

# Health Letter

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## Drivel from the Drug Industry/U.S. Government Axis

**T**he pharmaceutical industry has provided invaluable medicines to cure and relieve millions of patients throughout the world. As an industry, it drives economic growth and employs thousands of skilled people. But it also uses false economics and makes up stories to justify higher prices. Higher prices strain budgets, causing millions of U.S. patients not to take the drugs their doctors think necessary. The pharmaceutical industry and the U.S. government want to blame other developed countries for these higher [U.S.] prices rather than make drugs more affordable."

So conclude researchers from the University of Medicine and Dentistry of New Jersey (Donald Light, Ph.D.) and from Toronto's York University (Joel Lexchin, M.D.), giving credit where credit is due and blame where it is appropriate. They have published a review in the *British Medical Journal* (October 22, 2005, pages 958-960) enticingly entitled "Foreign free riders and the high price of U.S. medicines".

They state that "The United States government is engaged in a campaign to characterise other industrialised countries as free riding on high U.S. pharmaceutical prices and innovation in new drugs. This campaign is based on the argument that lower prices imposed by price controls in other affluent countries do not pay for research and development costs, so that Americans have to pay the research costs through higher prices in order to keep supplying the world

with new drugs. Supporters of the campaign have characterised the situation as a foreign rip-off. We can find no evidence to support these and related claims, and we present evidence to the contrary. Furthermore, we explain why the claims themselves contradict the economic nature of the pharmaceutical industry."

Among their findings are:

- "Contrary to claims of American dominance, pharmaceutical research and development in the U.S. has not produced more than its proportionate share of new molecular entities. The U.S. accounts for just under 48% of world sales and spent 49% of the global total on research and development to discover 45% of the new molecular entities that were launched on the world market in 2003, less than its proportionate share. European countries account for 28% of world sales, 36% of total research and development

spending, and 32% of new molecular entities, more than its proportionate share."

- "A report from the U.K. Pharmaceutical Price Regulation Scheme documented that drug companies in the United Kingdom invest proportionately more of their revenues from domestic sales in research and development than do companies in the U.S. Prices in the U.K. are much lower than those in the U.S. yet profits remain robust."

- "In Canada the 35 companies that are members of the brand name industry association report that income from domestic sales is, on average, about 10 times greater than research and development costs. They have profits higher than makers of computer equipment and telecommunications carriers despite prices being about 40% lower

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# Saving Money When Buying Prescription Drugs

## Part II: Generic Drugs

Last month, we told readers that to save money on prescription drugs, they should try nondrug treatments before getting a prescription. If a prescription is necessary, we warned that Do Not Use drugs and Do Not Use for Seven Years drugs should

be avoided, both to save money and to prevent unnecessary adverse events. This month, we'll look at generic drugs in depth and dispel some harmful myths about generic drug use, leading to money-saving rule number 4: Buy generic drugs when possible. Next

month we'll look at another way of purchasing less expensive drugs — the Internet. Rule number five warns readers to purchase drugs on the Internet with caution.

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**HIGHER PRICES**, from page 1  
than in the U.S..”

- “Mark McClellan, the former commissioner of the Food and Drug Administration [now — unfortunately — head of Medicare and Medicaid], maintained that low prices are “slowing the process of drug development worldwide.” This assertion is contradicted by the industry’s data. The European Federation of Pharmaceutical Industries and Associations reported that, between 1990 and 2003, its members increased their research and development investments in Europe by 2.6-fold and in the U.S. by fourfold.”

- “‘Free rider’ is both a vivid public image of someone jumping on for a free ride and a highly misleading economic term. Technically it refers to a method for allocating fixed costs in proportion to the prices that different groups pay. For example, if Group A (call it Europe) pays \$1 per pill and Group B (call it the U.S.) pays \$2 a pill and each buys a million pills, then this accounting method would assign half as much of the fixed cost to Group A as to Group B. If, however, the fixed costs are only \$300 000 (a tenth of the total revenue) for the two million pills, the fixed costs could be allocated by volume rather than by price (\$150 000 for each group) and conclude that Group A more than pays the fixed costs and Group B pays much more than it has to. In short, the free riding argument economically is the artifact of an accounting convention and can be eliminated by Group B (the U.S.)

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cutting its prices in half, rather than forcing Group A (Europe) to double its prices.”

It is our view that these researchers have put their fingers on an important new way of looking at the issue of price discrepancies between the U.S. and the rest of the world. If anything, the entity getting a “free ride” is the pharmaceutical industry, which has bludgeoned the U.S. Congress out of imposing price controls or negotiated prices on drugs for the 40 million Medicare recipients in this country. Thus, although the industry is already extremely profitable in Europe and elsewhere, in the U.S. its price-gouging — masquerading as necessary for the preservation of research, most of which is for developing me-too drugs — is unconscionable and must be stopped.

