



## In the Public Interest — Abuses From the ‘Merchant Class’

*The following article was written by Ralph Nader. It has been reprinted with permission.*

There is a reason why, so many centuries ago, every major religion warned its adherents not to give too much power to the “merchant class.” That reason is still here — the commercial drive knows few self-imposed boundaries, especially when it resides in large corporations.

A cruel manifestation of this singular drive for maximizing profit is how companies treat those who are most powerless, most vulnerable or most preoccupied.

### Serious failures in law enforcement

1. Protecting pre-teen children. The direct marketing to children knows no limits of decency. Undermining parental authority with penetrating marketing schemes and temptations, companies deceptively excite youngsters to buy massive amounts of products that are bad for their safety, health and minds. Think junk food — loaded with fat, salt and sugar that increase obesity, diabetes and predisposition for high blood pressure.

Obesity produces sickness, death, disability and large medical bills.

Marketers also are selling ever

more violent entertainment and soft porn with delivery systems that escape parental review or supervision. Television is no longer the only route to

children. A 14-year-old, then-startling book — *Children First: a Parent's Guide to Corporate Predators* — now reads as an understatement.

2. Protecting the poor. Whether white, African-American, Hispanic or Native American, merchants make the poor pay more. Loan sharks, shoddy merchandise,

sub-standard food products and inadequate medical care have plagued the poor and been the subject of many studies and too few prosecutions.

3. People preoccupied by their bereavement often get preyed upon by the funeral industry. The Federal Trade Commission has an ample file on overcharges and deceptive practices from the unscrupulous merchants in that trade.

4. People with rare diseases often require so-called “orphan drugs.” Under a 1983 law, drug companies receive a seven-year monopoly with no price restraints on drugs. Drug companies also are given huge tax credits for research and development costs associated with orphan drugs.

*The Wall Street Journal*, in “How Drugs for Rare Diseases Became Lifeline for Companies,” published on Nov. 15, 2005, called these drugs “lucrative

niches.” With no competition, these monopoly drugs come with staggering prices for desperate patients.

5. Your tax dollars are being used for hyperprofiting corporate profits: Henry Blair was working on an experimental enzyme under government contract as a researcher at Tufts University Medical School. Working with scientists at the National Institutes of Health, they made the enzyme work as a treatment for Gaucher disease, which swells organs and deteriorates bones.

In 1981, Mr. Blair started Genzyme Corporation and got the government contract to make the enzyme, which he brought to market in 1991. The average price was — get this — \$200,000 a year per patient!

In 1992, the Congressional Office of Technology Assessment (OTA) (banished by Newt Gingrich in 1995) reported that Genzyme spent \$29.4 million on the drug, with much of the initial research funded and done by government scientists at the National Institutes of Health.

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*Editor*

Sidney M. Wolfe, M.D.

*Managing Editor*

Marina Harmon

*Contributor*

Sidney M. Wolfe, M.D.

*Graphic Designer*

James A. Decker

*Public Citizen President*

Robert Weissman

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Two years later, Genzyme found a much cheaper way of making the drug. Yet in 2005, *The Wall Street Journal* wrote that the Gaucher drug was still priced at \$200,000 per patient per year. The company says it gives the drug at no cost to about 10 percent of patients. The rest either rely on the insurance companies (good luck) or pay (or die).

6. The Health Uninsured are charged full price by hospitals, which *The Wall Street Journal* reported "is far more than the prices typically paid by insurance companies." This is the case, *The Journal* added, in spite of an annual taxpayer subsidy of \$22 billion to hospitals "to care for the uninsured."

7. Amputees who need prosthetic devices find that the devices in the United States (compared to other Western countries) are very highly priced. Health insurance companies make these products leading candidates for rising co-payments. This can mean tens of thousands of dollars from the patients or they are forced to go without their devices. These shocking co-payment requirements are often in the fine print.

Many of these devices also come

about with taxpayer-funded research and development. Profit margins are large because of the users' dire necessity to have them for mobility, for work and for human dignity.

8. Protecting low-credit-score credit card holders. The relentless credit card economy requires plastic to buy more and more things and services. The credit score becomes the hammer. A story recounted by MSNBC's Bob Sullivan in his engrossing new book, *Stop Getting Ripped Off*, describes: "the card promised an attractive 9.9% interest rate. But there was a catch buried in the fine print: account setup fee: \$29; program fee: \$95; annual fee: \$48; monthly servicing fee: \$84 annually; additional card fee: \$20 annually."

Then this clincher sentence: "If you are assigned the minimum credit limit of \$250, your initial available credit will be \$71 (\$51 if you select the additional-card option)."

No wonder the vendors call them "fee-harvesting" cards. Who needs loan sharks? These credit card vendors fleece the poor wearing a three-piece suit and sitting in air-conditioned skyscrapers.

Such is the fate of the poor or the vulnerable under the boot of commercial avarice. ♦



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# Television Leads to Obese Children

*The following article originally appeared in Health Letter 25 years ago, in the July/August 1985 issue. The data cited in this piece are therefore out of date. However, the article's focus on the connection between excessive television watching and childhood obesity is still pertinent today.*

*As you will see at the end of the article, we have added current information about TV and other media use and its link to obesity in children.*

**T**he 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 7,000 youngsters aged 6 to 11 and nearly 6,700 kids between the ages of 12 and 17 [in 1985]. (About 2,000 of the participants were studied twice; once before they were age 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 time of year or the children's race, sex, other activities, parents' income or parents' educational level — 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 superobese increased 2 percent for each additional hour per day of television viewed. [Figure is from 1985.]

Writing in the May [1985] issue of *Pediatrics*, the journal of the American Academy of Pediatrics, the study's authors note that more time spent

watching television often means that a youngster has less time for strenuous activities that more efficiently burn calories.

But it's not only that, the authors 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 either 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 parents 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."

