

Health Letter

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Review Of Calcium Supplements; Ads Exaggerate Differences

The editors of *The Medical Letter On Drugs and Therapeutics*, a reference we frequently cite because of its high quality, reviewed calcium supplements in their April 3, 2000 issue. The stimulus for this review was the barrage of superiority claims on TV and in the print media for various calcium dietary supplements.

The Institute of Medicine, part of the National Academy of Sciences, recommends a daily intake of 800 milligrams (mg.) of elemental calcium for children 4 to 8 years of age; 1,300 mg. for 9-to-18-year-olds; 1,000 mg. for adults 19 to 50, including pregnant and lactating women, and 1,200 mg. for all older persons including those taking estrogen, such as conjugated equine estrogen (PREMARIN), or a bisphosphonate such as alendronate (FOSAMAX) for osteoporosis. In reality the average American consumes less than the 800 mg. recommended for young children.

Calcium, when combined with another chemical molecule such as carbonate, citrate, or phosphate, is referred to as a calcium salt. The carbonate, citrate, and phosphate parts of calcium pills have different weights. Thus, if the total weights of three different pills are the same, this means that they contain different amounts of calcium. For example, calcium carbonate and phosphate products contain the largest amount of elemental calcium, about 40 percent. Calcium citrate contains only 21 percent elemental calcium and calcium lactate and calcium gluconate contain 13 percent and 9 percent re-

spectively. Pay attention to the amount of elemental calcium listed on a label, not the weight of the salt.

The tables from *The Medical Letter* that accompany this article list some commonly available calcium products with the amount of elemental calcium and vitamin D per tablet. There is also a table listing dietary sources of calcium.

Calcium tablets must first break down and then dissolve in the intestinal tract before the calcium can be absorbed.

Most commercially available preparations meet the breakdown and dissolution standards of the United States Pharmacopeia (USP). Manufacturers claiming to meet these standards can list the initials USP on their calcium products' labels. You should buy only calcium supplements meeting the USP standards.

Absorption of calcium is incomplete, averaging about 20 percent to 30 percent of the amount ingested. The

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Table Supplement (supplier)	Elemental Calcium per Tablet (milligrams)	Vitamin D per Tablet IU (international units)
<i>Calcium Carbonate Containing Supplements</i>		
Generic	600	200
CalBurst (Nature Made)	500	200
Caltrate +D (Lederle)	600	200
Os-Cal +D (SK Beecham)	500	200
Tums 500 (SK Beecham)	500	0
Viactive (Mead Johnson)	500	100
<i>Calcium Citrate Containing Supplements</i>		
Citracal +D (Mission)	315	200
Calcium Citrate +D (Nature Made)	315	200
<i>Calcium Complex (carbonate, lactate, gluconate) Containing Supplements</i>		
Calcet (Mission)	150	100
<i>Calcium Phosphate Containing Supplements</i>		
Posture-D (Selfcare)	600	125

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absorption of calcium requires adequate amounts of vitamin D and varies with age, decreasing after puberty. Taking calcium with food in doses of 500 milligrams or less increases absorption, particularly in patients who do not make enough stomach acid and in those taking histamine blockers such as ranitidine (ZANTAC) or proton pump inhibitors such as omeprazole (PRILOSEC). But, some foods containing oxalic or phytic acids, such as spinach, rhubarb, wheat bran and other forms of unrefined flour, can decrease calcium absorption.

Different calcium salts may vary in their absorption properties. *The Medical Letter* editors reported that a recent study comparing calcium carbonate and citrate found that when 17 premenopausal women took 300 milligrams with breakfast, the absorption of the carbonate was 34 percent, and of the citrate 38 percent. In another study, when 10 men and 10 postmenopausal women took 1,000 milligrams of each of these salts, the absorption decreased to 30 percent with the carbonate and to 27 percent with the citrate. A type of statistical summary known as a meta-analysis found that the absorption of calcium citrate was 27 percent higher than that of calcium carbonate when the products were taken on an empty stomach, and 22 percent higher when taken with meals. The studies used in

Calcium Content of Some Foods Food	Serving Size	Calcium Content (milligrams)
Milk, skim	1 cup	302
Yogurt (low-fat, fruit-flavored)	8 ounces	300
Gruyere cheese	1 ounce	287
Swiss cheese	1 ounce	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 ounce	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

the meta-analysis included patients of different ages, a wide range of calcium salts and dosages, and various methods of measuring calcium absorption.

In our opinion, the studies directly comparing the extent of absorption of various calcium salts (which appears to be quite small) are more reliable than the meta-analysis.

Evidence indicates that increasing vitamin D intake may enhance calcium absorption from both supplements and

dietary sources. The recommended daily intake of vitamin D is 200 International Units (IU) for adults less than 50 years of age, 400 IU for those 51 to 70 years old, and 600 IU for people over 70. Vitamin D supplementation may be very important for older adults because both the production of vitamin D on the skin and its absorption may be impaired.

Adverse gastrointestinal (GI) effects
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Long-acting Calcium Channel Blockers Inferior To Older Blood Pressure Lowering Drugs in Preventing Heart Attacks and Heart Failure

Research presented at the European Society of Cardiology meeting in Amsterdam on August 29, 2000, found that long-acting calcium channel blocker (CCB) drugs were inferior to older proven and less expensive products in preventing cardiovascular complications of high blood pressure such as heart attacks and heart failure. The new research is a statistical summary of nine published clinical trials known as a meta-analysis and was conducted by scientists from Wake Forest University School of Medicine, the University of Washington-Seattle, and Albert Einstein College of Medicine.