When our elected representatives start paying more attention to the health needs of Medicare recipients and, for that matter, of all people in this country, instead of being led around by the more than 600 drug industry lobbyists in Washington and by the industry’s close to 100 million dollars a year of campaign contributions, the drug industry’s “free ride” will end and prescription drugs will finally become affordable for a large proportion of people in this country. ■



# **Rule 4. Buy Generic Drugs When Possible**

Unless you want to waste a large amount of money — often hundreds of dollars a year — by using brand-name instead of generic drugs, you should ask for the generic version, especially if you are starting on a drug for the first time. (See table below.) One of the few bits of comparative information about prescription drugs readily accessible to consumers is the retail price of brand-name versus generic drugs. You can get this information easily by asking your pharmacist. The table accompanying this article was prepared by simply phoning a local pharmacy.

In 1984, generic drugs accounted for less than 19% of all prescriptions filled. Today, generic drugs represent more than 54% of all prescriptions dispensed in the United States. In addition, even though generics account for more than half of prescriptions dispensed, generics account for less than 16 cents of every dollar spent on prescription drugs. Today there are more than 7,800 generic versions of the approximately 10,668 FDA-approved pharmaceuticals.

Brand-name drug manufacturers have gone to extraordinary lengths to mislead doctors, pharmacists, and the public into believing that their products are produced to higher standards,

## **Myths and Facts About Generic Drugs**

**Myth:** Generics take longer to act in the body.

**Fact:** The firm seeking to sell a generic drug must show that its drug delivers the same amount of active ingredient in the same time frame as the original product.

**Myth:** Generics are not as potent as brand-name drugs.

**Fact:** FDA requires generics to have the same quality, strength, purity, and stability as brand-name drugs.

**Myth:** Generics are not as safe as brand-name drugs.

**Fact:** FDA requires that all drugs be safe and effective and that their benefits outweigh their risks. Since generics use the same active ingredients and are shown to work the same way in the body, they have the same risk-benefit profile as their brand-name counterparts.

**Myth:** Brand-name drugs are made in modern manufacturing facilities, and generics are often made in substandard facilities.

**Fact:** The FDA won't permit drugs to be made in substandard facilities. The FDA conducts about 3,500 inspections a year in all firms to ensure standards are met. Generic firms have facilities comparable to those of brand-name firms. In fact, brand-name firms account for an estimated 50% of generic drug production. They frequently make copies of their own or other brand-name drugs but sell them without the brand name.

**Myth:** Generic drugs are likely to cause more side effects.

**Fact:** There is no evidence of this. The FDA monitors reports of adverse drug reactions and has found no difference in the rates between generic and brand-name drugs.

and thus are safer and more effective than the same drugs produced by generic companies. These strategies have included setting up sham patient groups to lobby state legislatures to

protect their brand-name drugs, and the suppression of scientific research by at least one brand-name company that showed their brand-name product

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## **Examples Of Savings With Generic Drugs**

Conditions	Drugs (Brand Name/Generic)	Dosing <sup>(1)</sup>	Retail Cost Per Day (All Brand) <sup>(2)</sup>	Retail Cost Per Day (Generic) <sup>(3)</sup>	Generic Savings Per Day (\$)	Generic Savings (% of Brand Cost)
Asthma	VENTOLIN/albuterol <sup>(4)</sup>	2 puffs every 4-6 hours as needed	\$1.44	\$0.69	\$0.75	52.3%
Hypertension	PRINIVIL/lisinopril	20 mg per day	\$1.16	\$0.60	\$0.57	48.5%
Congestive Heart Failure	LASIX/furosemide	40 mg per day	\$0.38	\$0.20	\$0.18	47.1%

(1) All medication is taken once per day unless otherwise noted.

(2) Prices are average retail prices in brick-and-mortar pharmacies (i.e., chain, independent, and food-store pharmacies, excluding Internet, mail-order, and long-term care pharmacies) across all payer types (cash-only, Medicaid, and other third-party payers) for the first quarter of 2004.

(3) Generic prices are calculated in the same fashion using the median price among generic manufacturers. A weighted average price would have been preferable, but no prescription volume data were available at the time by which to weight the different manufacturers.

(4) Patients using albuterol are assumed to need seven puffs on an average day.

Data Source: IMS Health, National Prescription Audit Plus™; first Quarter 2004; extracted April 2004; analysis conducted by the FDA.



## GENERIC DRUGS, from page 3

was no better than those of generic companies.

The quality of prescription drugs, brand-name or generic, does not depend solely on the manufacturer but also on a strong and vigilant FDA. Both brand-name and generic drug companies are regulated by the FDA using the same standards for manufacturing facilities, quality and purity, and content of prescription drugs.

### The Question of Brand-Name Quality

Many brand-name drug companies such as Warner-Lambert and its subsidiary, Parke-Davis, denigrate the quality of generic drugs in an attempt to hold market share from generics and protect profits. However, the facts about this brand-name manufacturer bear examining.