## Current Information

In 2003, the American Medical Association (AMA) recommended that television viewing for children over age 2 be limited to two hours per day, and television viewing for children under age 2 be avoided altogether. However, according to a September 2010 article in *Pediatric Annals*, most U.S. families do not adhere to these recommendations.

These same researchers say that school-age children spend, on average, three to four hours per day watching television. And with newer media included (e.g., video games and computers), children's

actual time spent before a screen climbs to between five and seven hours daily.

Since 1985, many more studies have found that children who spend excessive time watching television (or using other screen media) are at increased risk for childhood obesity, and are therefore at increased risk for becoming obese adults. In fact, according to the same September 2010 *Pediatric Annals*, as the number of hours children spend watching television rises, so does their body fat percentage.

Childhood obesity is a U.S. epidemic and is expected to increase the rates of heart disease and other chronic medical problems such as hyperlipidemia, hyperinsulinemia (pre-diabetes), hypertension and early atherosclerosis (a condition in which an artery wall thickens as the result of a buildup of fatty materials such as cholesterol). It is important that parents are educated about this issue and put their children on healthy media diets from a young age.

In January 2008, *The ANNALS of the American Academy of Political and Social Science* published promising strategies for reducing the negative effects of media use on children's weight:

- Eliminate TV from children's bedrooms. Eliminating bedroom screen media may reduce overall screen time and may help to limit nighttime use that may interfere with children's healthy sleep.
- Encourage mindful viewing by monitoring screen media, budgeting TV time and fostering media literacy. Parents should collaborate with children on establishing appropriate amounts of screen media use and sharing and discussing the content to which children are exposed.
- Turn off the TV while eating. Separating food and TV viewing may increase awareness of food consumption, while also increasing family communication and decreasing total TV-watching time. ♦



# Nine Essential Steps for Regulating Your Blood Pressure

*The following article, by Erin Marcus, M.D., was originally published on [www.HuffingtonPost.com](http://www.HuffingtonPost.com) on Aug. 6, 2010. It has been reprinted with permission.*

When her gynecologist told her she had high blood pressure, Marie Alcindor had a simple solution: switch doctors. After all, she had gone to him for a different problem, and this was the first time he had ever checked her blood pressure. "He said, 'Oh my God, you're like a bomb waiting to explode,' and I said, 'I didn't come here for that, I came here for something else,'" she recalled.

Two years later, she went to see her general medical doctor, who was also a family friend. "He looked me dead in my face and said, 'I've known you since you were a teenager and you don't want to die. Would you like somebody to be wiping the dribble from your mouth? Would you like to walk with a dragging foot?'"

This time, she heeded her doctor's warning. She began the medications he prescribed, even though she didn't like taking pills. She also began making changes in her everyday life. These behavioral changes, or "lifestyle modifications," are recommended by the federal government's National High Blood Pressure Education Program (NHBPEP). The program also recommends these changes for people with "pre-hypertension," meaning blood pressure that's above normal but not yet in hypertensive range (120-139 for the top, or systolic, number, and 80-89 for the bottom, or diastolic, number).

Lifestyle changes alone aren't sufficient for many people with high blood pressure. But combined with medicine, they worked for Marie. After two years, her blood pressure is now in normal range, and she no longer needs pills. The headaches and shortness of breath that she used to experience have also resolved.

High blood pressure is rampant, and it's one of the most common reasons why people develop strokes, heart problems and kidney failure. It usually does its damage insidiously, and many people with high blood pressure don't have any symptoms until they have a stroke or heart trouble. Below are lifestyle modifications recommended by the National Heart, Lung and Blood Institute (NHLBI), as well as some behavioral changes that helped Marie. Note that while these changes are important, they are not a substitute for medication, if that's what your doctor recommends.

These changes not only improved Marie's health but also transformed other aspects of her life. She now works as a health educator for the University of Florida Extension Service and believes others can succeed at making these changes in their daily lives, if they are motivated. "I'm not only teaching it, I lived it," she said. "I'm not telling you anything I didn't experience myself."

## 1. Weight reduction

If you are overweight, getting your weight to a normal range is one of the most potent things you can do to lower your blood pressure, according to the NHBPEP. The NHBPEP recommends that people ideally get their weight down to normal range, which they define as a Body Mass Index (BMI) of 18.5 to 24.9. If that's not possible, even losing 10 pounds can help many overweight people lower their systolic blood pressure (the top number) by an average of five to 20 points (millimeters of mercury, to be exact).

The BMI is sometimes elevated in people who are very muscular. Heart disease risk is also affected by waist circumference, which should be less than 35 inches in women and less than 40 inches in men.

It's safest to aim for a weight loss of about one to two pounds a week. The

NHLBI advocates weight loss through a combination of increasing activity and restricting calories (about 1,000 to 1,200 daily for women, 1,200 to 1,600 daily for men, though this may vary if the person is heavier or very active). Specific foods to avoid include those with lots of sugar and saturated fat, such as high fat dairy products, lard, coconut and palm oil, processed meats, and ground beef. It's also crucial to limit the size of the portions you consume, and the NHLBI has a nice website illustrating how to do this (<http://hp2010.nhlbi.nih.gov/portion/index.htm>).

Marie lost 75 pounds by exercising and ending her lifelong habits of eating lunch at McDonald's and drinking soda. "It was like a wake-up call," she said. "I just did a 180."

## 2. Follow the DASH diet

The DASH diet consists of fruits, vegetables, low fat dairy products and foods that are low in fat. ("DASH" stands for "Dietary Approaches to Stop Hypertension.") According to the NHBPEP, adopting the DASH diet will drop systolic blood pressure about eight to 14 points on average. The DASH diet contains a lot of potassium, and people with kidney problems should check with their doctors before adopting it, since they are at risk of developing dangerously high potassium levels. Marie began cooking more fish and vegetables, and learned to include more vegetables and less oil in her favorite Bahamian dishes.

