

Health Letter

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Worst Pills, Best Pills News Now Available Online!

In January 2003, Public Citizen launched an online version of its long-running monthly newsletter *Worst Pills, Best Pills News*, which contains vital information on drug safety and effectiveness, dangerous dietary supplements, drug-induced symptoms and drug interactions.

Subscribers to the online version of *Worst Pills, Best Pills News* can get access to archived newsletter articles from the past two years, which mention more than 400 prescription and over-the-counter medications and dietary supplements that could have dangerous adverse effects. Users can search the data by drug name, disease or condition, or drug-induced adverse effect.

Public Citizen's Health Research Group began publishing *Worst Pills, Best Pills News* in 1995, seven years after it first published the book *Worst Pills, Best Pills*, which has sold more than 2 million copies in multiple editions. Subscribers to the newsletter learned about potential dangers of medications months or even years before they were withdrawn from the market. These drugs include:

- Baycol (cerivastatin) — readers warned in March 1998, withdrawn three years later;
- Rezulin (troglitazone) — readers warned in January 1998, withdrawn two years later;
- Propulsid (cisapride) — readers warned in August 1998, withdrawn a

"There are hundreds of medications on the market that are extremely dangerous, either by themselves or when taken in combination with other drugs."

year and a half later; and,

- Lotronex (alosetron) — readers warned in August 2000, withdrawn from the market three months later (it has recently been put back on the market but we continue to strongly advise against its use).

Users of www.worstpills.org will find out why they should not use best-selling arthritis drugs such as Vioxx, Celebrex and Arava, the oral contraceptive Yasmin, the diabetes drug Starlix, the antidepressant Serzone, the weight reduction drug

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Selling “New” Drugs Using Smoke and Mirror (Images)

A former drug company executive, who also was a physician, noted while testifying before the U.S. Senate that the pharmaceutical industry is “. . . unique in that it can make exploitation appear a noble purpose.” The testimony was given over 40 years ago and is as true today as it was then. Capitalizing on their decades-old charade of nobility, the pharmaceutical industry is increasingly selling expensive “new” patented drugs that are chemically identical to the old drugs they replace. Remarkably, physicians prescribe them and patients pay exorbitant prices, both groups somehow believing, while being exploited, that an old drug with a new name is a therapeutic breakthrough.

How is such a sleight of hand possible? “Smoke and mirrors” aptly describes the technique. The smoke consists of phony “breakthrough”

Capitalizing on their decades-old charade of nobility, the pharmaceutical industry is increasingly selling expensive “new” patented drugs that are chemically identical to the old drugs they replace.

advertising, and the mirrors are represented by a chemical gimmick involving isomers.

We all know what advertising is, but what is an isomer? It is, chemically speaking, a molecule containing identical atoms to another molecule, but differently arranged: a mirror image, to be precise. Consider

two isomers of a certain molecule to be like a pair of gloves — same number of fingers, just arranged differently.

So it is with many pharmaceuticals. Many exist as equal parts of a chemically identical compound that are mirror images of each other. All of the atoms in the drug molecule are the same, only their spatial orientation is different. Separating these mirror images and selling only a single mirror image as a “new” drug is a successful business scheme, *not* a strategy to improve public health. This may be likened to selling one glove and claiming that it is as good as or better than two.

In this article, we will look at seven pairs of drugs, one of each pair having been approved in the U.S. since the mid-1990s. The older drug of the pair is the original mix of mirror images, while the new drug is only one of the mirror images. In all seven cases, the single mirror image has never been shown to be therapeutically superior to the original mixture of mirror images. Indeed, in one case, the single mirror image was found more toxic than the mixture, and the mirror image was never marketed as a new drug.

ONLINE, from page 1

Meridia, the dietary supplements ephedra and Kava Kava and dozens of other drugs with better alternatives. More than 1 million Americans die or suffer from dangerous drug-induced illness every year.

“There are hundreds of medications on the market that are extremely dangerous, either by themselves or when taken in combination with other drugs. Others haven’t been tested long or thoroughly enough, and others are ineffective,” said Sidney Wolfe, director of Public Citizen’s Health Research Group. “Patients will be able to use this site to educate and protect themselves, often long before the government issues any kind of warning or drug companies issue a recall.”

The free information at www.worstpills.org includes: how patients can protect themselves from adverse drug effects; advice on reporting adverse drug effects;

myths about generic drugs; Public Citizen’s petitions to the FDA to ban or relabel drugs; information on clinical trials of drugs; and the political activities and influence of the drug industry.

