SJ4, PA028SJ1. EXP date for all lots: 07/20/01; 171,850 caplets distributed in Puerto Rico; SmithKline Beecham, Dungarvan Ltd., Count Waterford, Ireland. Recalled by SmithKline Beecham, Consumer Health, Parsippany, New Jersey
Q-V Tussln Elixlr (Hydrocodone Bitartrate, Pseudoephedrine HCL and Chlorpheniramine Maleate), in 1-pint bottles, under Qualitest and Vintage labels; Class III; Lack of assurance chlorpheniramine maleate will maintain potency throughout labeled shelf life	Product Code: N0071-0562-20, Lot #40697D EXP 7/00; 21,251 bottles distributed nationwide; Warner Lambert Company, Morris Plains, New Jersey. Recalled by Parke Davis, Division of Warner Lambert Company, Morris Plains, New Jersey
Seroquel (Quetiapine Fumarate) 25 mg Tablets , in 100-tablet bottles, Rx oral medication for management of the manifestations of psychotic disorders, including schizophrenia; Class III; Some tablets may have become wet during packaging	Lot numbers 038D8A EXP 04/00, 035F8A, 035F8B 05/00, 004G8A, 005G8A, 006G8A EXP 06/00, 034M8A EXP 11/00; 47,157 bottles distributed nationwide; Vintage Pharmaceuticals, Inc., Huntsville, Alabama

DRUGS & DIETARY SUPPLEMENTS, cont.

Name of Drug or Supplement; Class of Recall; Problem

Sodium Iodide Capsules, Rx for diagnosing thyroid irregularities, packaged in 5-capsule packs; Class III; Incorrect date of calibration printed on labeling

Techni-Care Surgical Scrub/Prep Broad-Spectrum Topical Antiseptic Microbicide for Professional Degerming, in 4-fluid ounce bottles, OTC for wound care and general skin cleansing; Class I; Microbial contamination—*Pseudomonas aeruginosa*

Zen Liquid (1,4-Butanediol), in 35-fluid ounce bottles, OTC intended to be used as a sleep aid; Class I; Product is an unapproved new drug

Lot #: Quantity and Distribution; Manufacturer

Code 4750B EXP 10/01; 26,316 bottles distributed nationwide; AstraZeneca, Newark, Delaware

Lot numbers: I-3306-1C2, I-3306-1C1; 187 5-packs distributed nationwide; Syncor Pharmaceuticals, Inc., Golden, Colorado

Lot #1723 EXP 06/02; 24,322 bottles distributed nationwide; Care-Tech Labs, Inc., St. Louis, Missouri

MEDICAL DEVICES

Device recalls are classified in a manner similar to drugs, Class I, II or III, depending on the seriousness of the risk presented by leaving the device on the market. Contact the company for more details. You can also call the FDA's Device Recall and Notification Office at (301) 443-4190. To report a problem with a device, call 1-800-FDA-1088. The FDA website is <http://www.fda.gov>.

Name of Device; Class of Recall; Problem

Forex Natural Skin Condoms; Class II; Products may exhibit objectionable odor, have dried out or become brittle and unusable

Medical Tilt and Recline Chairs, allows patients to sit comfortably, includes tilt and recline features and has various accessories available including trays and headrests; Class II; Injury to patient's fingers may result when returning chair to upright position

Lot #: Quantity and Distribution; Manufacturer

Code 443, 443P, 444, 444R, 446, 451, 451R, 452, 452C, 452R, 462, 463; 1,016,146 units distributed nationwide; London International Group, PLC, Norcross, Georgia

Model numbers: HTR3000, HTR3500, HTR5000, and HTR5500. All serial numbers beginning with 96H through 99E, inclusive; 6,246 units sold nationwide and internationally; Invacare Corporation—Canada, Mississauga, Ontario, Canada. Recalled by Invacare Corporation, Elyria, Ohio

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 (CPSC), call their hotline at 1-800-638-2772. The CPSC website is <http://www.cpsc.gov>.