The long-acting CCB drugs included in the meta-analysis were amlodipine (NORVASC), diltiazem (CARDIZEM SR & CD), felodipine (PLENDIL), isradipine (DYNACIRC CR), nifedipine (ADALAT CC, PROCARDIA XL), nisoldipine (SULAR), and verapamil (CALAN SR, ISOPTIN SR). The CCBs were compared to the older drugs: angiotensin converting enzyme (ACE) inhibitors such as enalapril (VASOTEC); the beta-blocking drugs, such as atenolol (TENORMIN); and the diuretics, or water pills, such as hydrochlorothiazide (HYDRODIURIL).

The meta-analysis included all comparative randomized clinical trials of CCBs in the treatment of hypertension published to date and considered all

major cardiovascular outcomes including heart failure, which is a significant complication of high blood pressure primarily affecting the elderly. No trials were excluded. The clinical trials that were eligible for inclusion in the meta-analysis had to meet the following four criteria: (1) the trial had to study 100 patients or more; (2) it had to compare CCBs to non-CCBs; (3) it had to assess cardiovascular events such as heart attack and stroke; and (4) it had to follow patients for two years or more. Altogether, the treatment results from more than 27,000 patients were analyzed.

A list of the nine trials and their acronyms can be found at the end of this article.

The results of the meta-analysis showed that in the CCB-treated patients compared to those receiving older non-CCB drugs, the risk of a heart attack was 27 percent higher, the risk of heart failure was 26 percent higher, and the risk of any major cardiovascular event was 11 percent greater. There was no difference in the risk of stroke or total mortality, and there was no evidence of differences among the CCBs studied.

These results should not be interpreted as showing that the CCBs are harmful; rather, they are less effective than the older alternatives in preventing heart attacks and heart failure.

The researchers estimated that as many as 85,000 unnecessary heart attacks and cases of heart failure may occur worldwide every year among the estimated 28 million users of long-acting CCBs. They arrived at this number by finding that the risk of either a heart attack or heart failure was 1.5 percent per year for those treated with a long-acting CCB. The risk for users of the older drugs was 1.2 percent per year. Among the estimated 28 million persons worldwide being treated with a CCB, there would be 420,000 heart attacks or cases of heart failure per year. Treatment with the older drugs would bring the number down to 335,000 per year, a difference of 85,000. The number for the U.S. alone is 40,000 per year.

The cost savings would be astronomical in the U.S. if just half the estimated 12.7 million users of long acting CCBs such as Procardia XL 60 milligrams were switched to a low-dose water pill such as hydrochlorothiazide 25 milligrams. Based on the retail prices for these drugs at a Washington D.C. chain pharmacy the savings would be \$5.9 billion per year. A lot of prescription drug coverage could be provided for this kind of money.

Despite recommendations first issued in 1993 and most recently in

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such as constipation, intestinal bloating and excess gas occur frequently, particularly with calcium carbonate. Switching calcium salts or increasing fluid intake may relieve these symptoms. Doses of calcium carbonate that are too high can lead to a change in the acidity of the blood (milk-alkali syndrome), kidney stones, and decreased kidney function.

Patients who form urinary tract

stones containing calcium are generally advised to avoid calcium supplements, but a calcium intake which is too low can aggravate the risk of stone formation. Calcium can interfere with the absorption of some other minerals and drugs including iron, zinc, drugs for osteoporosis in the same family as alendronate, and tetracycline antibiotics. Some natural calcium products such those derived from oyster shell may contain lead.

What You Can Do

You should buy only calcium supplements meeting USP standards.

Because there is little overall evidence that any calcium product is superior to another in preventing fractures from osteoporosis, you should purchase the least expensive product but make sure you are taking enough calcium, between your diet and any supplements, to meet your requirements.

When Is a Patient Group Not a Patient Group?

You may have recently noticed a sudden surge of interest in the once little-discussed infection, hepatitis C. Newspaper articles. Bus shelter ads. Bills in state legislatures. Phrases like "The Millennium Epidemic" and "The Silent Killer." Eleven state coalitions to build awareness about the disease. It's been difficult to miss.

And the disease is certainly both common and serious. More than 170 million people worldwide (4 million in the U.S. alone), particularly blood transfusion recipients, illicit-drug injectors and individuals with many sex partners are estimated to be infected and are at greatly increased risk for liver cirrhosis and cancer. Moreover, there is neither a cure nor a vaccine available or on the horizon.

But in modern America, whenever public interest in a topic appears to gather steam spontaneously, you are best advised to look under the nearest rock. You may be surprised to find lurking there an ad man manipulating public opinion for the sake of a client's bottom line.

Reporter Robert O'Harrow, Jr. of *The Washington Post* recently rolled over a few boulders and uncovered not only apparent genuine interest in the plight of patients with hepatitis C, but also a campaign orchestrated by ad agencies for the multinational pharmaceutical company Schering-Plough to raise the sales of Rebetrone, the company's drug for hepatitis C. Although Rebetrone is not a cure, it has been shown to benefit pa-

tients with active hepatitis C disease.

