

# Health Letter

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May 2003 ♦ VOL. 19, NO.5

## Ephedra: Scientific Evidence Versus Money/Politics

*The following article by Health Letter editor Dr. Sidney Wolfe appeared in the April 18 issue of Science magazine.*

**D**oes it make a difference, in terms of FDA regulation, that a drug is natural, has been around for thousands of years and is dispensed as “servings” rather than doses, if the drug has been known for decades to cause increased blood pressure, increased pulse rate, and an increased risk of cardiac arrhythmias? For dietary supplements containing ephedra alkaloids, the answer is yes, it has made a difference.

Because of dangers and abuse potential, in 1983 the FDA (Food and Drug Administration) banned all over-the-counter (OTC) drugs that included both synthetic ephedrine and caffeine, the combination used most in dietary supplements containing ephedra alkaloids, and the agency is now finalizing the ban on OTC drugs that contain ephedrine alone. At a recent U.S. Senate Hearing on ephedra alkaloids, acting FDA Commissioner Lester Crawford conceded that if these products were drugs, not dietary supplements, they would be off the market. But he also stated that unreasonable risk of harm at the recommended doses is sufficient for withdrawal under the 1994 Dietary Supplements Health and Education Act (DSHEA), which allows marketing of naturally occurring products without requirements

for safety or efficacy studies and is the legal standard for FDA withdrawal.

In a review of 140 cases of adverse reactions to ephedra reported to the FDA by early 1999, hypertension was the most frequently named, followed by palpitations, tachycardia (rapid heart rate), stroke and seizures. The adverse effects included 10 deaths and 13 instances of permanent disability. Even one standard “serving” of a typical ephedra alkaloid-containing dietary supplement can be dangerous: The average increase in systolic blood pressure was 14 mmHg, 90 minutes after subjects took two capsules with a total of 20 mg of ephedra and 200 mg of caffeine. Three of the eight people studied had evidence of “mild clinical hypertension.”

Despite convincing evidence of heart attacks, arrhythmias, strokes and more than 100 reports to the FDA of

death, these products are still marketed in the United States. Notwithstanding FDA’s reluctance to take action, Army and Air Force commissaries and post exchanges recently voluntarily removed all ephedra-containing dietary supplements from their shelves. The FDA has received documentation of about 30 deaths in active duty personnel who were using these supplements, although no direct cause-and-effect relation has been established. The National Football League and the National Collegiate Athletic Association had previously banned ephedra. In June 2001, the Canadian government warned Canadians not to use these products, and in January 2002, it announced a recall of “ephedra/ephedrine products with labelled or implied claims for

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# Calcium By Any Other Name Is Still Calcium

The jackals selling unregulated dietary and herbal supplements have been hard at it bombarding the public with preposterous, unsubstantiated claims about the superiority of their particular miracle natural calcium products. Some disreputable companies have gone beyond just claiming a better calcium product and are now declaring that "coral calcium," for example if it is from Okinawa, is the secret to good health and a long life.

The Health Research Group has been in existence since 1972, and we view this latest surge in calcium promotion as the "third wave" of natural calcium miracles. At one time, it was calcium from the Dolomite Mountains in the Italian Alps as nature's perfect source of calcium and magnesium. Dolomite is the very common mineral, calcium magnesium carbonate. Some Internet Web sites still advertise it as "perfectly balanced nutritionally."

Oyster shell calcium followed the

dolomite craze as the next wave. Oyster shell calcium supplements contain calcium carbonate, the active ingredient in the antacid TUMS. One Web site maintains that it is used in traditional Chinese medicine to help with high blood pressure, heart palpitations, insomnia, dizziness, blurry vision, cold sweats and swollen lymph glands, among various other conditions.

The better choice for consumers, however, is chemically pure calcium products, rather than these so-called natural supplements.

One of the most important roles of calcium supplementation, and with the science to support it, is in osteoporosis. The rest of this article will focus on sources of calcium as applied to the prevention and treatment of postmenopausal osteoporosis.

The mainstays for decreasing the risk of postmenopausal osteoporosis are weight-bearing exercise, adequate calcium and vitamin D intake, and

when indicated, drug treatment. Postmenopausal women require an average of 1,500 milligrams of elemental calcium per day (see the explanation below of elemental calcium). Therefore, supplementation may be helpful for women who do not receive an adequate dietary intake of calcium. The table at the end of this article lists the elemental calcium content of a number of foods. Vitamin D supplementation of 400-800 International Units (IU) per day may also be required to ensure adequate daily intake in postmenopausal women.

Calcium is an element; it cannot be produced synthetically, and it can combine with a number of other molecules to form what chemists call "salts." Each of these other molecules weighs a different amount, while the weight of calcium stays the same. Thus, equal amounts of these salts, by weight, contain a different amount of calci-

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## EPHEDRA, from page 1

appetite suppression, weight loss promotion, metabolic enhancement, increased exercise tolerance, body-building effects, euphoria, increased energy or wakefulness, or other stimulant effects."