## 3. Restrict sodium

A recent column on [www.HuffingtonPost.com](http://www.HuffingtonPost.com), "10 Ways to Cut Sodium Without Sacrificing Flavor," offers advice on how to avoid sodium, an element that's in salt and is abundant in restaurant and in packaged food. According to the NHBPEP, lowering sodium intake to 2.4 grams a day (about 1 teaspoon of salt) will lower



systolic blood pressure by an average of two to eight points. For many people, following an even lower sodium diet — 1,600 mg combined with following the DASH diet — can be as effective at lowering blood pressure as a prescription medicine, according to the NHBPEP.

#### **4. Get aerobic physical activity**

Brisk walking, or some other regular aerobic physical activity, at least 30 minutes per day, will lower systolic blood pressure by four to nine points on average, according to the NHBPEP. After getting her heart checked by her doctor, Marie began walking for 30 to 45 minutes every day. She also increased her walking by parking in a more distant space at the grocery store.

#### **5. Limit alcohol consumption**

For men, this means no more than two drinks a day, and for women, no more than one drink a day. (A drink is one 12-ounce beer, 5-ounce glass of wine, or 1.5 ounces of whiskey.) The

NHBPEP says this will lower systolic pressure by two to four points on average.

#### **6. Don't smoke**

Smoking can trigger heart problems, and the combination of smoking and high blood pressure is dangerous. It is never too late to start trying to quit, and most smokers who succeed have made multiple attempts. Check out the resources listed on the Centers for Disease Control ([www.cdc.gov](http://www.cdc.gov)) and American Lung Association ([www.lungusa.org](http://www.lungusa.org)) websites for help.

#### **7. Learn to manage how you respond to stressful situations**

There's good clinical evidence that people who respond angrily to stressful situations are more likely to develop heart problems. Marie said she used to have tantrums before when she got frustrated, but now she takes life one day at a time. "You can't change things, so you have to relax and let it go," she said.

#### **8. Keep track of your blood pressure**

Many fire departments will check blood pressure for free, either at regular screening sessions or on a drop-in basis. Check with your local department. The National Heart Lung and Blood Institute offers a useful card for keeping track ([www.nhlbi.nih.gov](http://www.nhlbi.nih.gov)).

#### **9. Don't skip your medications**

Of all the medications doctors prescribe, blood pressure medicine is one of the most immediately important. Skipping a dose on your own can be dangerous. If you're having side effects, call your doctor or nurse practitioner right away. It's also important to tell them if you're worried you can't afford your prescriptions, since many highly effective, first-line blood pressure medicines are available in generic form, at a relatively low cost. ♦



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# Product Recalls

## August 18, 2010 - September 29, 2010

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

### DRUGS AND DIETARY SUPPLEMENTS

## Recalls and Field Corrections: Drugs – Class II

Indicates a problem that may cause temporary or reversible health effects; unlikely to cause serious injury or death

#### **Adderall XR (Mixed Salts of a Single-Entity Amphetamine)**

**Extended-Release Capsules**, 5 mg, 100-count bottle, Rx only. Lot #s: A56222A, exp. date 09/2013; A57502A, exp. date 11/2013. DSM Pharmaceuticals, Inc.

#### **Altace (Ramipril) Capsules**, 2.5 mg, 100-count bottle, Rx only.

Volume of product in commerce: 16,382 bottles. Subpotent (single-ingredient drug): stability samples found that this product was subpotent at the 6-month time point. Lot #: 57425, exp. date 10/2012. King Pharmaceuticals, Inc.

**Anastrozole Tablets**, 1 mg, 30-tablet HDPE bottle, Rx only. Volume of product in commerce: 7,192 bottles. Cross contamination with other products: a potential for some foreign tablets to be in bottles of anastrozole tablets. Lot #s: 870AF0010, 870AF00201, exp. date 05/2012. Fresenius Kabi Oncology Ltd.

**APS Coumadin (Warfarin Sodium Tablets USP) Crystalline**, 1 mg, 100 UD. Volume of product in commerce: 244 units. This sub-recall was initiated to comply with Bristol-Myers Squibb recall (dated June 25, 2010) that determined that some tablets, over time, may not meet specifications for isopropanol, which is required to maintain the active ingredient in a crystalline state. Lot #s: 084982, 090200, 090300, 090468, exp. date 06/2011; 093585, exp. date 12/2011; 095406, 097000, exp. date 01/2012; 100165, 100585, exp. date 06/2012, 101565, exp. date 11/2012. Bristol Myers Squibb Holdings Pharma., Ltd.

**Arthrotec (Diclofenac Sodium/Misoprostol) Tablets**, 50 mg/200 mcg, 75 mg/200 mcg, 60-count bottle, 90-count bottle, Rx only. Volume of product in commerce: 160,300 bottles. Tablet separation: this product may contain broken tablets. Lot #s: C080071, exp. date 07/2011; C090149, exp. date 09/2012; C090972, exp. date 02/2013. Pfizer U.S. Pharmaceutical Group.

**Azathioprine Tablets USP**, 50 mg, 100-tablet bottles, Rx only. Volume of product in commerce: 647,057 bottles. CGMP deviations: failure to fully investigate dissolution problems prior to releasing product. Multiple lots. Sandoz, Inc.

**Benazepril Hydrochloride Tablets**, 5mg, 100-count bottles, Rx only. Volume of product in commerce: unknown. CGMP deviations: some products manufactured prior to August 2009 used API and raw materials that had passed the vendor's suggested expiration date. Lot #: HX5819, exp. date 07/2010. Apotex, Inc.

**Carbidopa and Levodopa Extended-Release Tablets**, 25/100 mg, 50/200 mg, 100-count bottle, Rx only. Volume of product in commerce: unknown. CGMP deviations: CGMP violations may have resulted in product cross contamination. Multiple lots. Apotex, Inc.