Here's how the campaign worked. The company hired a leading public relations agency called Shandwick International to form 11 state patient coalitions, each with a toll-free telephone number paid for by Schering. (Interestingly, Schering funds the coalitions out of its marketing branch, not its charitable branch.) Shandwick then helped prepare the scripts for the telephone operators and the "educational" materials sent out by the coalitions. Convergys Corporation, a telemarketing company in Utah, handles the phone calls and says it has a contract directly with Schering.

Whether Schering controlled the content of the "educational" materials is likely to prove critical. The Food and

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CALCIUM CHANNEL BLOCKERS, from page 3

1997 by the National Institutes of Health's National Heart, Lung, and Blood Institute that water pills and beta-blockers should be used first in the treatment of mild to moderate high blood pressure, the CCBs remain the largest selling family of high blood pressure lowering drugs in the U.S. These recommendations were based on well done clinical trials showing that water pills and beta-blockers reduced the risk of heart attack and stroke. Equivalent trials testing the CCBs have not been com-

pleted even though the CCBs have been on the market since the early 1980s.

In the absence of scientific evidence of benefit from the CCBs, why do they remain top sellers? The most likely explanation is that too many doctors base their prescribing decisions on drug company advertising and other promotion rather than on science. In other words, a drug company may be prescribing your drugs. Government and health care professionals must work harder to keep the big drug companies out of your medicine cabinet.

In 1995, Public Citizen's Health Re-

search Group filed a petition with the Food and Drug Administration (FDA) to add warnings to the labeling of all CCBs about the increased risk of heart attack and death. Our petition helped to bring about important labeling changes in February 1996 on one of the CCBs, the short-acting form of nifedipine. The labeling for this form of the drug now warns doctors that it should not be used for the treatment of high blood pressure.

The FDA should require that manufacturers of long-acting CCBs change their labeling to limit the use of these drugs to those patients who do not respond to or cannot tolerate the more effective and safer alternatives—water pills, beta-blockers, and ACE inhibitors.

What You Can Do

Do Not stop your high blood pressure medication without first talking to your doctor.

If you are not taking one of the older, more effective alternative drugs for the treatment of your high blood pressure, such as low-dose water pills, you should ask your doctor why not.

Study Included in the Meta-Analysis	Acronym
Appropriate Blood Pressure Control in Diabetes	ABCD
Cardiovascular Study in the Elderly	CASTEL
Fosinopril/Amlodipine Cardiovascular Trial	FACET
International Nifedipine GITS study	INSIGHT
Multicenter Isradipine/Diuretic Atherosclerosis Study	MIDAS
Nordic Diltiazem Study	NORDIL
National Intervention Cooperative Study in Elderly Hypertensives	NICS-EH
Swedish Trial of Older Patients - 2	STOP - 2
Verapamil in Hypertension and Atherosclerosis Study	VHAS

Product Recalls

September 7—October 11, 2000

DRUGS & DIETARY SUPPLEMENTS

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.

The recalls noted here reflect actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority. A Class I recall is a situation in which there is a reasonable probability that the use of or exposure to the product will cause serious adverse health consequences or death. Class II recalls may cause temporary or medically reversible adverse health consequences. A Class III situation is not likely to cause adverse health effects. If you have any of the drugs noted here, label them *Do Not Use* and put them in a secure place until you can return them to the place of purchase for a full refund. You can also contact the manufacturer. If you want to report an adverse drug reaction to the FDA, call (800) FDA-1088. The FDA web site is www.fda.gov.

Name of Drug or Supplement; Class of Recall; Problem

Aluminum Hydroxide Gel, Antacid, 320 mg/5mL, mint flavor, in 12 and 16-fluid ounce bottles; Class III; Resuspension problems

Augmentin Oral Suspension (Amoxicillin 400mg/Clavulanate Potassium 57 mg), 400 mg/5mL, in 100 mL multi-dose bottles; Class II; Subpotency of Clavulanic Acid (9 month stability station)

Carbamazepine Tablets, 200 mg, Rx; Class II; Label mix-up—A portion of the lot was labeled as tetracycline 500 mg

Cephadrine Capsules, 500 mg, 100-count bottles, Rx antibiotic; Class II; Subpotency (stability)

DesOwen Cream (Desonide Cream), 0.05%, 60g tube; Class III; Mislabeling—Shipping cases were incorrectly labeled as containing ointment not cream form of product

Glucose Tolerance Test Beverage, (Carbonate), Cola, Lemon Sour, and Orange Flavors, 100 gms D-Glucose, in 10-fluid ounce bottles, under the brand Qualadex, OTC used as a diagnostic test solution for diabetes testing; Class II; Subpotency

Headache Powder BC Brand (650 mg Aspirin, 195 mg Salicylamide, 33.3 Caffeine), packaged in 2's, 6's, 24's and 50's; Class III; Discoloring of glassine envelopes holding product

Homatropine Hydrobromide Ophthalmic Solution, 5% Dropperettes, 1 ml, Rx for treatment of iritis and diridocyclitis, for relief of cillary spasm, and also as an aid in refraction; Class III; Potency not within USP specifications (stability)

Lot #: Quantity and Distribution; Manufacturer

Lot Numbers 9113 and 9111; 14,359 bottles distributed nationwide; Pharmaceutical Associates, Inc., Greenville, South Carolina

Lot #MR2754 EXP 2/01; 59,940 units distributed nationwide; SmithKline Beecham Pharmaceuticals, Bristol, Tennessee