As a *Health Letter* reader, you can try *Worst Pills, Best Pills News Online* at a special introductory offer of \$15 for 12 issues. Subscribers receive access to the searchable database of back issues of *Worst Pills, Best Pills News*, 12 new monthly issues, and e-mail alerts about new drug warnings from the FDA and other sources. Each month the Table of Contents is delivered directly to the subscriber by e-mail.

How to Sign Up

Go to www.worstpills.org, click on Learn More, enter Promotion Code HLMar3 and start enjoying the benefits of *Worst Pills, Best Pills News Online* now!

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SMOKE AND MIRRORS, from page 2

Esomeprazole (NEXIUM) and Omeprazole (PRIOSEC)

The "new purple pill" esomeprazole is really only one of the two mirror images that make up the "old purple pill" omeprazole. Despite the fact that esomeprazole was only approved by the Food and Drug Administration (FDA) in February 2001, due to clever marketing and uncritical physicians, this drug was dispensed almost 4 million times in U.S. pharmacies by the end of 2001.

Esomeprazole and omeprazole are both produced by the same company, AstraZeneca Pharmaceuticals based in Wilmington, Del.

We reviewed esomeprazole in the November 2001 *Worst Pills, Best Pills News* and recommended that if you are currently taking omeprazole and your symptoms are being adequately controlled, there is no medical reason for you to switch to esomeprazole.

The FDA Medical Officer who evaluated the new drug application for esomeprazole wrote in no uncertain terms:

The sponsor's [AstraZeneca] comparisons of H 40 [esomeprazole 40 milligrams] vs O 20 [omeprazole 20 milligrams] do not yield valid conclusions about the superiority of H [esomeprazole] over O [omeprazole], although these comparisons are adequate to demonstrate that H is active in the

assessed indications. Therefore, the sponsor's conclusion that H 199/18 [esomeprazole] has been shown to provide a significant clinical advance over omeprazole in the first-line treatment of patients with acid-related disorders is **not supported by data** (emphasis supplied by the Medical Officer in the original).

What was AstraZeneca's motive in developing esomeprazole, a drug that has not been shown to be any better than omeprazole? Omeprazole was the largest selling prescription drug in the U.S. in 2000 with over \$4 billion in retail sales that year, but was due to lose patent protection in the near future. When patent protection is lost, a manufacturer can expect a 40 to 60 percent drop in sales in a very short period of time as other drugmakers pick up production and marketing of the product. This would be a loss in the neighborhood of \$2 billion for AstraZeneca, an amount that would make stockholders and mega-stockholding company executives very unhappy.

Levofloxacin (LEVAQUIN) and Ofloxacin (FLOXIN)

Levofloxacin is a fluoroquinolone antibiotic and was the 40th most frequently dispensed drug in U.S. pharmacies in 2001, accounting for almost 11.5 million prescriptions. It is one of the two mirror images of ofloxacin. Levofloxacin is the active

mirror image in the ofloxacin mixture. The other has no pharmacologic activity.

At this time, there is no price advantage for patients with either drug, even though ofloxacin is no longer patent protected. However, in Canada a generic ofloxacin is sold for about one-half the price of levofloxacin — the same drug at half the price.

Both levofloxacin and ofloxacin are produced by Ortho-McNeil of Raritan, NJ. If a generic company decides to market ofloxacin, Ortho-McNeil can still sell levofloxacin as a patent-protected monopoly drug.

Levalbuterol (XOPENEX) and Albuterol (PROVENTIL, VENTOLIN)

Levalbuterol is approved by the FDA for the prevention and treatment of bronchospasm (reversible airway diseases such as asthma) and is one of the two mirror images that make up the old asthma drug albuterol.

Levalbuterol is produced by Sepracor, Inc. of Marlborough, Mass. This company has several other single mirror images under development as "new" drugs.

The editors of the highly respected *Medical Letter On Drugs and Therapeutics* concluded their evaluation of this drug saying, "Levalbuterol, which is available only for use with a nebulizer, appears to have no clinically significant advantage over racemic
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SMOKE AND MIRRORS, from page 3

[a technical term for the mixture of the two forms of albuterol] albuterol.”

We reviewed levalbuterol in the September 1999 issue of *Worst Pills, Best Pills News* and listed it as a DO NOT USE drug because there is no evidence that it is any safer or more effective than albuterol. We compared the price of levalbuterol to the equivalent dosage of a generic brand of albuterol at a Washington, DC chain pharmacy. A 32-day supply of levalbuterol in a dosage of 1.25 milligrams taken three times a day costs \$237.99. At the same pharmacy a 32-day supply of generic albuterol in a dosage of 2.5 milligrams given three times a day would run \$37.14, one-sixth as expensive or an astonishing difference of \$200.85 for an approximate one-month supply of these two drugs — about \$2,400 a year.