**Citalopram HBr Tablets**, 40 mg, 100-count bottles, Rx only. Volume of product in commerce: unknown. CGMP deviations: some products manufactured prior to August 2009 used API and raw materials that had passed the vendor's suggested expiration date. Lot #: JH2204, exp. date 07/2011. Apotex, Inc.

**Citalopram Tablets USP**, 40 mg, 1,000-tablet bottles, Rx only. Volume of product in commerce: 1,462 bottles. Superpotent (single-ingredient drug): oversized tablets found. Lot #: 11004340, exp. date 03/2012. Apotex, Inc.

**Clonazepam Tablets USP**, 0.5 mg, 2 mg, 100-count bottle, 500-count bottle, Rx only. Volume of product in commerce: unknown. CGMP deviations: CGMP violations may have resulted in product cross contamination. Lot #s: HX8305, HY6874, HY6870, HY6871, exp. date 08/2010; JE7102, JE7105, JE7406, JE7525, exp. date 04/2011; HX8306, exp. date 08/2010. Apotex, Inc.

**Coumadin (Warfarin Sodium Tablets USP) Crystalline**, 1 mg, hospital-unit dose blister pack of 100, sample blisters of 10, Rx only. Volume of product in commerce: 144,762 units. Some tablets may not meet specification for isopropanol, which is required to maintain the active ingredient in a crystalline state. The firm's medical assessment indicates that the use of tablets with low isopropanol could, in some cases, potentially lead to patient-to-patient variation in bioavailability. Lot #s: 8F34006B, exp. date 06/2011; 8K44272A, exp. date 12/2011; 8K46168A, 9A48931A, 9A48931B, 9A48931C, exp. date 01/2012; 9F4437A, exp. date 06/2012; 9K58012B, exp. date 11/2012. Bristol Myers Squibb Holdings Pharma., Ltd.



## DRUGS AND DIETARY SUPPLEMENTS

**CycloSPORINE Capsules USP**, 25 mg, 100 mg, 30-count bottle, Rx only. Volume of product in commerce: unknown. CGMP deviations: CGMP violations may have resulted in product cross contamination. Lot #s: HP9576, HW5445, exp. date 05/2010; HY6968, HY6969, exp. date 08/2010; JD6291, exp. date 03/2011; JE8040, exp. date 04/2011; HW5450, exp. date 05/2010; HY6964, JC0283, exp. date 08/2010; JD6290, exp. date 03/2011. Apotex, Inc.

**Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate (Mixed Salts of a Single-Entity Amphetamine Product) Extended-Release Capsules**, 5 mg, 10 mg, 100-count bottle, Rx only. Lot #s: A55529B, exp. date 03/2013; A55700A, exp. date 04/2013; A55701A, exp. date 07/2013; A57636A, A56189A, A57635B, exp. date 11/2013. DSM Pharmaceuticals, Inc.

**Diclofenac Potassium Tablets**, 50 mg, 100-count bottle, Rx only. Volume of product in commerce: unknown. CGMP deviations: CGMP violations may have resulted in product cross contamination. Lot #s: HX3581, HZ4734, exp. date 09/2010; HZ4735, JD1676, exp. date 01/2011. Apotex, Inc.

**DILT-CD, DILTZAC (Diltiazem Hydrochloride) Extended-Release Capsules USP**, (once-a-day dosage), 120 mg, 180 mg, 240 mg, 300 mg, 360 mg, 30-count bottle, 90-count bottle, 500-count bottle, Rx only. Volume of product in commerce: unknown. CGMP deviations: CGMP violations may have resulted in product cross contamination. Multiple lots. Apotex, Inc.

**DILT-XR (Diltiazem Hydrochloride) Extended-Release Capsules USP**, (once-a-day dosage), 180 mg, 240 mg, 100-count bottle, 500-count bottle, Rx only. Volume of product in commerce: unknown. CGMP deviations: some products manufactured prior to August 2009 used API and raw materials that had passed the vendor's suggested expiration date. Lot #s: HW4437, HY3540, HW4435, HY3541, HY3576, exp. date 09/2010. Apotex, Inc.

**Diovan HCT® Valsartan and Hydrochlorothiazide USP**, 320 mg/12.5 mg, 90-tablet bottle, Rx only. Volume of product in commerce: 15,835 bottles. Labeling mix-up: bottles labeled to contain Diovan HCT 320/12.5 mg tablets actually contained Diovan HCT 320/25 mg tablets. Lot #: F0130, exp. date 04/2012. Novartis Pharmaceutical Corp.

**Divalproex Sodium Delayed-Release Tablets USP**, 125 mg, 250 mg, 100-count bottle, 500-count bottle, Rx only. Volume of product in commerce: unknown. CGMP deviations: CGMP violations may have resulted in product cross contamination. Multiple lots. Apotex, Inc.

**Eplerenone Tablets**, 25 mg, 50 mg, 30-count bottle, 90-count bottle, 500-count bottle, Rx only. Volume of product in commerce: unknown. CGMP deviations: CGMP violations may have resulted in product cross contamination. Lot #s: HW0774, exp. date 10/2010; JC6593, JC9429, JC6601, JC9477, JC6604, JC9428, HY7640, exp. date 03/2011; JH2193, JH2190, JF4992, exp. date 06/2011. Apotex, Inc.

**Gemfibrozil Tablets USP**, 600 mg, 500-count bottles, Rx only. Volume of product in commerce: unknown. CGMP deviations: some products manufactured prior to August 2009 used API and raw materials that had passed the vendor's suggested expiration date. Lot #s: JD4444, JD4448, exp. date 04/2011. Apotex, Inc.