Lot #S302QJ EXP 10/31/01; 4,532 bottles distributed in Virginia; Pharmaceutical Corporation of America, Carmel, Indiana

Lot Numbers 57450 EXP 9/00 and 57988 EXP 6/01; 11,999 units distributed nationwide; Teva Pharmaceuticals USA, Fairfield, New Jersey

Lot #PGCN; 4,920 units in 410 shipping containers distributed nationwide; DPT Laboratories, Inc., San Antonio, Texas. Recalled by Galderma Laboratories LP, Fort Worth, Texas

All lots manufactured on or after August 1999; 44,231 bottles distributed in California; Irenda Corporation, Los Angeles, California. Recalled by Breen Labs, Los Angeles, California

Lot Numbers: M000580 through M000583, M000857 through M000866, M001703 through M001712, M002205 through M002214, M002771 through M002774, M002780, M002903 through M002912, M003265, M003390 through M003398, M003420, M003428 through M003437, M004001, M004049 through M004053; Over 516,940 distributed nationwide; Block Drug Company, Memphis, Tennessee

Lot Numbers W152 EXP 8/00, X2123 EXP 3/01, X2124 and X2125 EXP 8/01, X2126 and X2127 EXP 9/01, X2128 and X2129 EXP 10/01; 8,229 units distributed in Puerto Rico; OMJ Pharmaceuticals (OMJ), San German, Puerto Rico. Recalled by Ciba Vision Ophthalmic (CVO), Duluth, Georgia (distributor of finished product, responsible for labeling text)

D R U G S & D I E T A R Y S U P P L E M E N T S *cont.*

Name of Drug or Supplement; Class of Recall; Problem

Leukeran (chlorambucil) Tablets, 2 mg, in 50-count bottles, Rx; Class III; Impurity specification failure (stability)

Levsinex Capsules (hyoscyamine sulfate), 0/375 mg, Timecap Extended Release, Rx for treatment of peptic ulcer; Class III; Insert incorrectly states product has clear capsule body and contains beadlets, product actually has a white capsule body and contains a tablet

Nitroglycerin Sublingual Tablets, 0.4 mg, in 25 and 100-count amber glass bottles; Class II; Metal particle contamination

Non-Aspirin Pain Reliever Tablets (Target), in 500-count bottles, OTC pain reliever; Class II; Product mix-up—Presence of buffered aspirin (325 mg) in some bottles

SangCya Oral Solution (Cyclosporine Oral Solution), 100 mg/mL, Rx for prophylaxis of transplanted organ rejection, for rheumatoid arthritis, and for treatment of plaque psoriasis; Class II; Product is not bioequivalent when taken with apple juice

Tri-Nasal (triamcinolone acetonide) Nasal Spray, 50 mcg, 15 mL, 120 metered sprays, Rx for treatment of seasonal and perennial allergic rhinitis in adults and children older than 12 years of age; Class III; Leaking containers

Vicodin Tablets (hydrocodone bitartrate 5 mg and acetaminophen 500 mg), in 500 count bottles, Rx indicated for relief of moderate to moderately severe pain; Class III; Dissolution failure

Lot #: Quantity and Distribution; Manufacturer

Lot OA1387; 36,463 units distributed nationwide and in Canada; Glaxo Wellcome, Inc., Zebulon, North Carolina

Lot #02580K EXP 2002; 299 bottles distributed in New York; Schwarz Pharma, Seymour, Indiana. Recalled by Med-Pro, Inc., Lexington, Nebraska

Codes N419R1 and N419W1 (25 tablets each) and N459W1 (100 tablets); 30,336 bottles distributed in Pennsylvania; Konec Limited Liability Company, Tucson, Arizona

Lot #8N00527 EXP 11/01; 2,400 bottles distributed nationwide; Leiner Health Products, Inc., Kalamazoo, Michigan

Lot Numbers: 2MG69M EXP 06/01/99, 1NC30P EXP 01/01/00, 1NG00M EXP 04/01/00, 1NE00N EXP 03/01/00, 2MH05N, 2MH04N EXP 05/01/00, 2MH06M EXP 07/01/00, 2MH06MA EXP 01/01/01, 2MH07M, 2MH52M, 2MH53M EXP 08/01/00, 2MH07MA, 2MH52MA, 2MR63N, 2MR64N 02/01/01, 2ND22M, 2NE50M EXP 04/01/01, 2ND22MA EXP 10/01/01; 15,418 bottles distributed nationwide and internationally; Eli Lilly and Company, Indianapolis, Indiana. Recalled by SangStat Medical Corporation, Fremont, California

Lot Numbers: 00305 EXP 11/01, 00306 EXP 12/01, 00105, 00205, 00406 and 00506, all EXP 11/02 (physician samples); 134,138 units distributed nationwide; Muro Pharmaceutical, Inc., Tewksbury, Massachusetts

Lot Numbers 0044-0727-03 1076-0418, 0044-0727-03 1076-0428 and 0044-0727-03 1076-0438 (500 tablets) EXP 09/02; 8,222 bottles distributed nationwide; Knoll Pharmaceutical Company, Whippany, New Jersey

M E D I C A L D E V I C E S

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 1-800-FDA-1088. The FDA web site is <http://www.fda.gov>.