Dexmethylphenidate (FOCALIN) and Methylphenidate (RITALIN)

Dexmethylphenidate (Focalin), approved by the FDA in November 2001 for attention deficit/hyperactivity disorder (ADHD), is simply one-half of the chemically identical mixture of mirror images that makes up the 40-year-old drug methylphenidate (Ritalin).

Both dexmethylphenidate and methylphenidate are produced by Novartis Pharmaceuticals of NJ.

Dexmethylphenidate was reviewed in the August 2002 issue of *Worst Pills, Best Pills News*. Novartis’s “spin” to sell its old product as a new and better drug was to claim that “the duration of activity [of dexmethylphenidate] was statistically significantly longer . . . than methylphenidate.” Unfortunately, this strategy works with many health professionals and patients. But the FDA medical officer who reviewed Novartis’s data wasn’t fooled, saying, “This statement is misleading for several reasons.”

We agreed with the conclusion of the editors of the *Medical Letter on Drugs and Therapeutics* in their May 13, 2002 review of dexmethylphenidate:

There is no evidence that dextmethylphenidate (Focalin) offers an advantage over any other formulation of methylphenidate (Ritalin and others). Older drugs with better established dosages and longer safety records are preferred.

Escitalopram (LEXAPRO) and Citalopram (CELEXA)

WARNING!

ESCITALOPRAM (LEXAPRO) IS A FORM OF CITALOPRAM (CELEXA). THE USE OF THESE TWO DRUGS TOGETHER MAY RESULT IN AN OVERDOSE.

Escitalopram was approved by the FDA in August 2002, bringing to six the number of selective serotonin reuptake inhibitor (SSRI) antidepressants now on the U.S. market. It is the most recent member of the mirror-image marketing rage, being one-half of the mixture that consti-

ed in their September 30, 2002 review of the drug that:

Escitalopram (Lexapro), the active enantiomer [one of the two mirror images] of citalopram (Celexa), is effective for treatment of depression, but it has not been shown to be more effective, more rapid-acting or less likely to cause adverse effects, including sexual dysfunction, than citalopram or any other SSRI.

In our January 2003 assessment of escitalopram, we agreed with *The Medical Letter’s* conclusion and invoked our “Seven-Year Rule.” We listed citalopram as a DO NOT USE FOR SEVEN YEARS drug (until October 2005) in the *Companion* to the 1999 edition of *Worst Pills, Best Pills*. We have also listed escitalopram as DO NOT USE UNTIL OCTOBER 2005 because for practical purposes, it is the same drug as citalopram and it has no therapeutic or safety advantage over citalopram or other SSRI antidepressants.

Many new drugs offer no health advantages to patients and are only marketed so that companies can maintain patent monopolies.

R-Fluoxetine and Fluoxetine (PROZAC)

In 1998, Eli Lilly, manufacturer of the enormously profitable SSRI antidepressant fluoxetine, announced an agreement with Sepracor, Inc., mentioned above, to develop r-fluoxetine, one of fluoxetine’s two mirror images. It was a flop and never made it to market.

R-fluoxetine was being hyped as having a more rapid onset of effect, greater efficacy for the treatment of depression, and fewer side effects than fluoxetine. Clinical trials of r-fluoxetine, however, were discontinued in October 2000 because at the highest dose tested, the compound demonstrated a small but statistically significant increase in prolongation of the QTc interval, a change in the heart’s electrical condition that can result in potentially fatal heart rhythm disturbances.

R-fluoxetine was going to be one part of Eli Lilly’s three-pronged attack *continued on page 5*

tutes citalopram. The other SSRIs currently available are fluoxetine (Prozac, Sarafem), fluvoxamine (Luvox), paroxetine (Paxil) and sertraline (Zoloft).

Both escitalopram and citalopram are produced by Forest Laboratories, Inc. of St. Louis.

The editors of *The Medical Letter on Drugs and Therapeutics* conclud-

Foggy Thinking As Inhaled Flu Vaccine Nears FDA Approval

It seemed like a great idea. Perhaps a vaccine that could be administered with a simple sniff in each nostril, rather than a painful jab, could revive languishing flu vaccination rates in people at risk for the complications of influenza (mostly those over 65 and those with underlying heart disease, lung disease or diabetes). (See January 2003 *Health Letter* article on adult vaccination.) But then public health and science came into conflict with profit — and we all know how that

all too often turns out.