From 1990 to the end of 1995, there were a total of 64 recalls of Warner-Lambert products as listed in FDA recall reports. In 1990, there were 3 recalls, 1 in 1991, 3 in 1992, 24 in 1993, 13 in 1994, and 20 in 1995. For their brand of phenytoin (DILANTIN) alone — a drug used primarily for treating seizure disorders and one where the amount of drug in the blood is critical — there have been 12 recalls during this period. Nine of these involved problems with dissolving of the drug, which can result in an insufficient amount being absorbed by the body. More than 975,000 bottles (some of which contained 1,000 capsules) and more than 30,000 injectable doses of Dilantin were affected by these recalls.

In this case, Warner-Lambert officials pleaded guilty to criminal charges for withholding important information about sloppy manufacturing practices from the FDA.

### FDA Repels Attacks on Generic Drugs

As discussed in last month's piece, it is in the first seven years after approval — when there is never any generic equivalent available because the patent has not yet expired, that most drugs are found to cause seri-

ous problems, not infrequently leading to their removal from the market.

Examples of such disasters, which collectively have killed hundreds of Americans and injured thousands more, have involved the arthritis drugs or painkillers Oralflex, Suprol, and Zomax;

*A 1990 study by FDA laboratories from all over the country found that for those classes of prescription drugs that theoretically could be most likely to pose safety or effectiveness problems if they were not manufactured properly, the generic drug met the applicable standards in virtually all cases.*

the antidepressant Merital; the high blood pressure drug Selacryn; the diet drugs Pondimin, one-half of the once popular "fen/phen" combination, and its close chemical cousin Redux; Posicor, a drug for high blood pressure and chest pain; the diabetes drug Rezulin; and the painkiller Duract. Because of the serious dangers of these 10 drugs, all were taken off the market.

But what about those drugs that have been on the market for a long enough time for the patents to have expired and that are available in both brand-name and generic versions? Which version is safer or more effective? It has always been our position

that there is no difference between generic and brand-name drugs as far as the odds that there will be something found wrong with the amount of active ingredient or the purity. Over the years, there have been recalls because of these kinds of problems with both generic and brand-name drugs.

A 1990 study by FDA laboratories from all over the country found that for those classes of prescription drugs that theoretically could be most likely to pose safety or effectiveness problems if they were not manufactured properly, the generic drug met the applicable standards in virtually all cases. The classes of drugs tested included contraceptives, antibiotics, and medications prescribed for asthma, epilepsy, high blood pressure, and abnormal heart rhythms. Of the 429 samples of the 24 different drugs tested, including both brand-name and generic drugs, there were no samples tested that posed a health hazard to patients when examined for potency and, where applicable, dissolution rate and content uniformity.

The reason that these 24 different drugs were chosen is that they all have a narrow therapeutic range. This means that unlike with most kinds of drugs, for which there is a relatively large range of dosages that are both effective and relatively safe, the amount of these drugs that gets into the body must be more tightly controlled. If it is not, the drug may too easily lose its effectiveness (if the dose is too low) or become toxic (if the dose is too high).

The drugs that tested included six asthma drugs, four for treating epilepsy, four high blood pressure drugs, four drugs for treating heart arrhythmias, a birth control pill, one antibiotic, a drug for treating depression, and a so-called blood-thinning drug. In six categories of drugs, both brand-name and generic versions were tested. In the case of the birth control pill, all of the major brand names, but no generic version, were tested.

For 23 of the 24 different drugs, there was no difference between the brand-name and the generic versions in the FDA laboratory tests for purity or quality. For aminophylline, an



asthma drug that we do not recommend as a first-line treatment, five batches from two manufacturers failed to meet the FDA standards. Although none of these five batches posed a health hazard, all were recalled.

As can be seen in the accompanying table, over the course of a year, for drugs such as the high blood pressure drug lisinopril, which must be taken daily, the savings — 365 times \$.57 per day — are a hefty \$208 in one year; and the savings are hundreds more for others that many people may be using.

### What Is Bioequivalence?

Generics are not required to replicate the extensive clinical trials that have already been used in the development of the original, brand-name drug. These tests usually involve a few hundred to a few thousand patients. Since the safety and efficacy of the brand-name product has already been well established in clinical testing and frequently many years of patient use, it is scientifically unnecessary, and would be unethical, to require that such extensive testing be repeated in human subjects for each generic drug that a firm wishes to market. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent (i.e., performs in the same manner) to the pioneer drug.

One way scientists demonstrate bioequivalence is to measure the time it takes the generic drug to reach the bloodstream and its concentration in the bloodstream in 24 to 36 healthy, normal volunteers. This gives them the rate and extent of absorption — or bioavailability — of the generic drug, which they then compare to that of the pioneer drug. The generic version must deliver the same amount of active ingredients into a patient's bloodstream in the same amount of time as the pioneer drug.

Using bioequivalence as the basis for approving generic copies of drug products was established by the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act. Brand-name drugs are subject to the same

bioequivalency tests as generics when their manufacturers reformulate them.