Name of Device; Class of Recall; Problem

Power Chairs; Class II; Chairs' controller program does not meet the original engineering specifications

Lot #: Quantity and Distribution; Manufacturer

Rascal Model Numbers RAS 545 and RAS 445 and Chauffeur Model Numbers P48, S45, X48, and X48E. Identified chairs are: PC004492, PC004493, PC004494, PC004501, PC004502, PC004508, PC004511, PC004527, PC004532, PC004534, PC004536, PC004552, PC004553, PC004555, PC004556, PC004579, JS004709; 17 chairs distributed; Electric Mobility Corporation, Sewell, New Jersey

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 1-800-638-2772. The CPSC web site is <http://www.cpsc.gov>.

Name of Product: Problem

All-Terrain Vehicles; Drive belts can break, and pieces of the belt can lock up the transmission, including the wheels, causing the vehicle to stop suddenly causing the operator to lose control of the vehicle

Baby Hammocks; Without spreader, hammocks can suddenly twist around childrens' necks and strangle them. Also, infants sleeping on soft bedding can become wedged in positions in which they cannot breathe

Camper Stoves; Stoves could have been shipped with butane already in the fuel compartment, posing a fire and burn hazard. Also, because of a possible problem with the fuel control mechanism, the stoves could flare up or catch fire when operated

Cigarette Lighters; Lighters do not have child-resistant mechanisms, as required by federal law

Cigarette Lighters; Lighters can burn with a high flame and can fail to extinguish, presenting fire and burn hazards

Extension Cords (Outdoor) and Cord Reels; Plastic housing of locking plug can separate or break, exposing users to live wires and shock and electrocution hazards

Fire Extinguishers; May fail to discharge when trigger is activated

Food Processors. Recall to repair; Cap on blade unit can dislodge during use and get mixed in with food, presenting a choking hazard

Lot #: Quantity and Distribution: Manufacturer

Prairie ATV 1997-1999 models KVF 300-A1, KVF 400-A1, KVF 400-A2/L, KVF 400-C1. 2000-2001 model Prairie ATVs have the new generation belt, but are included to provide an addendum to the owner manual and a warning label. These include models: KVF 300-A2, KVF 300-A3, KVF 400-C2, KVF 400-C3; 47,000 sold nationwide from September 1996 through August 2000; Kawasaki Motors Corp. U.S.A., Irvine, California (866) 802-9381

Model HA005 6 ft. hammocks woven from thin cotton strings with nylon end strings in solid or multi-stripped colors; 53 sold on the company's web site from January through April 2000; Call CPSC for information.

American Camper Compact Butane single burner stoves; 9,600 sold nationwide from May 1999 through July 2000; Zebco, Tulsa, Oklahoma (800) 558-9876

"BIC" oval tube-shaped and mini disposable; 294,000 sold in the eastern U.S. from January through April 2000; Vaid Enterprises, Jersey City, New Jersey (800) 638-2772

Oval disposable tube-shaped with "TURBO 2000" printed on the body; 350,000 sold nationwide from June 1999 through May 2000; Halpern Import Co. Inc., Atlanta, Georgia (800) 624-5280

2 or 3 prong plugs with words LOCK, WOODS(r), OPEN or LOCK, OPEN embedded on locking button. Cords sold under "Woods LockJaw(tm)" and "Yellow Jacket(r) LockJaw(tm)" brand names. Cord reels are 30 feet long, sold under "Woods' ACDelco" and "LumaPro" brand names; 500,000 cords and 19,000 cord reels sold nationwide from January 1996 through July 2000; Woods Industries Inc., Carmel, Indiana (888) 755-6535

First Alert model FE1A10G with serial numbers beginning with RH, RK, RL, RP, RT, RU, or RW; 600,000 sold nationwide from September 1999 through September 2000; BRK Brands Inc., Aurora, Illinois (866) 669-2736 http://www.firstalert.com/more_information/index.htm

Models Little Classic, 7-Cup Little Ultra Power and Ultra Power 5-cup and 7-cup names numbers beginning with KFP300, 4KFP300 and RRKFP300 (Little Classic), KFP350, 4KFP350 and RRKFP350 (Little Ultra Power) and KFP450 and RRKFP450 (Ultra Power). Serial numbers begin with WJG, WJH, WJI, WJJ, and WJK00 to WJK33; 220,000 sold nationwide from April 1997 through August 2000; KitchenAid Home Appliances, Benton Harbor, Michigan (866) 444-3574 <http://www.kitchenaid.com/fpblade/fpblade.htmls>

Name of Product; Problem

Hockey Face Guards; Can become dislodged on impact causing them to fall off, leaving the user's face exposed to possible injury

Hunting Treestands and Treeseats; Seats can collapse, causing the consumer to fall to the ground

Klackeroo Infant Toys; Brightly colored end knobs can detach and allow small, geometric-shaped pieces to come loose, posing a choking hazard to infants and young children

Mountain Bikes; Because some were not welded properly, the front suspension forks on these bicycles can break apart during use

Play Sets. Recall to replace swing chains; Chains can break while children are swinging and cause the swing seats to fall to the ground

Playground Swings. Recall for repair; The connectors, which attach the top bar to the end supports, can crack and the top bar can break off and hit children on the swings

Power Mowers; Due to wear caused by the mulch fan, mowers' blades can crack and break off. Broken pieces of the blade can be propelled from underneath the mower

Road Bikes and Handlebar Stems; Bolts on handlebar stems can break, resulting in handlebars detaching from the bike and causing riders to lose control and crash