### Political Influence

According to the *Washington Post*, Metabolife, the nation's leading seller of ephedra products, spent more than \$4 million between 1998 and 2000 in Texas to lobby against state regulations. There have also been accusations that Metabolife has attempted to exert influence in Texas through political connections to members of the Bush administration. According to *Business Week*, federal efforts to remove ephedra have been hampered "by deep-pocketed industry lobbying. Metabolife, has contributed . . . to national politicians since 1999, . . . according to the Center for Responsive Politics." In

California, Metabolife ranked fourth in the state for "soft money" contributions, with \$493,000 in 2000. Additional federal and state influence-peddling has taken the form of soft money contributions to political parties, whereby Metabolife gave \$1,718,000 during the 1999-2000 and 2001-2002 election cycles.

### Act Now

The recent Rand report reviewing published literature on ephedra and adverse reaction reports takes away the last excuse given by the government for not yet acting on our 5 September 2001 petition to ban all dietary supplements containing ephedra alkaloids. However, the government is still equivocating and has announced, in a 7 March 2003 *Federal Register* Notice, that they want comments on any new information on ephedra risks, public opinion as to whether the legal standard for a ban can be met, and

whether a proposed warning label makes sense. Much of this flurry of "activity" is in the wake of the death of Baltimore Oriole pitcher, Steve Bechler, whose death has been partially attributed to the use of ephedra dietary supplements.

"Regulation" is now coming from the marketplace, operating in the vacuum created by FDA inaction. Several companies have announced that they will stop selling ephedra-containing diet supplements. Even Metabolife has announced that the company launched an ephedra-free "alternative."

However, this alone is not an acceptable way to safeguard public health, and product labeling is not enough. We call on the FDA as an agency of the Public Health Service to fulfill their legal responsibility and to stop the occurrence of further preventable deaths and injuries by banning ephedra products.

**CALCIUM**, from page 2

um, actually elemental calcium.

Some of the most common calcium salts include calcium carbonate, calcium lactate and calcium gluconate. The table on this page lists the common calcium salts sold for calcium supplementation and the percentage of elemental calcium found in each.

For example, 1,000 milligrams, or 1 gram, of calcium carbonate would contain 400 milligrams (40% of 1,000) of elemental calcium while 1,000 milligrams of calcium gluconate would contain only 90 milligrams (9% of 1,000) of elemental calcium.

An issue that consistently comes up in the promotion of calcium supplements is the extent to which calcium is absorbed with the various products on the market, each company claiming that its calcium is better than the other.

In the late 1980s, it was found that some calcium supplements would not dissolve and passed straight through the bowel. The calcium salt must dissolve before the calcium can be absorbed into the body. The U.S. Pharmacopeia (USP), the organization that sets drug standards in this country, has since issued dissolution standards for calcium supplements.

The absorption of calcium is not complete and usually averages about 20 to 30 percent of intake. It requires an adequate intake of vitamin D in the diet and varies with age, decreasing after puberty. Taking calcium in doses of 500 milligrams or less with food increases absorption, particularly in patients with low levels of stomach acid (achlorhydria) and in those taking drugs such as the histamine-2 blockers cimetidine (TAGAMET) or ranitidine (ZANTAC) used for heartburn. Other drugs that lower stomach acid are the proton pump inhibitors such as omeprazole (PRILOSEC) or esomeprazole (NEXIUM), drugs also widely used for heartburn. Foods such as spinach, rhubarb, wheat bran and other forms of unrefined flour contain oxalic or phytic acids that can decrease the absorption of calcium.

Different calcium salts may vary

CALCIUM SALTS	PERCENTAGE OF ELEMENTAL CALCIUM
calcium carbonate	40 percent
calcium phosphate	40 percent
calcium citrate	21 percent
calcium lactate	13 percent
calcium gluconate	9 percent

somewhat in their absorption. However, there is little, if any, evidence that of the various calcium salts or calcium supplement products on the market, that one is more effective than another in reducing the risk of fracture due to osteoporosis.

Gastrointestinal adverse effects such as constipation, intestinal bloating and excess gas, particularly with calcium carbonate, are frequently seen with the use of calcium supplements. Those patients who form

but the absorption of lead from such preparations is generally low. We can think of no reason why anyone should take the chance by using a natural calcium product.

The editors of the well-respected *Medical Letter on Drugs and Therapeutics* concluded in their April 2000 review of calcium supplements that:

Patients of both sexes and all ages need an adequate intake  
*continued on page 4*

CALCIUM CONTENT OF SOME FOODS		
Food	Serving Size	Calcium Content (milligrams)
Milk, skim	1 cup	302
Yogurt (lowfat, fruit-flavored)	8 ounces	300
Gruyere cheese	1 ounce	287
Swiss cheese	1 oz	272
Figs, dried	10 figs	269
Tofu, raw, firm	1/2 cup	258
Calcium-fortified cereals	3/4 cup	250
Cheddar cheese	1 ounce	204
Calcium-fortified orange juice	6 ounces	200
Mozzarella cheese, part-skim	1 oz	183
Collards, cooked from frozen, chopped	1/2 cup	179
American cheese, processed	1 ounce	174
Blackstrap molasses	1 tablespoon	172
Creamed cottage cheese	1 cup	126
Sardines, canned in oil	2 sardines	92
Parmesan cheese, grated	1 tablespoon	69
Mustard greens	1/2 cup	52
Kale, boiled	1/2 cup	47
Broccoli, boiled	1/2 cup	36

# Bereavement

*A version of this article originally appeared in the December 1987 Health Letter.*

At least 8 million Americans lose a relative to death each year, and the result, for the survivors, is called bereavement. Medical writer Peggy Eastman has turned her personal tragedy, and her own response to it, into articles that have comforted many others.