The FDA has a public obligation to investigate thoroughly all allegations of drug product defects or failures. The agency has not found any of the allegations raised thus far in the brand-name versus generic drug controversy to be valid. The FDA also has an obligation to make known to health care professionals and to the public its conclusions that false or misleading reports are being generated.

### The Levothyroxine (SYNTHROID) Scandal

Boots Pharmaceuticals, which became the Knoll Pharmaceutical Company of Mt. Olive, New Jersey, in March 1995, suppressed publication of scientific research for more than two years in order to perpetuate the incorrect public impression that their brand-name version of levothyroxine (SYNTHROID) was more reliable than generic levothyroxine products from three competing companies. The cost to the American public in excessive charges for Synthroid over these two years has been estimated to be \$800 million.

Research that contradicted the Boots/Knoll superiority claim was finally published in the April 16, 1997, issue of the *Journal of the American Medical Association*. It found four generic and brand-name drugs — Synthroid and the three competing levothyroxines — to be bioequivalent by current FDA standards and interchangeable without loss of therapeutic efficacy in the majority of patients for treatment of hypothyroidism (low thyroid).

Knoll's predecessor, Boots, contracted with a faculty member and researchers at the University of California at San Francisco (UCSF) in 1987 for a bioequivalence study comparing Synthroid with three competitors' levothyroxine products. The company paid the researchers \$250,000 to do the study. In this case, a finding of bioequivalence would justify the use of less-expensive, equally effective generic products instead of Synthroid. Boots's expectation was that the study would find Synthroid to be superior to the generics.

The contract contained a clause giving Boots veto power over publication of the study's results. The problems began in late 1990, when it became known that Synthroid and the other three levothyroxines were the same.

Over the next four years, Boots waged a calculated campaign to discredit the researchers and their work. Once it was clear that the study would not support the claim of Synthroid's superiority, Boots alleged scores of deficiencies and errors in the study. The university conducted an investigation of how the research was done and found only minor and easily correctable problems. Some members of the investigating panel found Boots's interactions with the researchers to be "harassment" and characterized the company's actions as "deceptive and self-serving." The university concluded that the study was carefully done and complied fully with the terms of the contract.

The results of the study were submitted to the *Journal of the American Medical Association* in April 1994. The study was sent to five experts for peer review and was accepted for publication in November 1994, with its publication scheduled for the January 25, 1995, issue of the journal. On January 13, 1995, the researchers suddenly withdrew the study from publication, citing as the reason "impending legal action by Boots Pharmaceuticals, Inc. against UCSF and the investigators." Because of the clause in the contract giving the company veto power over publication, UCSF said it would not defend the researchers if the study was printed without the company's permission.

Then, in a move striking at the very core of ethical scientific standards, the company's senior director for medical research took the study results and, without giving credit to the UCSF researchers, published a misleading version in an obscure journal of which he was also an associate editor. The new version was used to support the company's previous assertion of Synthroid's superior reliability.

Six years after it was known that  
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# Product Recalls

October 19 — November 29, 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

**AccuHist PDX Syrup**, Each 5mL contains: Brompheniramine Maleate, USP 2mg, Detromethorphan HBr, USP 5mg, Phenylephrine HCl, USP 5mg, and Guifenesin, USP 50mg, Alcohol Free, Grape Flavor, Rx only, Class III, Subpotent; phenylephrine HCl.

**Amino Acid Cervical Cream**, Urea 8.34%, Methionine 0.83%, Inositol 0.83%, Cystine 0.35%, Rx only, Class II, Method validation deviations for finished product testing.

**Benazepril Hydrochloride Tablets**, 40 mg, ETHEX brand, Rx only, Class II, Presence of Foreign Tablet.

**GoodSense brand Milk of Magnesia** (magnesium hydroxide) 400 mg, Oral Liquid, Original, Mint, and Cherry Flavor in 12 and 26 FL OZ bottles, Class II, Defective Container; tamper evident seal may be split.

**Ipratropium Bromide Inhalation Solution**, 0.02% (0.5mg/vial), For oral inhalation only, Rx only, Class II, Mispacked; pouches labeled to contain Ipratropium Bromide actually contain Albuterol Sulfate Inhalation Solution 0.083%.

**Micronefrin** (racemic epinephrine) Each 100 mL contains racemic methylamino-ethanol catechol 2.25g, For Inhalation Topical Pulmonary Chemotherapy (TPC), Mucosal Decongestant and Bronchodilator, Rx only, Class II, Lack of Assurance of Sterility.

**Nitroglycerin Tablets**, USP 0.4mg (1/150gr), Rx Only, Class II,

### Lot #: Quantity and Distribution; Manufacturer

Multiple lots and expiration dates; 462,127 units distributed nationwide; Vintage Pharmaceuticals, LLC, Huntsville AL.

Lot numbers: 40803E06/06, 40804E06/06, 41008E07/06, 50524E04/07, 50525E07/07, 50608E04/07, and 50609E04/07; 37,514 tubes distributed nationwide and in Puerto Rico; Hope Medical Enterprises, Inc., Scottsdale, AZ.