**Isosorbide Dinitrate Extended-Release Tablets USP**, 40 mg, 100-count bottle, Rx only. Volume of product in commerce: 9,804 bottles. Failed USP dissolution test requirements: out of specification results for dissolution at the nine-month time test interval. Lot #: 101937, exp. date 08/2011. Corepharma, LLC.

**Loratadine Orally Disintegrating Tablets**, distributed under the following labels: 1) CareOne Allergy Relief, 10-tablet-count box, 24-tablet-count box; 2) Good Neighbor Pharmacy, Allergy Relief, 10-tablet-count box, 12-tablet-count box; 3) H.E.B. Allergy Relief, 10-tablet-count box; 4) HyVee Allergy Relief, 12-tablet-count box, 24-tablet-count box; 5) American Fare Allergy Relief, 12-tablet-count box; 6) Leader Allergy Relief, 12-tablet-count box, 48-tablet-count box; 7) CVS Allergy Relief, 10-tablet-count box; 8) Sunmark Allergy Relief, 10-tablet-count box, 12-tablet-count box, 24-tablet-count box; 9) Rite Aid Loratadine, 30-tablet-count box; 10) Equaline Allergy Relief, 30-tablet-count box; 11) TopCare Allergy Relief, 10-tablet-count box, 12-tablet-count box, 24-tablet-count box; 12) Wal-Itin Aller-melts, 10-tablet-count box, 30-tablet-count box; 13) GoodSense Allergy Relief, 12-tablet-count box. Volume of product in commerce: 67,692 cartons. Stability data does not support expiration date: product failed stability test results at the 6-month time point. Lot #s: OBE1651, OBE1653, OBE1929, 9LE2445, 9LE2603, OAE1957, exp. date 05/2011. Watson Laboratories, Inc.

**Loratadine Tablets USP**, 10 mg, antihistamine, 100-count bottle, 1000-count bottle. Volume of product in commerce: unknown. CGMP deviations: some products manufactured prior to August 2009 used API and raw materials that had passed the vendor's suggested expiration date. Lot #s: HX8178, HY3556, exp. date 07/2010; JA9708, JA9709, exp. date 11/2010. Apotex, Inc.

**Lovastatin Tablets USP**, 10 mg, 20 mg, 40 mg, 60-count bottle, Rx only. Volume of product in commerce: unknown. CGMP deviations: some products manufactured prior to August 2009 used API and raw materials that had passed the vendor's suggested expiration date. Lot #s: JF0662, JF0660, JF0664, exp. date 05/2011. Apotex, Inc.



## DRUGS AND DIETARY SUPPLEMENTS

**Moexipril Hydrochloride Tablets**, 7.5 mg, 15 mg, 100-count bottle, Rx only. Volume of product in commerce: unknown. CGMP deviations: CGMP violations may have resulted in product cross contamination. Lot #s: JD7716, JD7717, exp. date 03/2011. Apotex, Inc.

**Nizatidine Capsules USP**, 150 mg, 300 mg, 30-count bottle, 60-count bottle, Rx only. Volume of product in commerce: unknown. CGMP deviations: some products manufactured prior to August 2009 used API and raw materials that had passed the vendor's suggested expiry. Lot #s: JC8097, JC8098, exp. date 02/2011. Apotex, Inc.

**Omeprazole Delayed-Release Capsules USP**, 10 mg, 20 mg, 40 mg, 30-count bottle, 90-count bottle, 100-count bottle, 500-count bottle, 1000-count bottle, 5000-count bottle, 100-count carton (10 x 10 unit dose), Rx only. Volume of product in commerce: unknown. CGMP deviations: CGMP violations may have resulted in product cross contamination. Multiple lots. Apotex, Inc.

**Ondansetron Hydrochloride Tablets**, 4 mg, 8 mg, 30-count bottle, Rx only. Volume of product in commerce: unknown. CGMP deviations: CGMP violations may have resulted in product cross contamination. Lot #s: HP9522, HX5296, JA3653, HP9549, HP9552, exp. date 07/2010. Apotex, Inc.

**Prilosec Omeprazole Delayed-Release Capsules USP**, 20 mg, 100UD. Volume of product in commerce: 52,791 units. GMP deviations (by manufacturer). Lot #s: 083321, 083132, exp. date 06/2010; 091476, 090656, exp. date 11/2010; 083150, exp. date 12/2010; 083150A, 092327, exp. date 01/2011; 093318, exp. date 02/2011. Apotex, Inc.

**Pepcid Complete (Famotidine, Calcium Carbonate, Magnesium Hydroxide) Tablets**, 10 mg, 800 mg, 165 mg; 50 tropical fruit flavor chewable tablets, bottle. Volume of product in commerce: 15,264

bottles. Defective container: a small number of bottles have been punctured at the bottom edge during the packaging process. Lot #: BEF062, exp. date 05/2013. McNeil Healthcare, LLC.

**Pepcid AC (Famotidine) Tablets**, 10 mg, 90-count bottle. Volume of product in commerce: 360 bottles. Defective container: a small number of bottles have been punctured at the bottom edge during the packaging process. Lot #: BFF010, exp. date 11/2012. McNeil Healthcare, LLC.

**Potassium Citrate Extended-Release Tablets USP**, 1,080 mg, 100-count bottle, Rx only. Volume of product in commerce: 3,514 bottles. Failed USP dissolution test requirements: out of specification value for dissolution at the three-month stability test interval. Lot #: 104238, exp. date 04/2012. Corepharma, LLC.