Toy Bars. Recall for repair; One of the toys, a car, can break during use resulting in a small plastic part that poses a choking hazard to young children

Lot #: Quantity and Distribution; Manufacturer

Model FX50, "OPTECH System" written on black side clips. "ITECH" is written at the top center of the plastic eye shield, the chin guard and the chin guard strap; 1,000 sold nationwide from July through August 2000; I-Tech Sport Products Inc., Montreal, Canada (800) 361-5595

Treestand models Alum-I-Lok, Alum-I-Lok Magnum, Pro-Lock and Pro-Lok Magnum. Bobcat Treeseat model AL910; 54,000 sold nationwide from January 1999 through August 2000; API Outdoors, a division of Outland Sports Inc., Tallulah, Louisiana (888) 530-6098

Colored toy with orange plastic rods and small geometric shapes that move through a center purple ball; 550,000 sold nationwide from October 1997 through September 2000; Playskool, Pawtucket, Rhode Island (888) 671-9764

26-inch Vertical XL2 model 8526-26 manufactured in July 1999, and 24-inch and 26-inch Magna Electroshock models 8504-90, 8504-96, 8548-78 or 8548-94, manufactured July 1999 through October 1999; 24,800 sold at Target stores nationwide from August 1999 through February 2000; Dynacraft Industries Inc., San Rafael, California (800) 551-0032

All models of Rainbow Play Systems, covered in yellow or green vinyl; 7,000 sold nationwide from March through June 2000; Rainbow Play Systems Inc., Brookings, South Dakota (800) RAINBOW <http://www.rainbowplay.com/safetyrecall.html>

Aluminum 2-Seat Arch Swing, model 0288 and the Add-A-Bay Arch Swing, model 0375; 370 sold nationwide from February 1998 through May 2000; Playworld Systems, Lewisburg, Pennsylvania (800) 233-8404

2-cycle, walk-behind, 21-inch power mowers with serial numbers from 8900001 to 8999999, and one of the following model numbers: 10247, 10250, 10323, 10324, 10331, 10332, 10424, 10425, 10525, 10527, 10547, 10548; 102,000 sold nationwide from February 1998 through August 2000; Lawn-Boy Inc., Bloomington, Minnesota (800) 444-8676 <http://www.lawnboy.com/recall.htm>

1999 Trek (19 different models) and 1999 Klein Model Quantum, Quantum T and Quantum Race road bikes. Icon brand Havana and Bordeaux stems that measure 0.75-inch or 17mm to 20mm across front of top clamp; 13,600 bikes and 4,700 handlebar stems sold nationwide from June 1998 through May 1999; Trek Bicycle Corp., Waterloo, Wisconsin (800) 313-8735

Tiny Love Super Car-Bar, made of multicolor fabric. Three toys attach by Velcro fasteners onto the toy bar; 20,000 sold nationwide from August 1999 through August 2000; The Maya Group Inc., Garden Grove, California (888) 521-2202

Television and Obese Children: A Strong Connection

The more children and teenagers watch television, the more likely they are to be fat. That's what turned up when two Boston scientists analyzed data that was collected on almost 7000 youngsters, aged 6 to 11, and nearly 6700 between the ages of 12 and 17. (About 2000 of the participants were studied twice; once before they were 12 and again afterwards.)

As part of their study, William H. Dietz, Jr. of the New England Medical Center and Steven L. Gortmaker of the Harvard School of Public Health looked at a long list of possible reasons—other than time spent with the tube—that might explain why some of the youngsters in their sample were obese while others were of normal weight.

When checked out, however, none of these other variables—such as the race, sex, or family income of the youngsters, their other activities, the educational

level of their parents, or the season of the year—was as clearly linked to excess poundage as the number of hours the youngsters did, or did not, watch TV. For example, among the 12 to 17-year olds in the study, the chances of their being obese or super obese increased 2 percent for each additional hour per day of television viewed.

Writing in *Pediatrics*, the journal of the American Academy of Pediatrics, the study's authors note that time spent watching television often means that a youngster has less time for more strenuous activities that more efficiently burn up calories.

But it's not only that, they add. It's also that children who watch TV are very likely to snack at the same time on such high calorie products as sugared cereals, candy bars, cakes, cookies and soft drinks.

It is no surprise that a lot of these goodies are heavily advertised on the

very programs kids are most likely to watch or that, having seen these ads, many youngsters put pressure on their mothers or fathers to buy the foods the ads promote. But something else occurred to Dietz and Gortmaker that may be even more insidious.

That something else is that most of the stars on the prime time programs where there is food advertising, references to food, or both, are themselves slim. And why should this be a problem? Because, say Dietz and Gortmaker, it may indirectly suggest to children that eating and drinking high caloric foods is of little consequence with regard to weight. The authors conclude that the prevalence of obesity could be reduced, and that the disease could, in some cases, be prevented by a reduction in television viewing and an increase in other activities.

PATIENT GROUP, from page 4

Drug Administration has indicated that it will review the creation of these coalitions to determine whether the company stepped over the line separating education and promotion.

The company's efforts didn't stop at the creation of these pseudo-patient groups. The American Liver Foundation has received \$2.5 million over five years from Schering, and the company also mounted an over \$400,000 campaign to cover hepatitis C treatment for veterans. The company also funded a conference to raise awareness about occupational transmission of hepatitis C to health care workers.