Lot #62794, exp. date 11/2006; 13,076/100-tablet bottles distributed nationwide; Ethex Corporation, Bridgeton, MO.

Multiple lots and exp. dates; 2,114,688 bottles distributed nationwide under many generic trade names; Perrigo Company, Allegan, MI.

Lot Number: P5013A, exp date 12/2006; 12,452 cartons of 30 vials in a foil pouch distributed nationwide; Nephron Pharmaceuticals Corp., Orlando, FL.

Lot 297, exp. date 03/2005; Lot 398, exp. date 12/2005; Lot 399, exp. date 06/2006; Lot 401, exp. date 02/2007; 64,517 bottles distributed nationwide and internationally; Viasys Respiratory Care, Inc., Palm Springs, CA.

Lot 101105 exp. 1/07; Lot 201105, exp. date 01/2007; 25,038 bottles

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### GENERIC DRUGS, from page 4

there was no difference between Synthroid and generic levothyroxine products, and more than two years after the UCSF research should have been published, the Journal of the

American Medical Association published the research just as it would have appeared in January 1995, had it not been for Boots's interference.

To sum it all up, generic drugs are just as effective and safe as brand-

name drugs. Unless you want to waste quite a bit of money, ask your pharmacist to fill your prescription with a generic drug. If the brand-name drug is not yet off patent, your pharmacist will advise you of this. ■



## DRUGS AND DIETARY SUPPLEMENTS *cont.*

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

Defective container; caps on bottles are loose which can impact product integrity.

**Oxycodone and Acetaminophen Capsules**, USP, 5 mg/500mg Capsules, Rx only, Qualitest(r) brand, Class III, Dissolution Failure.

**Premarin** (conjugated estrogens USP), 0.9 mg, Rx only, Class III, Exceeds dissolution specifications.

**Select Brand Nite Time Cold/Flu Relief**, (acetaminophen 1000mg, dextromethorphan HBr 30mg, doxylamine succinate 12.5mg and pseudoephedrine HCl 60mg), Cherry Flavor, OTC, Class III, Label fails to declare correct dye colors as FD&C blue #1 and FD&C red #40.

a) **Thyro-Tab**, .050 mg, Rx only, b) Levothroid (levothyroxine sodium tablets, USP), 50 mcg, Rx only, Class II, Subpotent (9-month stability).

**Urocit-K Potassium Citrate 10, 1080 mg. Tablets**, Rx only, Class II, Presence of particulate matter: Product may contain metal particles.

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

distributed nationwide; Pliva, Inc., East Hanover, NJ.

Lot number C0821203A; 2,768 bottles distributed nationwide; Vintage Pharmaceuticals, Inc., Charlotte, NC.

Lot A45568, exp. date 12/2005; 99,793 bottles distributed nationwide; Wyeth Pharmaceuticals, Richmond, VA.

Lot #L034A05A, exp. date 03/2007; Lot #L034A05L, exp. date 03/2007; Lot #L022E05K, exp. date 06/2007; 15,896 bottles distributed in Arkansas; Vintage Pharmaceuticals LLC, Huntsville, AL.

a) Bulk: HA27104, HB27104, HC27104, HD27104, and HE27104, exp. date 10/2005; b) 100 count bottle: 110409, 110410; 1000 count bottle: 110433, 110434, and 110435, exp. date 10/2006; a) 9,537,370 tablets, b) 37,610/100-tab. bottles, and 3,792/1,000-tab bottles distributed nationwide; Lloyd Pharmaceutical, Shenandoah, IA.

Lot Number: 4M113; 14,417 bottles distributed nationwide; Mission Pharmacal Co., San Antonio, TX.

## 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 purifiers.** An overheating capacitor in these air purifiers can cause arcing in a connecting wire which poses the risk of fire. Perfect Air Ultra™ Air Purifiers; about 15,000 sold on television infomercials and via direct sales on Thane's Web site, Feb-Dec 2004; Thane International Inc., of La Quinta, Calif.; (800) 895-0986, [www.thane.com](http://www.thane.com), or [thane@ecustomerresponse.com](mailto:thane@ecustomerresponse.com).

**Amplified volume controls.** The amplifier in the keypad can overheat, posing a burn or fire hazard.

**ATVs.** The protective boots covering the steering system's tie-rod ends (universal joints) on the recalled ATVs could be pinched during installation or adjustment, cutting a hole in the rubber. If this occurs,

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

Perfect Air Ultra™ Air Purifiers; about 15,000 sold on television infomercials and via direct sales on Thane's Web site, Feb-Dec 2004; Thane International Inc., of La Quinta, Calif.; (800) 895-0986, [www.thane.com](http://www.thane.com), or [thane@ecustomerresponse.com](mailto:thane@ecustomerresponse.com).

Architectural Audio and HomeTech In-wall Volume Controls; about 650 sold at custom installation dealers and through homebuilders nationwide, May 2003-Jun 2005; Dana Innovations, of San Clemente, Calif.; (888) 484-6782.