Back in 2001, Flumist, an influenza vaccine made from live rather than killed virus, came before a Food and Drug Administration (FDA) Advisory Committee, seeking approval for use in healthy people aged 1-64 years. But the Committee soon detected hints that the vaccine was causing asthma in young people and requested more information. The vaccine's sponsor reached deep into its bag of corporate tricks and came up with the notion not of

redesigning the vaccine to minimize its asthmatic propensity but rather of seeking approval only for people five years old and above. Sure, Flumist's market would be reduced, but MedImmune's stockholders would be happy that the vaccine was approved. Besides, everyone knows that doctors often prescribe "off label" (outside of FDA guidelines) and drug companies' "detail men" are famous for encouraging such off-label prescribing.

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SMOKE AND MIRRORS, from page 4 to protect fluoxetine from generic competition. The company was successful in partially keeping a monopoly position for the drug by marketing Prozac Weekly and Sarafem, which is fluoxetine approved for the treatment of premenstrual dysphoric disorder (PMDD).

Many new drugs offer no health advantages to patients and are only marketed so that companies can maintain patent monopolies. These newly marketed single mirror images of old mixtures are prime examples.

Dexfenfluramine (REDUX) and Fenfluramine (PONDIMIN)

The diet drug dexfenfluramine (Redux) was approved by the FDA in June 1996 and shortly thereafter began to register blockbuster sales as a "breakthrough" and a "cure" for obesity. This miracle of modern pharmaceutical industry hype (masquerading as innovation) was nothing more than one of the mirror images of fenfluramine (Pondimin), a diet drug approved in the U.S. in 1972 over the objections of the FDA Medical Officer.

Dexfenfluramine had been available in some European countries since the 1980s and was sold by Wyeth-Ayerst of Philadelphia in the

U.S. It was simply an old European drug recycled in this country because the company knew it could sell a diet drug that patients and physicians thought was new.

We listed dexfenfluramine as a DO NOT USE drug in 1996 when it first came on the market because no diet pill had ever been shown to confer a health benefit for those using it (see *Worst Pills, Best Pills News*, July 1996).

Fenfluramine was the "fen" portion of the notorious "fen-phen" diet drug combination that severely injured so many unsuspecting patients. Dexfenfluramine and fenfluramine were removed from the market in September 1997 for causing heart valve damage and a condition of the lungs known as primary pulmonary hypertension. Clearly, dexfenfluramine was neither more nor less dangerous than fenfluramine.

The original intent of patent protection was to reward genuine intellectual creativity and true innovation. The patenting and promotion of single mirror images of old drugs fulfills neither of these criteria; indeed, it perverts the patent's original purpose. It is nothing more than an abuse of the system for purely corporate economic goals that calls for congressional correction of the

law. (Lotsa luck, the power of the pharmaceutical lobby on Capitol Hill being what it is.)

Readers please note: an excellent overview of the egregious behavior of the pharmaceutical industry was published in the December 16, 2002 issue of *The New Republic*. The authors, Drs. Marcia Angell and Arnold S. Relman, are both former editors of *The New England Journal of Medicine*, one of the most highly regarded medical journals now in publication. Angell and Relman have long been critical observers of the drug industry and this article is well worth the read.

What You Can Do

You should avoid these single mirror images of old drugs, not out of concern about their safety or effectiveness, but because they are the same as the old drugs. In the long run, they cause economic harm both to individuals and to the health care system because they have come on the market with extended monopoly protection.

In the short run, the single mirror image drugs may be sold at a discount compared to the older mixtures as an inducement to get patients and physicians to switch. Purchase wisely.

Product Recalls

January 15, 2003 — February 5, 2003

This chart includes recalls from the Food and Drug Administration (FDA) Enforcement Report for drugs, dietary supplements and medical devices, 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.

Name of Drug or Supplement; Class of Recall; Problem

Clemastine Fumarate Syrup, 0.5mg/5mL, 4 fluid ounces (118 mL) bottles, Rx only; Class III; Degradation, product exceeds specification at 18 month timepoint

Lot #: Quantity and Distribution; Manufacturer

Lot number 1A950, exp. 02/2003; 2,083 bottles distributed nationwide; Novex Pharma, Richmond Hill, California

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VACCINE, from page 5

But this created a small scientific problem. The best designed study demonstrating Flumist's effectiveness (because it measured actual decreases in laboratory-proven influenza infection) included 1- to 7-year-olds, but now most of that age group was excluded from the new target population. And the study in adults 18-64 only measured clinical disease, rather than the more accepted standard, in which laboratory proof of the presence of influenza virus is required. Moreover, the adult study failed to demonstrate statistical improvement in the main clinical outcome ("any febrile illness"), although it did for many of the secondary outcomes (e.g., "febrile upper respiratory infection"), and included relatively few people over the age of 50. In fact, in an analysis of the 50- to 64-year-olds planned after the study was complete, there was little evidence of vaccine efficacy, even for the secondary outcomes. The studies also showed that, despite investigators' efforts,

many patients with asthma, who were supposed to have been excluded from the trial, slipped through and were vaccinated. This is likely to be even more common in actual clinical practice.