**Stomach Relief Tablets**, Bismuth Subsalicylate, 262 mg, 30 chewable tablets, distributed under the following labels: GoodSense Stomach Relief Tablets Chewables, Kroger Chewables Stomach Relief, TopCare Stomach Relief Chewables, Equaline Chewables Stomach Relief, Stomach Relief, HEB Stomach Relief, Meijer Stomach Relief Tabs, Chewable Tablets Stomach Relief, Leader Chewables Pink Bismuth, Hannaford Chewables Stomach Relief, Sunmark Stomach Relief Tablets, Hy-Vee Chewables Stomach Relief Tablets, Giant Eagle Chewable Stomach Relief Tablets, Longs Wellness Chewable Tablets Stomach Relief, Publix Stomach Relief Chewable, CareOne Stomach Relief. Volume of product in commerce: 1,431,887. Label lacks warning: the label does not include the required calcium content warning statements. Multiple lots. L. Perrigo Co.

**Terazosin Hydrochloride Capsules**, 1 mg, 100-count bottle, 500-count bottle, Rx only. Volume of product in commerce: unknown. CGMP deviations: some products manufactured prior to August 2009 used API and raw materials that had passed the vendor's suggested expiration date. Lot #s: JE0404, JE0403, exp. date 04/2011. Apotex,

## CONSUMER PRODUCTS

Contact the Consumer Product Safety Commission (CPSC) for specific instructions or return the item to the place of purchase for a refund. For additional information from the Consumer Product Safety Commission, call its hotline at (800) 638-2772. The CPSC website is [www.cpsc.gov](http://www.cpsc.gov). Visit [www.recalls.gov](http://www.recalls.gov) for information about FDA recalls and recalls issued by other government agencies.

### Name of Product; Problem; Recall Information

**20" Glass Vases.** The glass vases can break or fracture, posing a laceration hazard to consumers. The Gerson Company, (877) 461-6298 or [www.gersoncompany.com](http://www.gersoncompany.com).

**Asurion Counterfeit BlackBerry-Branded Cell Phone Batteries in Refurbished Devices.** The counterfeit batteries can overheat, posing burn hazards. Asurion, (866) 384-9175 or [www.001batex.com](http://www.001batex.com).

**Bamboo Roll-Up Blinds with Valence.** Strangulation can occur when the lifting loop slides off the side of the blind and a child's neck becomes entangled on the free-standing loop, or if a child places his/her neck between the lifting loop and the roll-up blind material. Jo-Ann Fabric and Craft Stores, (888) 739-4120 or [www.joann.com](http://www.joann.com).



## CONSUMER PRODUCTS

**Beaba Express Steam Baby Bottle Warmers.** The bottle warmers can overheat liquids and baby food, posing a burn hazard to adults and babies. Williams-Sonoma, Inc., (877) 548-0850 or [www.williams-sonoma.com](http://www.williams-sonoma.com).

**Bella Kitchen Slow Cookers.** The slow cooker's control panel can overheat and melt, posing a fire hazard. Sensio, Inc., (888) 296-9675 or [www.acbpromotions.com/sensiorecall](http://www.acbpromotions.com/sensiorecall).

**Black & Decker and Craftsman Cordless Electric Lawnmowers.** The lawnmower's motor and blade can unexpectedly turn on after the mower's safety key is removed, posing a laceration hazard to consumers. Removing the safety key is designed to keep this from occurring. Black & Decker (U.S.), Inc., (866) 229-5570 or [www.blackanddecker.com](http://www.blackanddecker.com).

**Black & Decker Random Orbit Sanders.** The black plastic disc (called the platen) that holds the sandpaper can fly off or break apart during use and the disc, or pieces of the disc, can hit the user or those nearby, posing a laceration hazard. Black & Decker (U.S.), Inc., (866) 220-1767 or [www.blackanddecker.com](http://www.blackanddecker.com).

**Brigade Hickory Handle Sledge Hammers.** The head of the sledge hammer can loosen and detach, posing a risk of impact injury to consumers. White Cap Construction Supply, Inc., (877) 281-4831 or [www.whitecap.com](http://www.whitecap.com).

**Char-Broil Vertical Gas Smoker.** When the temperature setting is "low," the smoker's hose/valve/regulator (HVR) assembly does not allow sufficient gas to flow, causing the flame to extinguish. Gas continues to flow and build up inside the smoker. If the smoker is reignited the build-up of propane gas can cause an explosion that bursts the smoker's door open, posing an injury hazard. Char-Broil, LLC, (866) 671-7988 or [www.charbroil.com](http://www.charbroil.com).

**Chuck E Cheese's Light-Up Rings and Star Glasses.** If crushed or pulled apart, the plastic casing can break into small pieces and possibly expose the batteries, posing an ingestion hazard to children. If ingested, the batteries may be damaging to the stomach, intestine, esophagus or nasal mucus membrane. CEC Entertainment, Inc., (888) 778-7193 or [www.chuckecheese.com](http://www.chuckecheese.com).

**Click Armband Bracelets, Klick Klick Balls and BoBo Balls.** The small balls on the end of the toy's arms can detach, posing a choking hazard to young children. The toys were marketed for children age 3 and over. CPSC staff has designated these toys for children between the ages of 19 to 35 months. Fun Stuff, Inc., (888) 386-7833 or [www.funstuffinc.net](http://www.funstuffinc.net).

**Coleman® WaterBeam™ 4D Water-Activated Floating Spotlights.** The lens assembly can come apart from the main housing of the spotlight with force and pose a risk of impact injuries to consumers. The Coleman Company, Inc., (800) 835-3278 or [www.coleman.com](http://www.coleman.com).

**Electroluminescent Night Lights.** The night lights can become hot to the touch and melt, resulting in risk of possible shock or fire. Molenaar, LLC, (877) 719-4442 or [www.miline.com](http://www.miline.com).

**FIXIT One Million Candlepower Rechargeable Spotlights.** The spotlight's charging adapter can overcharge the battery, forcing it to rupture and leak battery acid. This poses a chemical burn hazard to consumers. Innovage, LLC, (888) 408-1140 or [www.spotlightrecall.org](http://www.spotlightrecall.org).