"Nothing is more devastating than losing someone close to you, especially a spouse," says Ms. Eastman. Her husband, James Eastman, was a passenger on a small commuter plane that crashed in Maine, killing him, young activist Samantha Smith and six others. Her first reaction was "violent tears of protest," and she later had nightmares, bouts of depression and spiritual struggles.

One month after her husband's death, she says, "I set out to research my condition, in a desperate attempt to understand what was happening to me. . . . I felt it might be the only thing that would help."

Bereavement is defined as "loss through death." The inevitability of death makes bereavement, like pregnancy, a common and natural occurrence that results in changes in both function and behavior. As each person is different, so each death is different, and every bereaved person has some unique reactions, which may depend on the deceased person's age, suddenness of death

and type of death.

## The Phases Of Grief

Grief is frequently described as occurring in phases, in which one follows another, although some people move back and forth between them. The boundaries between the phases may be blurred.

### Phase 1

The first phase begins immediately after the loss, and may last up to a few weeks. The survivor experiences shock, numbness and disbelief. Other common symptoms include crying, sighing, tightness in the throat and a sense of unreality. The shock may be more pronounced if the death is sudden and unexpected.

### Phase 2

The second phase of grief is characterized by preoccupation with the deceased and a yearning to recover the lost person. The survivor frequently re-examines the past relationship, including disagreements, conflicts and unresolved anger. Emotions can fluctuate wildly, from intense sadness, to anger, to guilt. Dreams of the deceased may be intense and vivid. Weakness and fatigue are also common. If this phase extends beyond several months and does not progress to further stages, it may signal the need for treatment, as this constitutes "pathological grief."

Pathological grief may refer to

several abnormal patterns of grief. Absent grief, delayed grief and distorted grief are three forms of pathological grief. Distorted grief usually involves persistence of the second stage of grief. This may show itself through compulsive overactivity without a sense of loss, acquisition of the symptoms associated with the deceased, loss of health, social isolation or alienation, or severe depression. Any of these symptoms may require medical attention, or increased social support. However, cultural norms may differ, and in some cultures a single symptom listed above may not represent a true problem.

### Phase 3

Disorganization and despair characterize the third phase, although the end result is that the survivor accepts the permanence and the fact of loss. The survivor ceases attempts to recover the lost person. Sadness persists in this phase, along with feelings of emptiness, and loss of interest in usual activities.

### Phase 4

The fourth phase involves resolution and reorganization of behavior. Normal activities resume, and the bereaved person regains interest in usual activities. Some new social contacts are made. Occasional feelings of sadness, emptiness and crying spells may occur, but less frequently than before, or with less

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## CALCIUM, from page 3

of calcium. There is little evidence that any calcium supplement is more effective than any other in preventing osteoporotic fractures. Calcium carbonate may cause more adverse gastrointestinal effects. Calcium citrate may be better absorbed. Taking any calcium supplement in doses of 500 mg

or less with meals may improve absorption.

### What You Can Do

You should avoid calcium-containing dietary supplements making claims that sound too good to be true. They probably are not true.

You should consider dietary sources of calcium as part of a plan to ensure adequate intake of calcium.

If you decide to use one of the

many calcium salts that are available, check the label for the amount of elemental calcium. You should only purchase calcium salts that meet the USP standard for dissolution.

Some of the best sources of calcium are dietary. The table on page 3 appeared in the April 2000 issue of *The Medical Letter on Drugs and Therapeutics* and lists the elemental calcium content, in milligrams, of some common foods.

## **BEREAVEMENT, from page 4**

intensity. The result may not be a complete return to previous activities, but a loss of the preoccupation with the deceased. Past events with the deceased person can be recalled with some pleasure.

The distress of grief and mourning was formerly thought to be short-lived, but recent studies have shown that such feelings can persist for many years. In fact, some think that it can normally last a lifetime. This has prompted some to conclude, "You really don't get over it, you get used to it." As noted before, there is a tremendous amount of individual variation.

### **Interventions**

Grief is normal and adaptive, and in most cases does not need to be "medicalized" into an illness. However, if help is needed, there are people to turn to.

1. *Support groups*, where people who have had similar experiences meet and discuss topics of concern. Peggy Eastman joined such a group about three months after the death of her husband. "My church started a new weekly support group for people who had experienced a loss of a loved one. It was made clear that this was to be a support group rooted in the healing power of love, not a psychotherapy group." Topics can include social adjustment, research discussions, the grieving process and how to avoid stumbling blocks. She concludes, "Nonjudgmental, confidential, peer-directed support groups are one of the best ways to resolve loss because they reassure the griever that he or she is not alone."