Yamaha Bruin 250, Bruin 350 4WD and 2WD, Big Bear 400, Kodiak 400, Kodiak 450, and Wolverine 450 ATVs; about 70,000 sold by Yamaha dealers nationwide, 2004-Oct 2005; Yamaha Motor

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<i>Type of Product; Problem</i>	<i>Lot #: Quantity and Distribution; Manufacturer</i>
grease could escape, and contaminants such as sand or mud could get into the assembly through the hole, causing accelerated wear. This could result in abnormal steering free play. If the ATV continues to be operated without repair, the ball and socket portion of the tie-rod end could wear to the point that they separate, resulting in loss of steering control, which could cause a vehicle crash with injury or death.	Corporation U.S.A., of Cypress, Calif.; (800) 227-5963 or <a href="http://www.yamaha-motor.com">www.yamaha-motor.com</a> .
<b>ATVs.</b> Use of an improper tie rod adjustment procedure during assembly could lead to separation of the tie rod end housing from the attachment shaft. This could cause the rider to lose control of the ATV and result in injury or death.	Suzuki 2005 model year LT-A700XK5 King Quad ATVs; about 19,600 sold by Suzuki dealers nationwide, Sept 2004-Oct 2005; American Suzuki Motor Corp., of Brea, Calif; (800) 444-5077 or <a href="http://www.suzukicycles.com">www.suzukicycles.com</a> .
<b>Battery packs.</b> These battery packs can short circuit, causing them to overheat and possibly melt, posing a burn hazard to consumers.	Nikon Rechargeable Battery Packs with Model Number EN-EL3; about 200,000 batteries sold at camera, mass merchandise, catalog, Internet, and office supply stores nationwide, May 2004-Nov 2005; Nikon Inc., of Melville, N.Y.; (800) 645-6678 or <a href="http://www.nikonusa.com">www.nikonusa.com</a> .
<b>Bike rack.</b> The bike racks do not have sufficient hardware to support its weight on the wall. This can cause the bike rack to unexpectedly fall, hitting a nearby consumer.	Picasso Two Bike Folding Rack; about 3,500 sold at LL Bean, Bike Nashbar and independent bike shops nationwide, Jan 2002-Sept 2005; Delta Cycle Corp., of Foxboro, Mass.; (800) 474-6615 or <a href="http://www.deltacycle.com">www.deltacycle.com</a> .
<b>Candle holders.</b> The recalled candleholders could allow tea lights to have a high flame. This poses a fire hazard and risk of burn injuries to consumers. This product was previously recalled by Pottery Barn on October 16, 2002.	Spooky Tree Tea-Light Holder; about 900 sold at 13 Pottery Barn Outlet and Williams-Sonoma Marketplace Outlet stores nationwide, Sept-Oct 2005; (800) 586-5615.
<b>Candle holders.</b> These votive glass candle holders can break unexpectedly during use.	Glass votive candle holders included with Old Taylor Estate Candelier; about 288,800 units sold by Southern Living At Home consultants at home parties nationwide, Jun-Sept 2005; Southern Living At HOME, of Birmingham, Ala.; (800) 898-0128 or <a href="mailto:slathomerecalls@timeinc.com">slathomerecalls@timeinc.com</a> .
<b>Candles.</b> The paint coating on the outside of the candle can ignite, posing a fire hazard.	Pillar Candles With Jewels; about 17,000 sold at Target stores nationwide, Aug 2005; Target, of Minneapolis, Minn.; (800) 440-0680 or <a href="http://www.target.com">www.target.com</a> .
<b>Candles.</b> The recalled candles can burn with a high flame and melt the plastic holders. This poses a fire hazard and a burn hazard to consumers.	Home® Brand Tea Light Candles; about 290,000 sold at Target stores nationwide, Mar-Sept 2005; Target, of Minneapolis, Minn.; (800) 440-0680 or <a href="http://www.target.com">www.target.com</a> .
<b>Christmas tree miniatures.</b> The tree could overheat and melt, posing a fire hazard.	Miniature Musical Bells Christmas Trees; about 3,700 sold at Cracker Barrel Old Country Store(r) locations nationwide, Aug-Sept 2005; Cracker Barrel Old Country Store® of Lebanon, Tenn.; (888) 296-2721 or <a href="http://www.crackerbarrel.com">www.crackerbarrel.com</a> .
<b>Cribs.</b> The crib's paint contains high levels of lead. Lead poisoning in children is associated with behavioral problems, learning disabilities, hearing problems and growth retardation.	Lov's "Europa" Natural Color Cribs; about 335 sold at at Toys R Us nationwide, Jul 2004-Aug 2005; Delta Enterprise Corp., of New York, N.Y.; (877) 660-3777 or <a href="http://www.deltaenterprise.com">www.deltaenterprise.com</a> .
<b>Fans.</b> Internal electrical arcing in the fan can cause a fire hazard.	Oscillating Electric Tower Fan; about 150,000 sold at discount department stores nationwide, Feb 2004-Nov 2005; Haier America Trading LLC, of New York, N.Y.; (866) 601-8073 or <a href="mailto:productinfo@haieramerica.com">productinfo@haieramerica.com</a> .