In a complicated vote, the Advisory Committee decided that there was insufficient evidence of vaccine efficacy in 50- to 64-year-olds. The Committee thus in effect recommended approval exclusively for those for whom the Centers for Disease Control and Prevention (CDC, like FDA, a part of the Department of Health and Human Services) does not recommend flu vaccination: healthy people aged 5-50. The vote was also a landmark in that, with the support of the FDA, it permitted approval for a vaccine based on clinical rather than laboratory outcomes (recall that laboratory-confirmed outcomes were available only for the five-, six- and seven-year-olds). And a live virus vaccine at that, with concomitant risks of transmission to unvaccinated persons.

Compounding these problems was the FDA's failure to insist on any

studies comparing Flumist to the existing killed virus vaccine. So consumers and physicians are left in the lurch, devoid of the data that should have been produced prior to approval and now probably never will be generated.

What You Can Do

If the FDA follows its Advisory Committee's recommendations, as it usually does, what are consumers to do? We recommend that you stick with the CDC, which is more immune to industry influence than the FDA. (At least the CDC is not dependent upon the industry it regulates for a large portion of its funding.) If you're over 65, get vaccinated. If you're between 50 and 64, get vaccinated if you are in a high-risk group. In any event, get vaccinated with the old, proven inactivated flu vaccine, rather than one with so much murky science behind it as Flumist. We also do not recommend the use of Relenza (zanamivir) and Tamiflu (oseltamivir) in the treatment of influenza.

DRUGS AND DIETARY SUPPLEMENTS *cont.*

Name of Drug or Supplement; Class of Recall; Problem

Estrace Tablets (estradiol tablets), 2 mg, 100 and 500 count bottles, Rx Only; Class II; Dissolution failure

Fluoxetine Capsules, 20 mg, 500 and 1000 count bottles, Rx only; Class III; Product exceeded specification for impurity level (1 month stability)

Garamycin Ophthalmic Ointment (Gentamicin Sulfate), 0.3%, 3.5g tube, Rx only; Class II; Lack of assurance of sterility

Megace Tablets (megestrol acetate), 20 mg, 100 count bottles, Rx Only; Megace tablets (megestrol acetate), 40 mg, 100 count bottles, Rx Only; Class III; Dissolution failure, tablets are below specification

Nabumetone Tablets, 500 mg and 750 mg, 100 count bottles, Rx only; Class III; Mislabeling — some bottles labeled to contain 750 mg tablets actually contain 500 mg tablets

Premphase Tablets (conjugated estrogens 0.625mg and medroxyprogesterone 5mg) dial dispenser containing 28 tablets, Rx only, and **Premarin Tablets** (conjugated estrogens) 0.625 mg, Rx only, unit dose packages of 100, bottles of 100 and 5,000; Class III; Failure to meet dissolution specifications at the 24 month/2-hour timepoint

Pulmicort Turbuhaler (budesonide inhalation powder) 200mcg, 200 Metered Doses, Rx only, Professional Sample; Class III; Fine particle size out of specification, patient may not receive full dose to lungs

Lot #: Quantity and Distribution; Manufacturer

Lot no. 0K28404, exp. 10/2003, Lot no. 0J41630, exp. 10/2003; 4,587 bottles distributed nationwide and in Canada; Bristol-Myers Squibb Company, New Brunswick, New Jersey

Lot 105458, exp. 02/2004, Lot 104926, exp. 02/2004; 2,991 bottles distributed nationwide and in Puerto Rico; Ivax Pharmaceuticals, Northvale, New Jersey

Numerous lots; Undetermined quantity distributed nationwide and internationally; Schering Corp., Kenilworth, New Jersey

Numerous lots; 44,779 bottles (20 and 40 mg) distributed nationwide and internationally; Bristol-Myers Squibb Company, New Brunswick, New Jersey

Lot 021159, exp. 10/2004; 1,533 bottles distributed nationwide; Eon Labs Manufacturing Inc., Laurelton, New York

Lot numbers 9001385 and 9001386 exp. 02/2003, 9001216 exp. 05/2003, 9000986 and 9000846 exp. 05/2005; 41,220 units Premphase and 198,676 units Premarin distributed nationwide; A.H. Robins, Richmond, Virginia

Lot number DA1625 exp. 07/2003; 23,232 units (50 each) distributed nationwide; Astra Zeneca Pharmaceuticals LP, Wilmington, Delaware

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 information. You can also call the FDA's Device Recall and Notification Office at (301) 443-4190. To report a problem with a medical device, call (800) FDA-1088. The FDA web site is www.fda.gov.