**"Flourish" Tea Sets.** Sparking from the metallic decorations can result if used in a microwave oven, posing a risk of fire. International Coffee & Tea, LLC, (800) 832-5323 or [www.coffeebean.com](http://www.coffeebean.com).

**Giant Starbuilders and Giant Stars Building Sets.** Plastic knobs can break from the center of the star, posing a choking hazard to children. Edushape Ltd., (800) 404-4744 or [www.edushape.com](http://www.edushape.com).

**Hooded Jackets and Sweatshirts.** The hooded jackets and sweatshirts have drawstrings through the hood and/or waist that can pose a strangulation or entrapment hazard to children. In February 1996, CPSC issued guidelines to help prevent children from strangling or getting entangled on the neck and waist drawstrings in upper garments, such as jackets and sweatshirts. Burlington Coat Factory, (888) 223-2628 or [www.burlingtoncoatfactory.com](http://www.burlingtoncoatfactory.com).

**Infant and Toddler Hammock Metal Stands.** The C-shaped metal stand can break where the curved arm attaches to the leg of the metal frame, posing a fall hazard to an infant in the hammock. MamaLittleHelper, LLC, (866) 612-9986 or [www.mamalittlehelper.com](http://www.mamalittlehelper.com).

**Infant and Toddler Hammocks.** The side-to-side shifting or tilting of the hammock can cause the infant to roll and become entrapped or wedged against the hammock's fabric and/or mattress pad, resulting in a suffocation hazard. MamaLittleHelper, LLC, (866) 612-9986 or [www.mamalittlehelper.com/recall.htm](http://www.mamalittlehelper.com/recall.htm).

**"Love Tester" Mood Rings and Necklaces.** The metal rings and necklaces contain high levels of lead. Lead is toxic if ingested by young children and can cause adverse health effects. D&D Distributing-Wholesale, Inc., (800) 262-9435 or [www.dddist.com](http://www.dddist.com).



## CONSUMER PRODUCTS

**Magnetic Maze Boards.** The magnetic maze board's plastic wand can separate and expose a magnet that can be a choking hazard to children. Also, if a child has more than one of these toys and the magnets detach and are swallowed, the magnets can attract each other and cause intestinal perforations or blockages, which can be fatal. Lakeshore Learning Materials, (800) 428-4414 or [www.lakeshorelearning.com](http://www.lakeshorelearning.com).

**Paradigm Cinema 70 CT Subwoofers.** The subwoofer can overheat when the speaker system is played at high outputs for an extended period of time, posing a fire hazard to consumers. Paradigm Electronics, (877) 419-1994 or [www.paradigm.com](http://www.paradigm.com).

**"Play With Your Veggies" Toys.** The metal wire in the toy asparagus can become exposed, posing a laceration hazard to children. The Land of Nod, (800) 933-9904 or [www.landofnod.com](http://www.landofnod.com).

**Quickie® Shark Bikes.** The custom footrests can break, posing a risk of injury to the rider. Sunrise Medical (U.S.), LLC, (888) 208-4901 or [www.sunrisemedical.com](http://www.sunrisemedical.com).

**Sand and Water Transportation Station Toys.** The light blue plastic wheels on the train cars can detach, posing a choking hazard to young children. Step2 Company, (800) 347-8372 or [www.step2.com](http://www.step2.com).

**Sanus Vision Flat-Screen Television Wall Mount.** The elbow joint components on the wall mount's arm do not fit together properly, causing the attached television to tilt and possibly fall when the television is adjusted. This could pose an injury hazard to a consumer. Milestone AV Technologies, LLC, (877) 894-6280 or [www.milestone.com/recall](http://www.milestone.com/recall).

**Sharp 32-Inch LCD- TVs.** The TV's neck support can break and cause the TV to tip-over, posing a risk of injury to the consumer. Sharp Electronics Corp., (800) 291-4289 or [www.sharppusa.com](http://www.sharppusa.com).

**Siemens and Murray Circuit Breakers, Load Centers and Meter Combos.** The recalled circuit breakers have a spring clip that can break during normal use, leading to a loss of force to maintain a proper electrical connection in the panelboard. This can lead to excessive temperature, arcing or thermal damage at the connection point, and damage to the panelboard's electrical insulation, and can result in a fire, property damage, or personal injury. Siemens Industry, Inc., (800) 756-6996 or [www.usa.siemens.com](http://www.usa.siemens.com).

**Simms Fishing Wading Staffs.** The wading staff can collapse posing a fall hazard to consumers. Simms Fishing Products, (877) 789-6555 or [www.simmsfishing.com](http://www.simmsfishing.com).

**Sorelle "Prescott" Fixed-Sided Cribs.** These cribs are re-labeled fixed-sided Simplicity cribs that contain tubular metal mattress-support frames recalled in April 2010. The mattress support frames can bend or detach, causing part of the mattress to drop, creating a space into which an infant or toddler can become wedged, entrapped or fall out of the crib. Albee Baby, (877) 692-5233 or [www.albeebaby.com](http://www.albeebaby.com).

**Spektrum Receivers Used with Model Airplane Gliders.** The receiver can lose contact with the model airplane glider's radio control while within normal radio range limits. If this happens, the glider can fall from the sky and hit consumers, posing a risk of injury. Horizon Hobby, Inc., (877) 504-0233 or [www.horizonhobby.com](http://www.horizonhobby.com).

**"STUFF" and Paw Wall Hooks.** Paint on the metal hooks and on the blue paw hook contains excessive levels of lead, violating the federal lead paint standard. Midwest-CBK, Inc., (800) 422-5583.

**THHN Electrical Wire.** While the actual electrical wire has "14 gauge" printed on it, the packaging incorrectly labels the electrical wire as 12 gauge. If used as a 12 gauge wire, it can overload, posing a fire hazard to consumers. Cerro Wire, Inc., (866) 572-3776 ext. 269 or [www.cerrowire.com](http://www.cerrowire.com).