As noted in a National Institute of Mental Health publication, "Mutual-help groups do not intend to replace physicians, therapists and other skilled professionals. Rather, the groups function in the belief that many of our physical and mental health needs go beyond the bounds of formal care measures."

2. *Counseling* is another intervention which may help deal with grief. At its simplest, counseling may be

support from friends and family; however, health care personnel can provide this service. The basic goal is to facilitate passing through the phases of mourning by accepting the reality of the loss, dealing with feelings and emotions and readjusting to the new environment.

3. *Medications* are a controversial part of the bereavement process, particularly because of the risk of delayed or distorted grief. Some people feel that the reason for the widespread use of medications is that physicians find it easier to write a prescription than to deal with feelings. Some bereaved persons, however, do legitimately need a short (7-10 day) course of sleeping pills or tranquilizers. Longer courses of treatment may lead to addiction or other complications. Research into this area, as recommended by the National Academy of Sciences, is sorely needed.

4. *The hospice movement* has initiated preventive efforts for those with loved ones who have a chronic and fatal disease. They can help prepare for the eventual loss.

### **Recommendations**

The Institute of Medicine/National Academy of Sciences released a report in 1984 titled "Bereavement: Reactions, Consequences, and Care."

The report recommends:

- Health professionals and institutions have a continuing responsibility to the bereaved.
- Schools should train nurses and physicians to look for warning signs, and should refer people at high risk

for pathological grief for counseling.

- The integration of social workers and chaplains into hospital settings, particularly those involving terminal illness, has improved the care at some medical institutions.

- Increased public education may offer support indirectly to bereaved persons. The report notes that institutional care for the dying and geographic mobility have left many people unprepared to deal with death. Many people are surprised by the intensity of their emotional reaction to the death of a loved one.

- Further research is needed in several areas, notably the process and outcome of bereavement. The risk factors for death or disease following the death of someone close need to be studied to effectively plan ways to prevent such problems. Health consequences of bereavement in children, in minority groups and in other cultures, as well as expanded research into the biology and physiology of grieving, were all highlighted as major areas in need of research.

Research into the intervention strategies described above is needed to evaluate their effectiveness and whether they may be broadly applied to the general population. In particular, the panel noted the opportunities available to evaluate the rapidly evolving hospice movement. Finally, they recommended the establishment of a research review committee by the federal National Institute of Mental Health (NIMH) to coordinate bereavement studies of all kinds.

#### **What You Can Do**

Resources are available for mutual support groups. The national groups listed below may be able to refer people in need to a local group. Larger groups may be listed in the local telephone directory, and names and telephone numbers of many more are available from hospitals and local health and social service agencies.

##### **The Compassionate Friends, Inc.**

P.O. Box 3696  
Oak Brook, IL 60522-3696  
Phone: 630-990-0010  
Toll Free: 877-969-0010  
www.compassionatefriends.org  
*for bereaved parents, peer support*

##### **AARP Widowed Persons Service**

1909 K Street Northwest  
Washington, DC 20049  
Phone: 202-434-2260  
*for the widowed and peer support*

# Product Recalls

March 19, 2003 — April 16, 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](http://www.fda.gov).

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

**Acyclovir Tablets**, 400 mg, 100 tablet bottles, Rx only; Class II; Tablets contain fibers

**Antacid Liquid and Antacid Supreme Liquid**, various strengths, flavors and sizes sold under various brand names at drug, grocery and discount stores nationwide — contact your pharmacy for more information; Class II; Microbial contamination

**Avodart (dutasteride) Soft Gelatin Capsules**, 0.5 mg, blistercard package containing 70 capsules, Rx only; Class III; Mislabeled — blistercard incorrectly labeled "Sample — Not for Sale"

**Betaxolol Sterile Ophthalmic Solution** 0.5%, 5, 10 and 15 mL dropper tip bottles, Rx only; Class II; Defective container — insufficient tightness of caps resulting in evaporation of water in solution which may cause product to become superpotent

### Lot #: Quantity and Distribution; Manufacturer

Lot 553C21 exp. 04/2004; 16,482 distributed nationwide; Alpharma Purepac, Elizabeth, New Jersey

Numerous lots; 500,422 distributed nationwide; Aaron Industries, Inc., Lynwood, California

Lot RP44904BB exp. 09/30/2006; 3,059 distributed nationwide; SmithKline Beecham Corp., Zebulon, North Carolina

All lots and sizes; 29,319 distributed nationwide and in Puerto Rico; Novex Pharma, Richmond Hill, Ontario, Canada

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THE PUBLIC CITIZEN HEALTH RESEARCH GROUP

## Health Letter

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 Public Citizen Health Research Group  
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Annual subscription price is \$18.00 (12 issues). Mail subscriptions and address changes to Health Letter, Circulation Department, 1600 20th St., NW, Washington, D.C., 20009. Our Web site address is [www.citizen.org/hrg](http://www.citizen.org/hrg).