Name of Product; Problem

Battery Packs for use with various battery-operated tools; Clips can come loose, causing battery packs to fall and cause injury

Ceiling Light Fixtures; The light fixtures can short circuit, posing a fire hazard

Coffeemakers; Handle can break, causing the pot to fall

Lot #: Quantity and Distribution; Manufacturer

Model DW9095 with date codes from 9719 to 9810 (2.2 pounds); 755,000 sold nationwide from May 1997 through June 1998; DEWALT Industrial Tool Co., Baltimore, Maryland (877) 457-0478 www.dewalt.com

Model E181045; 126,000 sold at Wal-Mart from February 1998 through March 1999 and at Lowe's from January 1998 through January 2000; TSI Prime Inc., Coppell, Texas (877) 317-9237

Made of black plastic with glass pot and black plastic handle with red thumbrest; 31,000 sold at Tim Hortons coffeeshops in Kentucky, Ohio, Maine, Michigan, New York and West Virginia from October 1999 through February 2000; Tim Hortons Coffeeshops operated by TDL Group Ltd., Ontario, Canada (888) 273-9846 (BREWTIM) www.timhortons.com.

CONSUMER PRODUCTS, *cont.*

Name of Product; Problem

Infant and Toddler Jackets; Snaps on flap pockets of jackets could be removed, presenting a choking hazard to infants and young children

In-wall Electric Heaters; Heaters are defective and can overheat and catch fire

Mountain Bikes; Front suspension forks might not have been welded properly, and can break apart during use, resulting in serious injury to the rider

Power Strips; Wiring in these power strips is undersized and poses shock, electrocution and fire hazards

Socks; Heat-sealed Tommy Hilfiger flag logo appliques on these socks can detach, posing a choking hazard to young children

Storm Doors; Doors were manufactured without retaining pins in the upper windows. The upper window can fall out and could injure nearby consumers

Lot #: Quantity and Distribution; Manufacturer

Pink or blue gingham fabric with a hood and flap pockets, sold in infant sizes 6 months—24 months and toddler sizes 2T—4T. "Baby N" is on each collar label and "nowhere but nordstrom" is on jacket's hood label; 2,250 sold at Nordstrom's stores during January 2000; Nordstrom, Inc., Seattle, Washington (800) 695-8000

Cadet and Encore brand models FW, FX, LX, TK, ZA, Z, RA, RK, RLX, RX and ZC; More than 1.9 million distributed mainly in California, Idaho, Montana, Oregon and Washington. This recall was initiated in 1997 and has been announced as part of the resolution of the lawsuit filed by CPSC against the company on January 14, 1999; Cadet Manufacturing Co., Vancouver, Washington (800) 567-2613 www.cadetco.com/recallprogram.html

Vertical XL2 with chrome-colored frames. Label affixed to the frame near the crank reads "Model No. 8526-26" and "99.10.11," which shows they were manufactured the week of October 11, 1999; 19,000 sold nationwide at Target stores from November 1999 through February 2000; Dynacraft Industries Inc., San Rafael, California (800) 551-0032

Champion Brand Tools 6-outlet power strips. The back of the strip has a date code indicating it was manufactured on 4/97. Writing on the cord includes "Chang RVV 300/500V;" 35,000 sold at discount outlets nationwide from January 1997 through July 1998; Frieder Inc., Bedford Heights, Ohio (800) 321-8192

White socks with red, white and blue logo in sizes "S/M," for 6—12 months; "L/XL," for 12—24 months; and toddler shoe sizes 7—11; 360,000 pairs sold nationwide from January 1999 through January 2000; Mountain High Hosiery Ltd., San Diego, California (877) 729-4916 www.mtnhighinc.com

Product numbers 94816, 94800, 94801, 94832, 94833, 94802, 94803, 94892, 94893, 94856, 94858, 94924, 94860, 94862, 94925, 94864, 948666; 23,000 sold from June through December 1999; New Cole Sewell Corp., St. Paul, Minnesota, (800) 328-6596

MEDICARE SCREENING, from page 5 the use of preventive care, researchers found that enrollees in managed care plans were at least as likely as those in other plans to obtain colorectal cancer screening services. One-third of comparisons of colorectal cancer screening use found that managed care enrollees were more likely to use the services and two-thirds of comparisons found no difference in use between enrollees in managed care plans and nonmanaged care plans. Enrollees in group and staff model HMOs—which accounted for 4.4 percent of Medicare

beneficiaries in 1998—were significantly more likely than those in fee-for-service Medicare or other types of HMOs to obtain preventive services in general.

Analyzing use rates by patients' demographic characteristics, we found that use varied only slightly by age, race, gender, and geography. These rates also remained relatively constant over the five year study period. Specifically:

- Women had higher use rates in 1999 for fecal occult blood test (about 10 percent, compared with 8 percent for men) and similar rates for flexible

sigmoidoscopy and colonoscopy.