Apparently, some of the coalitions and educational materials mentioned "educational grants" or "unrestricted educational grants" from Schering, but failed to disclose the extent of the company's control of these coalitions. Even Schering itself admitted to *The Washington Post* that the term "educational grant" was misleading. Shandwick promised that all coalition materials from now on would declare that they are "supported by seed funding from Schering-Plough Corporation."

While the educational materials did

not mention Rebetron directly, a spokesperson for Schering acknowledged that the company knows this to be unnecessary because Rebetron is the "gold standard" treatment for hepatitis C. Rebetron sales increased from \$363 million to \$586 million in the past two years.

One of the dangers of accepting money from Schering is that it will divert attention from hepatitis C prevention efforts (through blood screening, condom use and needle exchange programs) to the more profitable approach of testing for the infection and treating it once detected. Ironically, the company has been under fire from true patient advocacy groups for pricing its drug at \$18,000 per

year.

These deceptive practices are emblematic of a larger problem: the creation, usually by corporate interests, of groups masquerading as grassroots organizations. Recently, for example, Public Citizen's Congress Watch revealed the extent of drug company funding of Citizens for Better Medicare, ostensibly a community-based group, but actually in large part a front for the drug industry's opposition to a government-funded Medicare drug benefit. This practice has become so common it even has its own moniker: "grasstops" (as opposed to grassroots) or "astroturf" organizing.

The message is clear: beware of the grass, for often a snake lurks in it.

Sitting Backwards Is Safer

There are occasions when kids have more sense than their elders give them credit for. To judge by a report in the *American Journal of Public Health* choosing where to sit when using mass transit is one of them.

Many studies have found that in the event of a head-on crash, people are less

likely to be seriously injured if seated facing towards the rear. Knowing this, Alison M. Trinkhoff, a graduate student at the Johns Hopkins School of Hygiene and Public Health wondered if it was true, as is frequently assumed, that travelers prefer seats facing the other way.

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HRG Petitions the FDA To Ban Dangerous Diet and Cough/Cold Drug in Over-the-Counter Products

The following are excerpts from an October 19th petition to the Food and Drug Administration (FDA) Drug Center Director Dr. Janet Woodcock to ban phenylpropanolamine (PPA) found in more than 100 over-the-counter drug products such as the appetite suppressants *AcuTrim* and *Dexatrim* and cough/cold preparations such as *Contac*, *Robitussin CF*, *Alka-Seltzer Plus Cold Medicine*, *Coricidin D*, *Dimetapp Cold and Cough Liquigels* and many others.

We hereby petition the FDA for an immediate ban of all uses of phenylpropanolamine (PPA) in over-the-counter products (OTC) including as the active ingredient in appetite suppressants and as a decongestant in cough/cold preparations. As an over-the-counter drug ingredient, the only way PPA would be able to stay on the market would be if the FDA continues to believe that it is safe and effective. Abundant evidence from well over 100 published reports about the dangers of PPA, the current industry-funded Yale study that found “PPA increases the risk for hemorrhagic stroke,” and reports in FDA’s adverse reaction system of at least 51 cases of hemorrhagic stroke in PPA users make it clear the drug cannot be considered safe. In fact, FDA’s Office of Post-Marketing Drug Risk Assess-

ment (OPDRA) has concluded that “PPA should not be generally recognized as safe” and that Office has made a recommendation that “PPA containing appetite suppressants [and]...cough/cold remedies should no longer be available as over-the-counter products.”

In conversations and in public presentations you have stated that an important ongoing function for the FDA is to remove older, outmoded drugs when they no longer serve any unique purpose and when there is evidence of their danger. PPA is such a drug that has been available for at least 53 years if not longer. I completely agree with the continuing relevance of the 1979 advice from *The Medical Letter*, an independent periodical that evaluates drug therapy—“There is no good evidence that phenylpropanolamine...or any other drug can help obese patients achieve long-term weight reduction. The only satisfactory treatment for obesity is a life-long change in patterns of food intake and physical activity.”

The decongestant use of PPA, while effective, makes no sense because there are many safer, equally effective alternatives such as pseudoephedrine or, safer yet, nose sprays or drops used for no more than three days. PPA is clearly an older drug, which should be immediately removed from the market. I hope this will be accomplished as quickly as possible. The longer the

delay, the larger the toll of preventable strokes and other serious damage to the public.

The background for the recent, well-designed Yale epidemiological study that found “PPA increases the risk for hemorrhagic stroke,” includes a long history of published serious adverse events including hemorrhagic strokes attributed to PPA going back to 1979. These cases can be attributed to the drug because they usually occur shortly after ingestion of PPA and because of the lack of other plausible explanations, especially in otherwise healthy younger people.

Additionally, there has been evidence for the specific mechanism by which these PPA-induced cerebral hemorrhages occur. Both PPA and amphetamines are known to cause cerebral vasculitis, a severe inflammation of the blood vessels in the brain, which, in combination with the blood-pressure-raising effects of the drugs, can result in cerebral or subarachnoid brain hemorrhages and strokes. In addition to strokes, other serious adverse reactions attributed to PPA include acute psychosis, convulsions, acute renal failure, heart damage and hypertension.

Ten years ago, a review of published cases of adverse reactions attributed to PPA found 142 such cases in 85 different publications, including 24 in

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tracranial (cerebral or subarachnoid) hemorrhages, eight seizures, and eight deaths, most due to stroke. The most common adverse effects were symptoms compatible with acute hypertension, with severe headache the most frequent complaint. About two-thirds of all adverse reactions occurred in females and two-thirds in patients under 30.