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

**Carteolol Hydrochloride Sterile Ophthalmic Solution** 1%, 5, 10 and 15 mL dropper tip bottles, Rx only; Class II; Defective container — insufficient tightness of caps resulting in evaporation of water in solution which may cause product to become superpotent

**Children's Pain Reliever Suspension Liquid (Acetaminophen)**, 4 and 8 fl oz bottles, bubble gum, grape and cherry flavors, sold under various brand names at drug, grocery and discount stores nationwide — contact your pharmacy for more information; Class II; Superpotency — inadequate validation of manufacturing operation

**Cromolyn Sodium Sterile Ophthalmic Solution** 4%, 10 mL dropper tip bottle, Rx only; Class II; Defective container — insufficient tightness of caps resulting in evaporation of water in solution which may cause product to become superpotent

**Diltiazem CD Capsules** (Diltiazem hydrochloride Extended Release Capsules) 180 mg, 90 capsule bottles, Rx only; Class III; Failure to validate a reduced batch size manufacturing process

**Doryx Capsules** (coated doxycycline hyclate pellets), 75mg, 6 blisterpack physician samples (2 tablets each) and 60 count bottles, Rx only; Class III; Lack of assurance of stability throughout labeled expiration

**Drituss GP Tablets** (Guaifenesin 1200mg and Pseudoephedrine hydrochloride 120mg) 100 count bottles, Long Acting, Dye Free, Rx only; Class III; Failure to validate manufacturing process

**Estrace (estradiol) Tablets**, 100 count bottles of 2 mg tablets, Rx only; Class II; Dissolution failure

**Kytril Tablets** (granisetron HCl), 1mg, 2 and 20 tablet packages, Rx only; Class III; Mispackaged — blistercard incorrectly contains two tablets rather than one

**Lanoxin (digoxin) Elixir Pediatric**, 50 mcg (0.05 mg), 60 ml bottle, Rx only; Class II; Product contains brown cardboard particles

**Levobunolol HCl Sterile Ophthalmic Solution** 0.5%, 5, 10 and 15 mL dropper tip bottles, Rx only; Class II; Defective container — insufficient tightness of caps resulting in evaporation of water in solution which may cause product to become superpotent

**Metformin Hydrochloride Tablets**, 1000 mg, 500 tablet bottles, Rx only; Class II; Product may contain iron/zinc particles

*Lot #: Quantity and Distribution; Manufacturer*

All lots and sizes; 725 distributed nationwide and in Puerto Rico; Novex Pharma, Richmond Hill, Ontario, Canada

Numerous lots; 2,736,842 sold nationwide and in Canada and Poland; L. Perrigo Co., Allegan, Michigan

All lots and sizes; 12,328 distributed nationwide and in Puerto Rico; Novex Pharma, Richmond Hill, Ontario, Canada

Lots 725D21 exp. 03/2004, 726D21 exp. 03/2004, 727D31 exp. 03/2004 and 728D21 exp. 01/2004; 33,005 distributed nationwide; Alpharma Purepac, Elizabeth, New Jersey

Numerous lots; 174,541 blisterpacks and 51,858 bottles distributed nationwide; Recalled by Warner Chilcott Labs, Rockaway, New Jersey and manufactured by Faulding Pharmaceutical/DBL, a division of F.H. Faulding & Co., Limited, Salisbury, South Australia

Lots 025L2A, 023L2A, 024L2A, 016B2RA, 015B2A, 003L1A, 010F2A; 18,499 distributed nationwide; Vintage Pharmaceuticals LLC, Huntsville, Alabama

Lots 011137 exp. 04/16/2003, 011780 exp. 06/23/2003, 011851 exp. 07/06/2003 and 012022 exp. 08/29/2003; 5,000 distributed nationwide; Recalled by AmeriSource Health Services Corp., Columbus, Ohio and manufactured by Bristol-Myers Squibb Co., Princeton, New Jersey

Lots 029055 exp. 04/2003, 029056 exp. 04/2003, 036198 exp. 03/2005, 036199 exp. 03/2005, 036200 exp. 03/2005, 039142 exp. 07/2005 and 028107 exp. 04/2003; 64,073 distributed nationwide; Hoffmann LaRoche, Inc., Nutley, New Jersey

Lots 1G605, 1F716, 1G608, 1H622, 1K618, 2D604, 2G704 and 2H602; 282,850 distributed nationwide; Recalled by SmithKline Beecham Corp., Zebulon, North Carolina and manufactured by Glaxo Wellcome, Research Triangle Park, North Carolina

All lots and sizes; 59,887 distributed nationwide and in Puerto Rico; Novex Pharma, Richmond Hill, Ontario, Canada

Lot 438F21 exp. 07/2004; 1,970 distributed nationwide; Alpharma Purepac, Elizabeth, New Jersey

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## DRUGS AND DIETARY SUPPLEMENTS *cont.*

