

Health Letter

SIDNEY M. WOLFE, M.D., EDITOR

May 2005 ♦ VOL. 21, NO.5

In Memoriam: Bill Hines, 1917-2005

Two months ago, Bill Hines, who had been a contributing editor for Health Letter for 13 years and of *Worst Pills, Best Pills News* for 9 years, died. In addition, Bill had written many articles for *Health Letter* over the years. Since we have no bylines in our publication, many readers will not know of his substantial contributions unless they happened to see his name listed with other contributors in each issue. We are including in this Bill Hines Memorial Issue, two articles he wrote for *Health Letter* that demonstrate his breadth of knowledge, his sense of humor and his prescience. In future issues of the newsletter, we plan to reprint additional articles.

Below are portions of obituaries appearing in the *Washington Post* and other publications:

William M. Hines, 88, a former *Washington Star* and *Chicago Sun-Times* reporter who was considered the godfather of NASA space reporting, died Feb. 28 of complications from treatment for pneumonia at Frederick Memorial Hospital. He lived in Washington before moving to Lovettsville in 1987.

Mr. Hines was born in San Jose and grew up in San Francisco, where his father was the publisher of the old *San Francisco Bulletin*. He attended Guilford College in Greensboro, N.C., for about three years. "But," his wife recalled, "when he was offered a job

at the *Chattanooga Times*, he took it."

During World War II, he served as an Army first lieutenant in the European theater. He worked briefly in the Pentagon's information office before joining the *Washington Star* as a reporter and later becoming Sunday editor.

Mr. Hines, who had a keen interest in science, persuaded his boss to allow him to report on the country's nascent space program shortly after the Russian spaceship Sputnik went up in 1957. "He told him he would be missing the boat if he don't get on it right away," said his wife, Judith Randall Hines.

When an Apollo spacecraft caught fire on Jan. 27, 1967, killing three astronauts, Mr. Hines wrote an article in the *Nation* magazine criticizing NASA's attempts to maintain its image as an agency that gave, as one official said,

"meticulous attention to the smallest detail." He prodded the agency and a congressional committee to look deeper for the root cause of the fire that killed Virgil I. "Gus" Grissom, Edward White and Roger Chaffee on Pad 34 at Kennedy Space Center.

"In these flack-driven times it is perhaps not surprising that the taxpaying public should be hoodwinked, falsely propagandized, deliberately misled, and on occasion even lied to by its servants," he wrote in 1967. "It is deplorable, however, and dangerous in the bargain that NASA has deluded itself into believing the reality of its own Image." Bill Hines also said, famously, that "NASA's initials are jokingly said to stand for 'Never A Straight Answer.'"

Mr. Hines, a probing, impatient, sometimes abrasive reporter, was

continued on page 2

CONTENTS

"...Makes You Stop and Think"

What news items are you missing?.....2

HMO-Medicare Crisis

Is Health Insurance for the Elderly on the Way Out?.....2

Recalls

March 17 to April 24, 2005

Children's scooters and pacifiers are on the list this month.....4

Outrage of the Month: The Causes of Misprescribing and Overprescribing

A continuation of last month's feature from Worst Pills, Best Pills ..12

HINES, from page 1

legendary among journalists for his thorough reporting and quick writing speed. In news conferences, where he would sit like a coiled cobra waiting to strike, he would sometimes leave NASA spokesmen speechless with his incisive questioning, colleagues said.

After leaving the Star in 1968, Mr. Hines worked at the *Chicago Daily News* and later became Washington bureau chief of the *Chicago Sun-Times*. He retired from the *Sun-Times*

in 1989 and continued to do freelance writing about space, physics, molecular biology and other topics. He frequently was on "Meet the Press" and other television news shows. Mr. Hines was proud to learn years ago that he was on President Richard M. Nixon's "enemies list."

In later years, he had a passionate interest in the proper use of the English language and, as his wife put it, "all things cats." Mouse Trap Farm became the name of his 18th-century

log cabin in Lovettsville. He was interested in preservation and was involved in the Old House Group in Lovettsville. He edited the group's newsletter, as well as one for Ralph Nader's Health Research Group.

He was an excellent cook who especially enjoyed preparing Indian food and entertaining. Survivors include his wife of 22 years, Judith Randall, one of the leading medical/science writers in the U.S. who has also written for the *Health Letter*. ■

"...Makes You Stop and Think!"

This feature article by Bill Hines first appeared in the December 2001 issue of Health Letter. We encourage subscribers to continue to send clippings to the address below!

With this issue of Public Citizen's Health Letter, we begin to offer you an occasional feature that we hope will amuse, baffle, appall or enrage you—health-related items gleaned from the media that may have escaped general attention. Like humor columnist Dave Barry, we will welcome contributions from "alert readers."

Bill Frist, a Republican from Tennessee, is the only medical doctor in the United States Senate, the man other lawmakers look to when questions of do's and don'ts in the health field arise. Dr. Frist was profiled in the October 27th [2001] *Washington Post* that included this passage: "As a Harvard Medical School student in the 1970s, Bill Frist

briefly made a habit of adopting stray cats from local animal shelters [and] then dissecting them. It was, he wrote later, a 'heinous and dishonest thing to do.'"