**"To Fro" Model Swing Sets.** The joint connection between the horizontal top beam and the vertical end bracket and support post system can crack and break, posing a fall and impact hazard to users. Kompan, Inc., (800) 624-4869 or [www.kompan.com](http://www.kompan.com).

**Toshiba Satellite T135, Satellite T135D and Satellite ProT130 Notebook Computers.** The notebook computers can overheat at the notebook's plug-in to the AC adapter, posing a burn hazard to consumers. Toshiba America Information Systems, Inc., (800) 457-7777 or [laptops.toshiba.com/about/consumer-notice](http://laptops.toshiba.com/about/consumer-notice).

**White Tiger Outdoor Folding Wooden Chairs.** The wooden frame of the chairs can break, posing a fall hazard to consumers. White Tiger Traders Co. Ltd, (800) 632-6900 or [www.kroger.com](http://www.kroger.com).



## CONSUMER PRODUCTS

**Zen Large and Small Room Rugs.** The large rugs fail to meet federal flammability standards and could ignite, posing the risk of fire and burn hazards to consumers. The small rugs fail to meet federal labeling requirements. Small rugs are not required to meet the federal flammability standard; however, they are required to be permanently labeled with the following statement: "FLAMMABLE (FAILS U.S. DEPARTMENT OF COMMERCE STANDARD FF 2-70): SHOULD NOT BE USED NEAR SOURCES OF IGNITION." Brumlow Mills, (877) 879-0176.

**Zooper Tango Double Strollers.** The stroller's frame latch above the front wheels can fail when the stroller hits an object, causing the stroller to unexpectedly collapse. This can result in minor scrapes, cuts and bruises. Zooper USA, (888) 966-7379 or [www.zooper.com](http://www.zooper.com).

### OUTRAGE from page 12

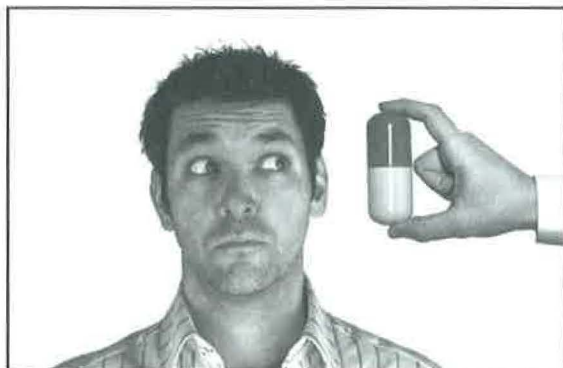
dose recommended for schizophrenia patients. A short time later, White died in his sleep."

A Veterans Affairs investigation concluded that White died from a rare drug interaction involving Seroquel and other drugs he was taking, but that he had received the "standard of care" for his condition.

The article stated that "it is unclear how many soldiers have died while taking Seroquel, or if the drug definitely contributed to the deaths. White's father has confirmed at least half-dozen deaths among soldiers on Seroquel, and he believes there may be many others."

The drug-related military suicides previously discussed and this case are

similar in that polypharmacy — the use of multiple drugs with greatly increased chances of drug interactions — may well be the culprit. As should be the case for all physicians, doctors in the military need to pay more attention to their prescribing practices. Maybe the standard of care is not high enough. ♦



## Are your medicines SAFE?

Many drugs that come to market have risks that outweigh their benefits. Others, found to have risks only after they are approved, are left on the market for dangerously long periods of time. Find out which drugs are safe — and which you should avoid — with Public Citizen's WorstPills.org and *Worst Pills, Best Pills News*.

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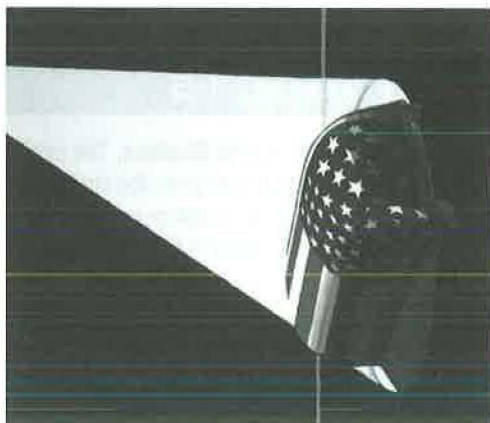


## U.S. Troops: More Deaths Related to Prescription Drugs

Last month in *Health Letter* we wrote about a military study finding that in U.S. troops, the increased use of suicide-linked antidepressants, antipsychotics and anti-seizure drugs exactly parallels the increase in troop suicides since 2005. Commenting on 32 deaths on prescription drugs in military Warrior Transition Units since 2007, an internal review found “the biggest risk factor may be putting a soldier on numerous drugs simultaneously, a practice known as polypharmacy.”

In August, Matt Perrone of The Associated Press published an article based on his investigation into another military drug prescribing problem that may also have resulted in deaths of soldiers. These deaths were not from suicides but were associated with life-threatening interactions between the antipsychotic drug Seroquel and other drugs.

Perrone wrote that “thousands of soldiers suffering from post-traumatic stress disorder (PTSD) have received the same medication [Seroquel] over the last nine years, helping to make Seroquel one of the Veteran Affairs Department’s top drug expenditures and the No. 5 best-selling drug in the nation.”



The article examined the case of a young Marine, Andrew White, who returned from a nine-month tour in Iraq with several PTSD-related problems including insomnia, nightmares and constant restlessness. Doctors tried to treat his symptoms using three psychiatric drugs, including Seroquel, a tranquilizer and a pain medication.

Because the nightmares persisted, according to Perrone’s investigation, “doctors recommended progressively larger doses of Seroquel. At one point, the 23-year-old corporal was prescribed more than 1,600 milligrams per day — more than double the maximum

continued on page 11

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