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

**Nature's Remedy Tablets**, a) Laxative (Cascara sagrada 150mg and Aloe 100mg), 15, 30 and 60 count blistercard packages and b) Stimulant Laxative (Sennosides 8.6mg), 15, 30 and 60 count blistercard packages; Class III; a) Subpotent, active ingredient (Aloe) (stability 12 month timepoint) and b) Superpotent, active ingredient (stability 12 month timepoint)

**Premarin (conjugated estrogens) Tablets**, 0.9 mg, 100 tablet bottles, Rx Only; Class III; Dissolution failure - 5 hour time point

**Premarin (conjugated estrogens) Tablets**, 1.25 mg, 5,000 count bottles, Rx Only; Class III; Dissolution failure — 5 hour time point

**Strattera Capsules (atomoxetine HCl)** 40mg, 24 count bottle, Rx only, Adult Sample Pack; Class III; Misbranded — bottle label is incorrectly printed as "First use blister"

**Terazosin Hydrochloride Capsules**, 1 mg, 500 count bottles, Rx only; Class II; Dissolution failure — 18 month timepoint (stability)

**Thyrolar 1/4 (liotrix) Tablets**, 12.5mcg, 100 tablet bottles, Rx only; Class III; Superpotent — excessive tablet weight specification limits

**Timolol Maleate Sterile Ophthalmic Solution** 0.25%, 10 and 15 mL dropper tip bottles, Rx only; Class II; Defective container — insufficient tightness of caps resulting in evaporation of water in solution which may cause product to become superpotent

**Timolol Maleate Sterile Ophthalmic Solution** 0.5%, 10 and 15 mL dropper tip bottles, Rx only; Class II; Defective container — insufficient tightness of caps resulting in evaporation of water in solution which may cause product to become superpotent

**Tobramycin Sterile Ophthalmic Solution** 0.3%, 5mL dropper tip bottle, Rx only; Class II; Defective container — insufficient tightness of caps resulting in evaporation of water in solution which may cause product to become superpotent

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

Numerous lots; 1,289,220 distributed nationwide and in Canada; GlaxoSmithKline, Parsippany, New Jersey

Lots 9981732 exp. 08/2003 and 9990073 exp. 08/2003; 74,211 distributed nationwide; A.H. Robins, Division of American Home Products, Richmond, Virginia

Lots 9000073 exp. 07/2004, 9010066 exp. 08/2003 and 9010248 exp. 08/2003; 1,893 distributed nationwide; A.H. Robins, Division of American Home Products, Richmond, Virginia

Lot 6AE95B; 89,360 distributed nationwide; Eli Lilly and Company, Indianapolis, Indiana

Lot 4336-707 exp. 06/2003; 50 distributed nationwide; Recalled by IVAX Pharmaceuticals, Miami, Florida and manufactured by Zenith Goldline Pharmaceuticals, Inc.

Lot 60135 exp. 06/2003; 8,235 distributed nationwide; Forest Pharmaceuticals, Inc., Earth City, Missouri

All lots and sizes; 15,804 distributed nationwide and in Puerto Rico; Novex Pharma, Richmond Hill, Ontario, Canada

All lots and sizes; 142,560 distributed nationwide and in Puerto Rico; Novex Pharma, Richmond Hill, Ontario, Canada

All lots and sizes; 1,937 distributed nationwide and in Puerto Rico; Novex Pharma, Richmond Hill, Ontario, Canada

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

### *Name of Device; Class of Recall; Problem*

**Glitter Eyes Daily Wear Soft Contact Lenses**; Class II; Lens may partially delaminate in area of one of the encapsulated cosmetic prints

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

Numerous colors and lots; 29,821 distributed nationwide and in Canada and Puerto Rico; Ciba Vision Corporation, Duluth, Georgia

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

### *Name of Device; Class of Recall; Problem*

**MediSense Blood Glucose Test Strips;** Class II; Glucose test strips may give high falsely positive readings

**One Touch SureStep Glucose Test Strips;** Class II; Test Strips have manufacturing errors in that the "Confirmation Dot" is off-center or split in half, and bottle cap is defective

**Permobil Chairman 2K powered wheelchair,** Model 1280; Class II; Incidents were reported where a drive wheel has come off its motor axle, due either to loosening of the wheel bolt or a broken wheel bolt

**Tarsys 1st Generation Seating System,** an optional accessory for Powered Wheelchairs; Class II; A short circuit within the charger harness may cause heat damage to the units with potential for fire

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

Numerous lots; 63,417 boxes distributed nationwide; Abbott Laboratories, Inc., Bedford, Massachusetts

Numerous lots; 3,374,000 distributed nationwide and internationally; Lifescan, Inc., Milpitas, California

Serial No. 1100068 to 1103702; 1,582 distributed nationwide and in Puerto Rico and Canada; Permobil, Inc., Lebanon, Tennessee

All model numbers (excluding 2nd generation models), Serial No. 931 to 02E; 20,956 distributed nationwide and internationally; Invacare Corp., Elyria, Ohio

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

### *Name of Product; Problem*

**Bicycle Helmets;** Helmets fail required CPSC impact testing, violating Consumer Product Safety Act

**Craftsman Electric Routers;** On-off switch could stick in "on" position, posing serious laceration risk

**Fiddlestick Wooden Instruments;** Caps can become loose, allowing ball bearings to spill from inside of sticks and posing a choking hazard