Name of Device; Class of Recall; Problem

Biogel Skinsense N, Non-Latex, Powder-free Surgical Gloves with Biogel coating, Neoprene, Made from a synthetic Elastomer, Sterile/R, REGENT, One Pair sterile gloves packaged 50 pair per box/4 boxes per case/total 200 pairs per case; Class II; Sulfur particles on the surface of gloves

Blue-Vis, CIBASOFT VISITINT, daily wear contact lens; Class II; Lenses were labeled with the wrong prescription

Lot #: Quantity and Distribution; Manufacturer

Lot numbers 01H0161 through 01H2668; 173,310 pairs distributed nationwide and in Canada, Venezuela and British Columbia; SSL Americas Inc., Norcross, Georgia

Lot number 1170119, exp. 10/2007, Prescription: base curve 8.9, diameter 13.8, power -1.50; 559 vials distributed in California, Georgia, Illinois, Minnesota, New Jersey, Texas, Virginia and internationally; Ciba Vision Corporation, Duluth, Georgia

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M E D I C A L D E V I C E S *cont.*

Name of Device; Class of Recall; Problem

FreshLook, TORIC, for Astigmatism (phemfilcon A) Contact Lenses, BC Median, DIA 14.5, Lot 041599, 2007-01; Class III; Mislabeling

Genuine One Touch Glucose 50 Test Strips; Class II; Products labeled "For Sale Outside The USA and Canada" were being offered for sale in the U.S.

SureStep 50 Test Strips; Class II; Products labeled "For Sale Outside The USA and Canada" were being offered for sale in the U.S.

Lot #: Quantity and Distribution; Manufacturer

Lots 049007 and 041599; Unspecified number distributed nationwide and in Australia and Canada; Ciba Vision Corporation, Duluth, Georgia

Lot 1666680A exp. 11/2003; 2,790 units distributed nationwide; River City Drug, Marietta, Georgia

Packaged as two bottles of 25 Test Strips, LIFESCAN Lot: E-169380A, exp: 01/2003; 576 units distributed nationwide; River City Drug, Marietta, Georgia

C O N S U M E R P R O D U C T S

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

Name of Product; Problem

Back-up Power Supply Devices; Power supply device can fail, causing unit to overheat, posing a fire hazard

Beanbag Chairs; Some have zippers that can be opened, allowing access to the polystyrene beads inside the chairs and posing a suffocation hazard

Dive Computers; Software in computers may inaccurately calculate desaturation times, resulting in possible decompression sickness under aggressive dive conditions

Large-Screen Televisions; A tear in a gasket can cause coolant fluid to leak from picture tube assembly, causing smoking, charring and electrical arcing inside of the television and posing a fire hazard

Portable Wood Cribs; If hardware used to assemble crib is not tight, mattress support platform and mattress can fall to floor, posing a risk of injury

Lot #: Quantity and Distribution; Manufacturer

Back-UPS CS350 and CS500 models; 900,000 sold nationwide between November 2000 and December 2002; American Power Conversion Corporation (APC), West Kingston, Rhode Island (866) APC-RELY (272-7359) www.apc.com/rely

Various designs with 12-inch double zippers including smiley face, football, baseball and basketball in solid green, yellow, pink and blue neon colors and tag that states "Made by Baseline Design"; 30,000 sold at Wal-Mart stores in the Northeast U.S. between September and December 1999; Baseline Design, Linwood, Pennsylvania (800) 497-3626, Ext. 3046 www.foamex.com

Aladin Air X NitroX dive computers manufactured in 1995 (manufacture date is located on back lower right hand corner and reads number of month followed by decimal point and year, e.g., "01.95"); 390 computers sold between July 1995 and March 1996; UWATEC AG, Hallwil, Switzerland (800) 806-0640 www.uwatec.com

46-60 inch screens manufactured between April 1995 and July 1997, and August 1998 through November 1998 (date of manufacture can be found on white label on back of set); 80,000 sold nationwide between April 1995 and April 1999; Zenith Electronics Corp., Lincolnshire, Illinois (800) 777-5195 www.projorecall.com