Further information about PPA and strokes comes from FDA's spontaneous adverse reaction reporting system. With estimates that the percent of cases of OTC adverse drug reactions which are sent to the FDA are between 5 percent and 10 percent of those that actually occur, this total of at least 51 reported cases of hemorrhagic stroke may mean as many as 510 to 1020 cases have actually occurred in people using PPA-containing products.

PPA is just another example in a long history of many serious public health hazards caused by drugs or medical devices which were allowed to continue endangering people much longer than they should—after sufficient evidence for action was available—because of industry-funded nit-picking with the methodology of the studies, often case-control studies, such as the one being discussed today.

Other examples in which we pleaded the case for FDA action long before it was eventually taken include: aspirin and Reye's syndrome, hyperabsorbent tampons and toxic shock, DES and clear-cell vaginal cancer in DES daughters, and menopausal

estrogens and uterine cancer. Eventually, action to ban or restrict was taken in each of these instances but much later than it should have been.

Even without any case-control or other epidemiological study, in an even larger number of cases, the number and specificity of cases reports of serious drug-induced diseases including death was well documented. However, here too, bans or restrictions on use were delayed because of drug-industry (and its experts') attempts to deny or trivialize the causal role of the drugs and because of FDA delays in proper regulatory action. Examples of this include Rezulin, Duract, Propulsid, Posicor, Grepafloxacin, and Trovafloxacin, and the Bjork-Shiley heart valve.

It has been more than 20 years since the first alarms were raised about the dangers of PPA and about the fact that there is no evidence in the long term that diet drugs such as PPA actually help to lose and retain weight losses. A 1981 study found that people who were on a weight reduction drug (fenfluramine) alone or the drug combined with behavior therapy or behavior therapy alone lost comparable amounts of weight. But they found that behavior therapy alone patients regained significantly less than pharmacotherapy patients or those who had the combined treatment, suggesting

that the use of the drug actually retarded the beneficial effects of behavior therapy.

Many early researchers who investigated PPA commented that the drug should not be available over-the-counter. One group of researchers stated, in 1987, that "The over-the-counter availability of PPA-containing medications may be inappropriate and in need of revision, since it does not appear to be in keeping with current standards of public safety." Since then, hundreds or more American patients have suffered strokes, psychotic episodes, heart damage and other known adverse effects of PPA for no documented benefit in the long term.

In light of the voluminous medical literature documenting the life-threatening adverse effects of PPA such as hemorrhagic strokes and the confirmatory evidence of this in the industry-funded epidemiological study, it is not possible for PPA to remain in the OTC category of safe and effective (category I). Thus, since all of this evidence mandates and FDA's OPDRA has concluded, "PPA should not be generally recognized as safe," the only choice is to remove the drug from all OTC products. We hope this will be accomplished as quickly as possible. The longer the delay, the larger the toll of preventable strokes and other serious damage to the public.

On the day that Public Citizen petitioned the FDA to ban PPA, an FDA advisory committee voted almost unanimously that the drug was not safe and should be banned from all over-the counter products (appetite suppressants and nasal decongestants).

SITTING BACKWARDS, from page 9

To find out, Trinkhoff took to riding the Washington, DC Metropolitan Transit system—the subway in the nation's capital, familiarly known as the Metro—during hours when there was a choice of seats because ridership was light.

According to the data she collected

when traveling between 19 stations, 75 percent of the riders who were clearly at least 12 years old did, indeed, pick out forward-facing seats. On the other hand, 66 percent of the obviously younger travelers, if given the opportunity, made the opposite choice.

The take home lesson, suggests

Trinkhoff, is that school buses and airplanes could be made safer if, in addition to being fitted with seat belts, at least some of their seats were reversed. Even many adult travelers might be willing to change their seating habits, she says, if they realized the added margin of safety riding backwards can confer.

“Too Much Corporate Power”?

Try to guess the origin of the headline quoted above and the following statements that accompanied it in the publication of origin:

- Most Americans think corporations have excessive influence over their lives.
- After almost a decade of prosperity, there’s a feeling that the real thing that’s getting fatter is Corporate America’s bottom line. For the rest of us? Puny raises, crappy airline service and cheapskate HMOs.
- 72 percent of Americans say business has *TOO MUCH POWER*.
- A sense of corporate invasiveness in hitherto private portions of people’s lives is growing.
- Huge corporate campaign contributions foster an aura of political corruption undermining democracy.
- People feel overworked and underpaid, especially in contrast with their CEOs, who now make nearly 500 times the average employee’s wages...boards of directors must curb the insane leaps of CEO compensation.
- People increasingly feel threatened by the products and services sold by corporations.
- Corporate America, ignore these trends at your peril.
- First, get out of politics.
- Spreading the wealth is key too.

[Stock options] have helped tremendously, but only a minority of employees have them. Many more should get them.

Despite the tone and content, this is not the progressive/leftish rhetoric to be expected in handed-out, low circulation publications nor the statements of the few truly progressive members of Congress. This exhortation appeared in the biggest circulating business magazine in the world—a veritable Voice of Corporate America—*Business Week*—in its September 11th issue plastered with the one-inch headline which started this Outrage, *TOO MUCH CORPORATE POWER?*

Our answer is a thundering *YES*.

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