- Beneficiaries aged 70 to 79 were most likely to use screening and diagnostic services, but their use rates were only about 13 percent higher than for those aged 65 to 69 or 80 to 84.
- White beneficiaries received the screening and diagnostic services at consistently higher rates (about 15 percent in 1999) than Asians (about 13 percent), African Americans (approximately 9 percent), or Hispanics (approximately 8 percent).
- In general, a higher percentage of

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Patients, Doctors Not Warned of Dangers of New Diabetes Drugs

Public Citizen Petitions FDA to Revise Labels for Three Drugs

The U.S. Food and Drug Administration (FDA) should immediately revise labels on three new diabetes drugs to warn doctors and patients that the drugs are of questionable effectiveness and can have serious side effects, Public Citizen's Health Research Group said in a petition to the FDA in March.

This petition is based on reviews by FDA medical officers, statisticians, and pharmacologists as well as transcripts of FDA advisory committee meetings, and a review of the scientific literature for troglitazone, rosiglitazone, and pioglitazone. We compared this information to the current professional product labeling and found that much of this information was never included in the label, or seriously understated. As a result, the labeling omits important safety and efficacy information to such an extent that physicians are likely to prescribe these drugs inappropriately.

The drugs, Rezulin, Avandia and Actos, are in a class of drugs called "glitazones." The drugs are used to treat type-2 diabetes, a less severe form of the disease in which patients do not require outside sources of insulin. Glitazones are used to help patients improve their sensitivity to their own insulin. An estimated 15 million people in the U.S. have type-2 diabetes.

Studies have shown that adverse effects of the three drugs can include liver damage, heart damage, weight gain, fluid retention, low blood pressure, anemia and possible changes in hormone levels. In addition, studies show that the three drugs are less effective than older drugs. However, this information is either omitted or underplayed in the current label.

These problems were well known to FDA medical officers who reviewed the drugs before they were approved. The medical officers' reviews, transcripts from advisory committee meetings, and Public Citizen's own reviews of the medical literature form the basis of the petition.

It is outrageous that this critical information is being kept from doctors and patients. They need to be aware of the dangers associated with these drugs. These drugs have extremely serious adverse effects and are not as effective as some of the older drugs.

One of the drugs, Rezulin, was pulled from the market in 1997 by British medical authorities because of 130 cases worldwide of liver damage, including six deaths. According to a recent statement by the FDA's director of the drug review center, 58 deaths

attributed to Rezulin have now been reported to the U.S. agency. Public Citizen petitioned the FDA in 1998 to ban Rezulin. According to a knowledgeable FDA physician, a large proportion of physicians at the FDA familiar with Rezulin's dangers think the drug should be taken off the market.

The petition states that:

- Results in 9 of 10 studies showed that the three drugs were less effective than older drugs. Blood sugar levels deteriorated when patients were switched from old drugs to these new drugs;
 - The FDA has received reports that patients using Rezulin had higher rates of heart failure than patients on older drugs used to treat diabetes. In just the first 18 months that Rezulin was on the market, the FDA listed 56 cases of heart failure associated with the drug compared to only four cases reported over a period of 13 years for glucotrol (a sulfonylurea), an older diabetes drug;
 - The new drugs led to weight gain in various studies of an average of 2 to 12 pounds;
 - Some patients using the drugs ex-
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MEDICARE SCREENING *from page 8*

beneficiaries in Massachusetts and Rhode Island (18 to 20 percent) received screening and diagnostic services consistently over the five year period than beneficiaries in other states.

Researchers have identified a lack of patient awareness, understanding, and inclination as the most significant factor inhibiting the use of colorectal cancer screening services. In a 1997 report, the Agency for Healthcare Research and Quality (AHRQ) found a very low level of awareness about the

risks of colorectal cancer and its symptoms among adults. It also found that people are more likely to participate in screening when they understand the nature of the disease and feel they are at risk for it. Good communication between health care providers and patients and the effective use of educational materials could enhance patient participation in screening, AHRQ researchers concluded.

The Centers for Disease Control and Prevention found that the participants were not aware that colorectal cancer is the third most

prevalent cancer, nor were they aware of the benefits of screening and early detection. However, the focus groups also revealed that older adults, particularly those older than 65, are unwilling to discuss issues of colorectal cancer screening, even with their physicians. Representatives of several physician and patient groups echoed these results, telling us that many people find colorectal cancer screening tests inconvenient or embarrassing or that they may be concerned about potential discomfort during the screening.