Gerry and Evenflo models 8212, 8222, 8232, 8242, 8252, 8282, 8301, 8302, 8311, 8312, 8321, 8322, 8331, 8332, 8341, 8342, 8351, 8352, 8381, 8382, 8512, 8522, 8532, 8542, 8552, 8582, 8712, 8752; 364,000 sold nationwide between January 1991 and December 2002; Hufco-Delaware Company, Miamisburg, Ohio and Evenflo Company Inc., Vandalia, Ohio (800) 582-9359 www.evenflo.com

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Name of Product; Problem

Snowshoe Bindings; Screws and other hardware used to keep bindings intact are too short, causing binding to separate from shoe and posing a fall hazard

Stuffed Bears; Nose can be pulled or twisted off, posing a choking hazard

Travel Mugs; Lids on some mugs can detach allowing hot liquid to leak, posing a burn hazard

Ultrex Thermal/Double Wall Frying Pans; Pans can explode or separate when preheated, used on high heat, or used for frying, posing a serious burn hazard

Lot #: Quantity and Distribution; Manufacturer

Bindings sold on "Karhu Meta Sweeper" and "Karhu Morph Sweeper" snowshoes; 420 bindings sold by Skiboards.com web site, LL Bean, Cabela's, Erewhon Mountain Outfitters and Vail Bicycle stores during November 2002; Trak Inc., d/b/a Karhu Inc., Burlington, Vermont (888) 288-2668

Includes 19-inch "Founding Bear," and 18-inch "Founding Bear II"; 80,000 sold at Build-A-Bear Workshop nationwide between March 2000 and December 2002; Build-A-Bear Workshop, St. Louis, Missouri (866) 236-5683 www.buildabear.com

15-ounce stainless steel travel mugs with black handle and black lid, "Always Fresh Tim Hortons Coffee" printed on mug, "Thermo-Serv," stamped on bottom; 6,500 travel mugs sold in Tim Hortons stores in New York, Michigan, Ohio, West Virginia, Kentucky, Maine and Canada between October 2002 and January 2003; Tim Hortons, Oakville, Ontario, Canada (888) 601-1616 www.timhortons.com

Includes 8-inch omelet pan, 8-inch fry pan, 9.5-inch fry pan and 11.5-inch chicken fryer; 8,700 sold on Home Shopping Network between October 2001 and September 2002; Innova Inc., Davenport, Iowa (800) 845-7447 www.hsn.com

OUTRAGE, from page 12

effects of sleeping pills such as Seconal, even though, unlike the amphetamines, they are not to be used in flight. For as long as 10 to 18 hours following a single dose of a sleeping pill, there can be decreased motor performance such that a National Academy of Sciences Institute of Medicine report on sleeping pills concluded that people who used sleeping pills the night before "may be unaware of their decreased performance following hypnotic [sleeping pill] use. This would seem to put them at potentially greater risk of harm when engaging in tasks requiring alertness and coordination such as operating an automobile, airplane or industrial machinery."

The Public Citizen Health Research Group is going to find out

*If we have to depend, for our national security,
on a military whose pilots are
periodically drugged — in accordance with
accepted policies — by uppers and downers,
we cannot really be very secure.*

if there is any evidence implicating such drug use in military crashes or near-misses and, even if luckily there is none yet, try to ban the use of these drugs by pilots.

If we have to depend, for our

national security, on a military whose pilots are periodically drugged — in accordance with accepted policies — by uppers and downers, we cannot really be very secure.

How To Report Adverse Reactions To The Food And Drug Administration

Consumers can play an important public health role by reporting any adverse experience with drugs, devices or dietary and herbal supplements to the Food and Drug Administration (FDA). This can be done through the MedWatch program, the FDA's medical products reporting system. The FDA emphasizes that it is not necessary to prove that a medical product caused an adverse reaction — a suspected association is sufficient reason to make a report to the agency.

The FDA is particularly interested in suspected adverse events that led to the following outcomes:

- *Death* — If an adverse reaction to a medical product is a suspected cause of a patient's death.
- *Life-threatening hazard* — If the patient was at risk of dying at the time of the adverse reaction or if it is suspected that continued use of a product would cause death. A pacemaker breakdown or the failure of an intravenous (IV) pump that could cause excessive drug dosing are examples.
- *Hospitalization* — If a patient is admitted or has a prolonged hospital stay because of a serious adverse reaction. For example, a serious allergic reaction to a product such as latex.
- *Disability* — If the adverse reaction caused a significant or permanent change in a patient's body function, physical activities, or quality of life. Examples of this type of outcome would be strokes or nervous system disorders brought on by drug treatment.
- *Birth defects, miscarriage, stillbirth or birth with disease* — If exposure to a medical product before conception or during pregnancy is suspected of causing an adverse outcome in the child.
- *Needs intervention to avoid permanent damage* — If use of a medical product required medical or surgical treatment to prevent impairment (e.g., burns from radiation equipment or breakage of a screw supporting a bone fracture).