***Type of Product; Problem***

**Heating and cooling units.** The unit's control board can ignite and, in certain units, can result in the ignition of flammable material adjacent to the unit.

**Hedge trimmers.** On some units, the engine mount springs between the gear case and handle/frame could separate from their receptacle in the frame during heavy operation. Continued use could cause the engine and blades to swing free of the frame and hit the user, possibly causing lacerations.

**Hooded sweatshirts.** The hooded sweatshirts have drawstrings, posing a strangulation hazard to children.

**Immersion heaters.** Moisture in the heating element could cause corrosion over time, presenting a shock hazard.

**Ladders.** The rung on the ladders could break near the side rail causing the user to fall.

**Metal necklaces and zipper pulls.** The recalled metal jewelry contains high levels of accessible lead in the metal and/or the paint, posing a serious risk of lead poisoning to young children.

**Party favors.** The fairy wand party favors can break apart, exposing sharp wires that pose a laceration hazard to children.

**Ride-on cars.** An electronic malfunction can occur in the ride-on vehicle's circuit board and/or battery connector, resulting in smoking and melting of components. This poses a vehicle fire hazard and a burn hazard to consumers if components are touched while malfunctioning.

**Rugs.** The large rugs fail to meet the federal mandatory standard for flammability under the Flammable Fabrics Act and could ignite, presenting a risk of burn injuries. The smaller size rugs are missing labels identifying them as flammable.

**Synthesizers.** Unit could emit loud "white noise" when turned off and turned on again under high temperature conditions, which could possibly damage a consumer's hearing.

**Teapots.** The teapots are labeled safe for microwave use, but the handles can become hot in the microwave oven. This poses a possible burn hazard to consumers.

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

Certain "Packaged Gas Electric" heating and cooling units, or "Gas-Packs"; about 27,800 units sold by heating, ventilation, and air conditioning dealers and contractors nationwide, Oct 2000-Sept 2005; International Comfort Products LLC, of Lewisburg, Tenn; (800) 649-4706 or [www.icpusa.com](http://www.icpusa.com).

Kawasaki Hedge Trimmer; about 1,500 sold by a nationwide network of independent Kawasaki Power Product dealers, Apr- Jul 2005; Kawasaki Motors Corp., U.S.A., of Grand Rapids, Mich.; (866) 836-4463 or [www.kawpowr.com](http://www.kawpowr.com).

Hooded Sweatshirt with Drawstring; about 3,400 sold through J.C. Penney's Catalog and Web site, Jun-Aug 2005; American Public Co., of New York, N.Y.; (800) 222-6161 or [www.jcpenney.com](http://www.jcpenney.com).

Immersion Heaters, about 472,000 sold at mass retailers, hardware and grocery stores nationwide, Jan 1999-Aug 2005; World Kitchen Inc., of Reston, Va.; (800) 853-6567 or [www.worldkitchen.com](http://www.worldkitchen.com).

Multi-Purpose, Step-to-Straight, Combination, Manhole and Extension Trestle Ladders; about 3,000 sold at industrial supply stores and home centers nationwide, Nov 2004-Jun 2005; Louisville Ladder Inc., of Louisville, Ky; (800) 660-4356 or [www.louisvilleadder.com](http://www.louisvilleadder.com).

Stravinia Personalized Metal Necklaces and Stravinia Personalized Zipper pulls; about 6 million sold at discount, toy, party, grocery and drug stores nationwide, Mar 2002-Sept 2005; Stravinia Operating Co., LLC, of Chatsworth, Calif.; (800) 964-0029 or [www.stravinia.com](http://www.stravinia.com).

DesignWare® 4 Fairy Wands; about 14,200 packages of 4 wands sold at discount, toy, drug, grocery, party and specialty gift stores nationwide, Mar 2003-Sept 2005; American Greetings Corporation, of Cleveland, Ohio; (800) 777-4891 or <http://americangreetings.com>.

Battery-Powered Ride-On Vehicles; about 141,000 sold at major toy stores and mass merchandise outlets nationwide under the brands Safety 1st and Kid Trax by Safety 1st, Jan 2004-Aug 2005; Dorel Juvenile Group USA, of Columbus, Ind.; (866) 611-3022 or [www.djgusa.com](http://www.djgusa.com).

Shag Leather Rugs; about 1,800 sold by Internet and catalog retailers nationwide, Sept 2002-Oct 2005; Hellenic Rug Imports Inc., of Brooklyn, N.Y.; (888)356-5284 or [www.flokati.com](http://www.flokati.com).

S90 ES Synthesizer; about 1,100 sold at musical instrument retailers and dealers, Aug-Oct 2005; Yamaha Corporation of America, of Buena Park, Calif.; (800) 975-4029.