DIABETES DRUGS,

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perienced fluid accumulation in their legs and lungs.

One FDA medical officer wrote, "I am concerned that long-term exposure to [Avandia] may give rise to a similar liver problem as with [Rezulin]" — that is, the liver failure that drove Rezulin from the market in Great Britain. Two published reports have already documented severe liver damage in patients taking Avandia, but none of the information is in the label.

Anemia was another side effect not adequately addressed in the labels, the petition says. The drugs' labels mention anemia under "laboratory abnormalities" but dismiss its significance. Although an FDA medical officer wrote of the potential for patients to develop anemia when taking Avandia along with another type-2 diabetes drug with which it is frequently used, the label states that there is no increase in anemia with that drug combination.

Similarly, the labels state that fluid retention occurred in animal and human studies of the drugs, but the labels lack a discussion of the reasons. Without that information, doctors may treat fluid retention with drugs such as calcium channel blockers that could be harmful when taken with the glitazones.

Weight gain was a common problem for all three drugs and appears to be related to how the drugs work in the body. Weight gain puts patients at higher diabetic risks, yet an FDA medical officer wrote that "[Avandia] appears to lower glucose levels by converting glucose to fat."

Doctors likely will prescribe these drugs inappropriately because they have not been provided any of this critical information that could seriously jeopardize patient health. The FDA should act immediately for the sake of diabetic patients throughout the country.

A copy of the petition is available on our web site at <http://www.citizen.org/hrg/publications/1514.htm>

On March 14th, Public Citizen's Health Research Group asked the Food and Drug Administration (FDA) to open a criminal investigation of Warner-Lambert/Parke-Davis for apparently illegally withholding from the FDA a compilation of data concerning liver toxicity of Rezulin (troglitazone) known to the company before marketing but not sent to the FDA until six months after the drug was on the market. Reprinted below are excerpts from a letter sent by Dr. Sidney Wolfe, *Health Letter* Editor to FDA Commissioner Dr. Jane Henney:

Prior to the marketing of troglitazone in March 1997, Warner-Lambert/Parke-Davis was aware of a significant number of "treatment-emergent" cases in which liver toxicity evolved in people after they were given the drug. These are highly significant adverse reaction data which were compiled as of February 3, 1997 (before marketing was begun) by the company but not submitted to the FDA as a compilation of what was clearly a pattern of drug-induced liver toxicity until October 21, 1997 (six months after marketing had begun).

In a November 12, 1997 memo by FDA reviewer Robert Misbin, M.D. commenting on this belated submission of compiled data, he states that: "As of February 3 [1997], (from the submission of October 21, 1997) Parke-Davis reported 21 patients with treatment-emergent elevations of transaminases greater than 3x normal which required troglitazone to be discontinued. The maximum ALT [liver enzyme] exceeded 10x ULN [upper limit of normal] in 13/21 cases and exceeded 1,000 in 5/21 cases. There are three cases of biopsy-proven hepatitis with peak transaminase levels of 1,000 U/L and jaundice in two cases."

This delay in reporting the compilation of these findings is

highly significant because had the data been submitted promptly, within 15 days, as required by Federal law, it is likely that the drug would, when first marketed, have had a more serious warning about liver toxicity and would clearly have had instructions to have liver monitoring tests done. It is thus likely that many of the estimated 400 patients who have suffered troglitazone-induced liver failure (as of now, with many cases not reported, there have been 89 cases of liver failure including 61 deaths reported) would have been spared had this compilation of cases been sent to the FDA promptly instead of eight months later. When the drug was first approved and marketed, there was no mention of the seriousness of the liver toxicity nor was there any label instruction to have any liver tests done. Upon belatedly learning in the fall of 1997 of the cases of liver toxicity which had occurred prior to marketing, along with other cases of severe toxicity occurring after marketing, the FDA for the first time, in late October 1997 required the label to be changed to request initial liver testing the first two months of treatment and subsequent tests for a total of five tests in the first year.

In the previous cases of successful criminal prosecution of pharmaceutical companies for temporarily and illegally withholding information from the FDA—Lilly for the arthritis drug Oraflex, SmithKline for the hypertension drug Selacryn and Hoechst for the antidepressant Merital—the drugs were taken off the market. Likewise, troglitazone is a doomed drug and it is only a matter of when, not whether it will come off the market.