**Girls' Hooded Winter Jackets;** Rubber petal and metal snap can break off jacket, posing a choking hazard

**Hitachi Circular Saws;** Lower blade guards can stick in open position, exposing blade and posing serious laceration hazard

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

Black, white or red Five 40 brand helmets with label inside reading "990803" and "540"; 1,250 sold at sporting good stores nationwide between October 1999 and September 2001; MOSA Sports, Hermosa Beach, California (800) 804-0211

Model number 315.17510 with date code A0304 or lower and packaged with cloth carrying bag under stock number 17518; 5,200 sold at Sears stores nationwide between November 2002 and January 2003; OWT Industries, Inc., Pickens, South Carolina and Sears Roebuck and Co., Hoffman Estates, Illinois (800) 932-3188 [www.sears.com](http://www.sears.com)

Wooden instrument is 7" long, 1" in diameter and hollowed out with steel balls inserted in middle to create a shaker sound; 32,000 sold by Kindermusik educators in the U.S. and Canada between December 2002 and January 2003; Kindermusik International, Browns Summit, North Carolina (800) 628-5687 [www.kindermusik.com](http://www.kindermusik.com)

Girls' sized jackets in various colors with style numbers 52913, 52813J, 12913K, B2913, 32813, 12816C, 3281J, 82819D, 82816D and 32816C; 37,000 sold nationwide between May and December 2002; S. Rothschild & Co. Inc., New York, New York (800) 301-3411

7 1/4-inch circular saws with model numbers C7SB2 or C7BD2 and serial numbers beginning C62, C72, C82, C92, C02 or CN2; 14,300 sold at home centers, hardware stores and industrial suppliers nationwide between August 2002 and March 2003; Hitachi Koki U.S.A., Ltd., Norcross, Georgia (800) 706-7337 [www.hitachi.com](http://www.hitachi.com)

*continued on page 10*

*Name of Product; Problem*

**Kenmore Refrigerators;** A screw inside refrigeration compartment on left side of refrigerator frame could pierce through electrical wire harness insulation, posing electrical shock hazard

**Lamaze Activity Toys;** Paint on metal wires contains excess levels of lead

**Maytag Gemini Gas Ranges;** Range can experience delayed ignition flashback fire in upper oven only, posing a fire and burn hazard

**Party Poppers;** Cone-shaped top can pop off rapidly, posing an injury hazard

**Playskool Magic Start Crawl 'n Stand Toys;** Toys can tip over during use, posing injury risk

**Plush Bears and Snowman Dolls;** Buttons on jackets can be pulled off, posing a choking hazard

**Polaris All-Terrain Vehicles;** ATVs may have loose or leaking oil cooler line clamps that can release hot, pressurized oil, leading to thermal burns, engine failure and posing a fire hazard

**Power Adapter Plugs;** Plugs can break open and expose live wires, posing electrocution or electric shock hazard

**Red Devil Gas Grills;** Design flaw allows consumers to light grill at air intake tube instead of burner, igniting gas inside air intake tube and posing burn hazard, also in grills manufactured before August 1998, damaged plastic support piece caused grill to fall to ground, posing burn hazard

*Lot #; Quantity and Distribution; Manufacturer*

Elite brand TRIO model with side-by-side upper doors and freezer drawer at bottom; 6,000 sold nationwide at Sears stores between December 2002 and January 2003; Maytag Corp., Newton, Iowa (800) 659-7026

Lamaze Flower Stroller Wrap (SKU #97222) and Lamaze Soft Bead Buddies (SKU #97325); 3,800 sold nationwide in March 2003; Racing Champions Ertl/Learning Curve Int'l., Inc. (RCE/LCI), Chicago, Illinois (800) 704-8697 [www.learningcurve.com](http://www.learningcurve.com)

Freestanding ranges with separate upper and lower ovens, model MGR6772 and "Maytag" and "Gemini" names and logos on control panel; 23,000 sold nationwide between July 2002 and February 2003; Maytag Corp., Newton, Iowa (866) 580-9177 [www.maytag.com](http://www.maytag.com)

Rocket-shaped TNT Big Fun Party Poppers with 3 1/2-inch wooden support sticks packaged in units of four; 4,000 sold nationwide at Wal-Mart stores between January and March 2003; American Promotional Events Inc. d/b/a TNT, Florence, Alabama (800) 243-1189

Multicolor plastic toy with round base and three arched legs that support an electronic activity center with "ITEM #06952" and "Made in China" on the underside; 300,000 sold nationwide at Wal-Mart stores between November 2002 and April 2003; Playskool, Pawtucket, Rhode Island (800) 509-9554 [www.playskool.com](http://www.playskool.com)