Ceramic Teapots; about 257 sold at certain large Starbucks stores nationwide, Aug-Sept 2005; Starbucks Coffee Company, of Seattle, Wash.; (800) 235-2883.

*continued on page 10*



## OUTRAGE, from page 12

School of Medicine notes, "People are going to ask whether this device is an attempt by Phillip Morris to undo all the damage the company did to the public health." Others will note that the company's prospects dim as Americans stop lighting up: The smoking rate for U.S. adults was 22%

in 2003, down from 26% in 1994. Hence the need for the company to diversify.

Thus, it seems, we need not mourn the downfall of Enron or Tyco. Perhaps Enron still has a rosy future turning its tax- and regulation-evading offshore shell corporations into group purchasers of AIDS drugs for the

Caribbean. Or maybe Dennis Kozlowski will donate the waiters' togas from his wife's \$2 million birthday bash in Sardinia to clothe the poor in Africa. For Fitzgerald was sometimes on the mark: "A big man," he once said, "has no time really to do anything but just sit and be big." ■

## CONSUMER PRODUCTS cont.

### Type of Product; Problem

**Television wall-mounting unit.** An undersized shaft within the wall mounting unit can cause the product's main support component to loosen. As a result, the unit and the television it is supporting can fall from the wall, posing a risk of injury to consumers.

**Toy cars.** The heads of figures and other small parts cars can detach, posing a choking hazard to young children.

**Toy sets.** Some of the toys in these trunks contain small parts, posing a choking hazard to young children.

**Vaporizers and diffusers.** A defective internal heater in the recalled vaporizers and diffusers can cause sparking and emit flames while in use. This poses a fire, burn and shock hazard to consumers.

### Lot #: Quantity and Distribution; Manufacturer

VisionMount model VMSA swing-arm television wall-mounting unit; 14,000 sold by Audio/Video stores, Dec 2004-May 4, 2005; Sanus Systems, of St. Paul, Minn.; (800) 359-5520 or [www.sanus.com](http://www.sanus.com).

Viking Chubbies Toy Cars and Flexitoys Monster-Size Vehicles; about 1,900 Viking Chubbies and about 6,000 Monster-Size Vehicles sold at specialty toy stores nationwide, Jun-Aug 2005 and May-Sept 2005; International Playthings Inc., of Parsippany, N.J.; (800) 445-8347 or [www.intplay.com](http://www.intplay.com).

10-in-1 Activity Trunks by Kid Connection; about 7,200 units sold at Wal-Mart stores nationwide, Jul-Sept 2005; Wal-Mart Stores Inc., of Bentonville, Ark.; (800) 925-6278 or [www.walmart.com](http://www.walmart.com).

Vapor-Eze Waterless Vaporizer and Vapor-Eze Aromatherapy Diffuser; About 10,000 Vaporizers and 5,000 Aromatherapy Diffusers sold at discount department and drug stores, including Wal-Mart, Jun-Sept 2005; Juvenile Products Corp., of Miami, Fla (OUT OF BUSINESS); contact Wal-Mart at (800) 925-6278 or [www.walmart.com](http://www.walmart.com), CPSC at (800) 638-2772, or the retailer where the item was purchased.

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## Health Letter

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## Second Chances: Big Tobacco Enters the Health Care Industry

**I**t was F. Scott Fitzgerald who famously declared that "there are no second acts in American lives." Was he ever wrong! In this age of reality TV actress Martha Stewart, Viagra huckster Bob Dole and Newt Gingrich (rehabilitated as a health-care lobbyist, no less), it seems even the most down-on-their-luck public figure can mount a lucrative second career.

Which raises an all-important question: is Fitzgerald's aphorism any more accurate when applied to the American corporation? And what better test case than the widely vilified tobacco industry, the source of some 400,000 deaths annually in the U.S. alone and now facing tens of billions of dollars in possible penal-

ties for fraud and deception for its decades-long denial of the hazards of tobacco?

Seems that years ago Philip Morris, in its search for a "safer" cigarette that could deliver the market-retaining (i.e., addictive) nicotine without the pesky carcinogens in smoke, developed an innovative drug delivery device named Aria. By sucking on the device (coincidentally, the way one would on a cigarette), the user could draw liquid nicotine through a thin tube over a heating element that turned the nicotine into a fine mist, suitable for inhaling (and getting hooked). Evidently, smoker disinterest in the product has convinced the company not to bring the product to market as a nicotine-delivery device.

But what if you could sell the device and a new image for the beleaguered industry in one fell swoop? According to the Wall Street Journal (October 27, 2005), Phillip Morris is now trying to adapt the device for the delivery of pharmaceuticals to treat multiple sclerosis, migraines and pain. The company claims that Aria will do a better job than conventional aerosols in delivering drugs to the lungs for absorption into the bloodstream. The ultimate irony: the device might have particular usefulness for treating smoking-induced lung diseases.

The company will have to face a skeptical public. James Donohue of the University of North Carolina

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