I look forward to a prompt response to this request for a criminal prosecution and to this now-third time request to ban this unacceptably dangerous drug.

OUTRAGE, from page 12

block at least four CIGNA newsletters, as documented in the box at the right.

If any physician were to conceal the dangers of smoking from Philip Morris employees, he or she would be guilty of professional misconduct. In addition to detailing the devastating impact of cigarettes on smokers, medical journals have published numerous articles documenting that second-hand cigarette smoke is responsible for thousands of asthma attacks and ear infections among children each year. But the employees of CIGNA and of StayWell (the company that produced the newsletter for CIGNA) demonstrated no ethical misgivings about denying life-saving health information to thousands of people. Rather than fighting censorship—the way any supposedly independent, and certainly any health-related, publication would do—the editors joined the censors.

The editors, in fact, apparently went out of their way to accommodate the big guys. As an example, one StayWell employee wrote a Philip Morris benefits manager in 1998, "One article I want to bring to your attention is the national piece on high blood pressure. It advises those who have high blood pressure to quit [smoking]. Other than that, I think everything should be appropriate for the Philip Morris employees. After you review the pages, please let me know if you find any

Newsletter	Philip Morris actions
Spring 1996	Deleted advertisement for CIGNA Time-Life videos featuring ex-Surgeon General C. Everett Koop prior to sending.
Summer 1996	Skipped entire issue because "several articles contained anti-smoking references."
Winter 1996	Skipped entire issue because "National article entitled 'A Breath of Fresh Air' listed smoking as one of the irritants in the environment which can trigger an asthma attack, and went further to say 'Do not allow smoking in your home or in any environment that you can control.'"
Spring 1998	Deleted reference to second-hand smoke causing ear infections from an article titled "Coping with your child's ear infection."

changes we should make."

The same employee helpfully wrote in February of 1999: "Please take a look at page 7, the asthma piece. It mentions cigarette smoking as a possible trigger for an attack. I thought I should bring that to your attention."

Significantly, CIGNA's (and StayWell's) concern on behalf of Philip Morris' interests did not extend to that of the thousands of employees who actually work for the tobacco manufacturer. This incredible collaboration exemplifies the danger of an employer-based health care system in which insurers

are responsible only to their "customers"—the companies that pay them—with no public scrutiny involved. By contrast, under a single payer health plan there would not be a mishmash of profit-seeking companies vying for business, and the single payer would be directly responsible to patients and subject to public oversight.

The CIGNA motto is "a business of caring." But caring for whom? Until our health care system is radically reformed, hundreds of thousands of Americans will be vulnerable to insurers whose true goal is to care for business.

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Health News Feels the Censor's Knife

Will a for-profit health insurer eagerly subordinate the well-being of patients to the interests of employers who pay for the patients' health coverage? When the insurer is CIGNA, and the employer is the cigarette manufacturer Philip Morris, the answer is a devastating indictment of profit-seeking in the health care system.

For three years ending in May 1999, CIGNA turned over editorial control of its own health newsletter to the giant tobacco company for those mailings sent to Philip Morris and Kraft (part of Philip Morris) employees, according to documents obtained by a researcher at the Minnesota Tobacco

Documents Depository.

Under the arrangement, CIGNA allowed staff in the Benefits Office at Philip Morris to censor virtually all references to the dangers of smoking in the "CIGNA Healthcare Well-Being Newsletter." The sanitized version (or better put, the de-sanitized version) was then sent to unsuspecting company employees. The terms of the deal: "Offensive local articles can be replaced with another of similar length at no cost to [Philip Morris]. If we opt to replace or modify a national article, it costs [Philip Morris] \$3,000 per issue."

How could CIGNA allow a cigarette manufacturer, whose products

kill thousands of Americans each month, to censor a health newsletter? The answer may be found in CIGNA's corporate vision: "Profitability is the ultimate measure of our success."

When confronted with the newly released documents, CIGNA spokesman Howard Drescher told the *Minneapolis Star-Tribune* that "Philip Morris was paying for a product that is specific to them and in that regard we have to listen to their requests. We work with our customers to try to help them meet their business needs."

Over the course of this unhealthy partnership, these "business needs" led Philip Morris censors to edit or

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