10-inch plush bear and snowman dressed in hat, jacket and scarf with label on back that reads "DIST BY: DOLLAR TREE" and "MADE IN CHINA" and ear tags that read "Christmas House Plush Bear" or "Christmas House Christmas Plush"; 407,000 plush bears and 221,000 snowman dolls sold nationwide at Dollar Tree, Only One Dollar, Dollar Express and Dollar Bills stores nationwide between June 2002 and March 2003; Dollar Tree Stores, Inc., Chesapeake, Virginia (800) 876-8077 [www.dollartree.com](http://www.dollartree.com)

2000 and 2001 Polaris Xpedition 325, Trail Boss 325 and Magnum 325 four-wheeled ATVs intended for off-road use; 56,000 sold by Polaris dealers nationwide between January 1999 and August 2000; Polaris Industries Inc., Minneapolis, Minnesota (800)-POLARIS

Plugs sold with 70-watt AC power adapters, model name "Targus" and model number PA-AC-70W-2 and "ChargeSource" printed on top; 125,000 sold nationwide between July 2002 and March 2003; Comarco Inc., Irvine, California (800) 859-7928 [www.regcen.com/comarco](http://www.regcen.com/comarco)

Red metal gas grills with tripod stand, logo on label of lid and grill base with the words "Red Devil" and "The Portable Outdoor Kitchen"; 2,800 sold at BJ's Wholesale Club stores between May 2000 and June 2002; BJ's Wholesale Club, Inc., Natick, Massachusetts (800) BJS-CLUB (257-2582) [www.bjs.com](http://www.bjs.com)

**Name of Product; Problem**

**Toro Snow Commander Snowthrowers;** Plastic fuel tank can crack and leak, posing fire and injury risk

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

2001 Toro Snow Commander snowthrowers with model number 38600 and 38602; 3,400 sold nationwide between October 2000 and March 2003; The Toro Company, Bloomington, Minnesota, (800) 689-8671 [www.toro.com](http://www.toro.com)

**Woody Dolls;** Buttons on clothing can detach, posing a choking hazard

Soft-bodied 13" doll with plastic head, hands, boots and hat, wearing blue jeans, checked shirt, spotted vest with sheriff's badge and red-patterned bandana; 40,000 sold at Disney resorts and the Orlando Airport between January 2000 and January 2003; Walt Disney Parks and Resorts (866) 228-3664 [www.waltdisneyworld.com](http://www.waltdisneyworld.com)

**OUTRAGE, from page 12**

have a lot of time for this. You are a chronic undercoder! You consistently code at a lower level than our directives mandate. Here is an example where you spent 45 minutes with the patient and coded for only 30 minutes. When you do that, the practice loses money it is entitled to collect."

"But some of my patients are uninsured — the working poor, without insurance," I countered. "I try to give them a break by coding downward."

"We are not a philanthropic organization," she said. "In a case like that, you are to refer the patient to Social Services for help."

"But we have no Social Services at the clinic."

"That does make it more difficult," she admitted, "but you cannot handle that problem by undercoding."

So there it was: I was a chronic undercoder. She gave me a complicated set of coding directions and a plastic bookmark with a listing of the most common codes. I departed with her expression of faith that I could become a correct coder with some study and effort.

The coding instructions were exquisitely detailed. Code for listening to lungs, examining the toes, doing the rectal exam, taking a family history, handing out a brochure, discussing smoking cessation and diet. But do not code for handholding, listening sympathetically, or chatting about the family or the weather to establish rapport (or to

establish Rappaport, as my Uncle Morris used to quip).

I no longer undercode. I keep track of every maneuver or action during the patient encounter. The

patient who comes to see me for a hangnail may wonder why I do a complete, codable neurological exam, but the business office understands.



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# The Uncovering Of An Undercoder: A Story Of Medicine Triumphant

I seldom receive any communications from the business office of the university group practice where I have worked as a primary care practitioner for over a dozen years. But here, marked "URGENT" in large red type, was a summons for a personal appearance before the Office of Quality Assurance. According to the solemnly worded missive, I had failed the chart audit and if I wished to continue to practice at our clinic, I was to undergo "remediation" immediately. I had not heard the term "remediation" before, but it sounded ominous. Wasn't that what the Chinese communists did to prisoners during the Korean War? Would I ever see my family again?

Puzzled and alarmed, I cast my

mind back to patients I had seen where I might have been hasty or careless. Perhaps the audit had discovered that I omitted some important test or part of the physical exam? I had always spent many hours writing legible chart notes so that other physicians could read them if needed - and so I could read my own notes, too. But now I had flunked the audit, and there was going to be hell to pay and remediation to follow.

On the appointed Remediation Day, I rose early after fitful sleep, dressed sharply and made my way nervously to the second floor of our clinic building, where the business office was located. I could not help noticing how clean and well decorat-

ed the business office was in contrast to the patient care area.

The Director of Quality Assurance greeted me graciously and directed me to a large table where she had spread out eight of my patient charts, each opened to a certain page marked by a bright yellow sticker. My anxiety rose at the sight of the evidence.

"You know sometimes I have so many patients scheduled, I am rushed in my exams and note taking, but I try to do a complete and thorough job," I whimpered apologetically. She seemed confused at this confession.

"Let's cut to the chase," she said, "I have a 2 p.m. meeting, so we do not

*continued on page 11*

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