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

- *Online* — Go to the MedWatch Web site at www.fda.gov/medwatch/ and follow the instructions for submitting a report electronically.
- *By mail* — Use the MedWatch form that accompanies this article and includes the address.
- *By phone* — The toll free number for reporting to the FDA is 1-800-FDA-1088.
- *By fax* — You can submit a completed form to MedWatch's fax number at 1-800-332-0178.

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting
by health professionals of adverse
events and product problems

Form Approved: OMB No. 0910-0291 Expires: 12/31/94
See OMB statement on reverse

FDA Use Only

Triage unit
sequence #

Page ____ of ____

A. Patient information

Patient Identifier In confidence	2. Age at time of event: or Date of birth:	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
---	--	--	---

B. Adverse event or product problem

1. ☐ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- | | |
|---|---|
| <input type="checkbox"/> death (mo/day/yr) | <input type="checkbox"/> disability |
| <input type="checkbox"/> life-threatening | <input type="checkbox"/> congenital anomaly |
| <input type="checkbox"/> hospitalization - initial or prolonged | <input type="checkbox"/> required intervention to prevent permanent impairment/damage |
| | <input type="checkbox"/> other: _____ |

3. Date of event
(mo/day/yr)

4. Date of this report
(mo/day/yr)

5. Describe event or problem

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1

#2

2. Dose, frequency & route used

#1

#2

3. Therapy dates (if unknown, give duration)
from/to (or best estimate)

#1

#2

4. Diagnosis for use (indication)

#1

#2

5. Event abated after use stopped or dose reduced

#1 ☐ yes ☐ no ☐ doesn't apply

#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)

#1

#2

7. Exp. date (if known)

#1

#2

8. Event reappeared after reintroduction

#1 ☐ yes ☐ no ☐ doesn't apply

#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only)

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device

- ☐ health professional
☐ lay user/patient
☐ other: _____

6. model #

catalog #

serial #

lot #

other #

5. Expiration date
(mo/day/yr)

7. If implanted, give date
(mo/day/yr)

8. If explanted, give date
(mo/day/yr)

9. Device available for evaluation?

(Do not send to FDA)

☐ yes ☐ no ☐ returned to manufacturer on (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #

2. Health professional?

☐ yes ☐ no

3. Occupation

4. Also reported to

- ☐ manufacturer
☐ user facility
☐ distributor

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



Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

U.S. Air Force Flies High On Dexedrine

Nearly fifteen years ago (Health Letter, September 1988), we printed the following Outrage of the Month regarding the use of amphetamines by military pilots. Recent events in the news also involving the use of amphetamines by Air Force pilots underscore the continuing dangers presented by this practice. Accordingly, a reprinting of our original Outrage is particularly timely.

Amidst all the understandable furor over the problem of drug abuse, the massively funded Federal effort to "just say no" and drug testing in the workplace, comes the United States military with a new approach: Don't fight 'em, join 'em!!

Instead of setting an example for youths and others in our society and solving such problems in a reason-

able way, it has recently been made public that the U.S. Air Force has a policy of writing prescriptions for uppers such as dextroamphetamine (Dexedrine, or "speed") for those pilots who might be too fatigued to safely fly a plane.

A U.S. military officer was recently quoted by the West German television network ARD as saying that "U.S. Air Force pilots use Dexedrine so they can fly when they haven't gotten enough sleep or don't feel fit enough." The ARD report said that pilots then take the sedative Seconal [a barbiturate or "downer"], but Air Force Lt. Colonel Ed Neunherz emphasized that a pilot would only use the sedative "once he's back on the ground."

If a commercial pilot were caught using amphetamines such as Dexedrine while flying, grounding if

not permanent suspension would be the result. In fact, commercial pilots are not allowed to fly unless they have gotten a certain amount of rest between flights.

Among the adverse reactions that someone can experience from taking amphetamines are psychoses or hallucinations (as in "freaking out"), tremor or dizziness, none of which are compatible with safely flying a plane. Since many of those using "speed" are fighter pilots, it is likely that not infrequently they are carrying a load of bombs which, if the wrong button were pushed, could do enormous damage in the United States, Europe or anywhere else the plane and its pilot are flying.

No less troublesome in terms of air safety are the frequent adverse

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