Another item in the *Post*, this time in the November 4 [2001] issue, disclosed that the state of Virginia has been playing fast and loose with the federal government's contributions to the State's Medicaid program. In order to make up for general revenue shortages caused by a popular cut in taxes on automobiles, the government at Richmond has been diverting money sent by Washington to augment the stat's relatively meager support for its less prosperous citizens.

Finally, an Associated Press report out of Chicago on November 5 [2001] quoted a medical products manufacturer, Baxter International, Inc., as acknowledging that filters intended for use in kidney dialysis machines to prolong the lives of persons with end-stage renal disease were contaminated

with a chemical solution that caused some of at least 51 deaths worldwide — including four in the US — that are now being investigated. Baxter International says it has closed down the facilities where the faulty products were made and, according to the AP, "is earmarking \$100 million to \$150 million for litigation and related expenses." The company, AP added, had "previously said it found nothing to indicate its products were at fault..."

Contributions from readers of the Health Letter for "...Makes You Stop and Think" or "Outrage of the Month" should include a clipping or photocopy of any item and should be mailed to Health Letter Clippings, 1600 20th St NW, Washington DC 20009 or faxed to 202-588-7796. E-mail entries to brg1@citizen.org will be accepted if they include actual attachments of or links to the published item showing source and date of issue. ■

HMO-Medicare Crisis

Is Health Insurance for the Elderly on the Way Out?

This article by Bill Hines originally appeared in the December 1998 issue of Health Letter.

There is a saying in Africa that "when elephants fight, the grass dies," meaning that little

people are the principal victims when big entities struggle for power.

Nowhere can the modern-day application of this old adage be better illustrated than in a story from the *New York Times* of October 20, 1998 headlined, "400 Doctors in Dallas Break

Contracts With Aetna's H.M.O." So what? Why should a dispute between some doctors in Texas and an insurance company concern anyone except the immediate participants? The second paragraph of the story provides the

continued on page 3

HMO-MEDICARE CRISIS, from page 2
answer:

"As a result [of the dispute], nearly 30,000 patients covered by Aetna must accept doctors who remain under contract to the company. If the patients choose to remain with the insurgent doctors, they face paying them cash for their care, at least for the three or four months it will take the patients to sign up with other companies."

"...if the patients can find other companies to sign up with," the paragraph might have added.

The crisis in Dallas is by no means a local anomaly. Aetna is the fourth largest health insurer in the country and the rebellious doctors' association is only one of many which, as the *Times* story points out, "have sprung up to help doctors build contracting influence against the insurance companies." In other words, this is a situation which, in various guises, is taking shape all over the country as doctors who deliver care and insurers who pay for it struggle for control, particularly in the troubled area of Medicare.

In the three decades since the start of the Medicare program of health care for the aged (later amended to include disabled persons of all ages), the Law of Unintended Consequences has come into play repeatedly. The Dallas affair — along with other crises from coast to coast that will be mentioned later — is only the latest example. And there is no reason to believe that if this problem is fixed old folks will be able to sleep more soundly.

A pair of articles in the *Los Angeles Times* of October 23, 1998 — one reflecting the consumers' point of view and the other that of HMOs — focused on this dilemma. "HMOs Dump Elders..." one headline read;

"... Yes, but for a Reason," said the other.

The charges first, then the explanation:

Jamie Court, director of a health care watchdog project in Santa Monica, California, points out that "just months ago, HMOs

aggressively sought the business of healthy seniors with enticements such as free prescriptions and eyeglasses. Now, claiming high costs, HMOs are summarily dumping seniors and the disabled in Medicare."

The operative words in the preceding paragraph are "healthy seniors." An HMO gets a flat monthly amount from the government — in the range of \$400 a month on the average, nationwide — for each Medicare client it enrolls, and gets to keep whatever is not spent on that person's care. So the strategy was to enroll the healthiest seniors and discourage sicker ones — a practice known in the health biz as "cherry picking."

And then the government caught on. "The U.S. General Accounting Office concluded in 1997 that the Medicare program paid HMOs \$1 billion more than it should have because HMOs enroll people who are healthier and less costly than the typical Medicare recipient," Court's article in the *L.A. Times* reports. "The GAO also found that seniors with chronic conditions tended to leave the HMOs on their own and return to the fee-for-service sector." This finding is completely separate from the common complaint that HMOs render all patients, regardless of age, the least service they can get away with — "CPA-administered health care," as this practice has been called.

What's the big deal where Medicare is concerned? Regardless of what HMOs may do, people over 65 and younger disabled people still have the federal program (a part of Social Security) to fall back on, don't they? Yes, but Medicare does not, and never did, pay all the costs of illness. That is where "Medigap" policies come in — supposedly to pay the difference between the doctor's fee and the 80 percent limit the government will pay, and to help out on such uncovered items as prescription drugs, which can run to big bucks for people with chronic diseases.

But out on the fee-for-service open market, doctors who will take on Medicare patients are becoming harder

and harder to find, and Medigap policies are frequently beyond the financial reach of retired people on limited, fixed incomes, even if they can find a plan suitable to their needs. So what's a poor oldster to do?

The question is more than a merely academic one in the case of Denise Longobardi of Benson, Arizona, who at 52 is eligible for Medicare because she has a permanently disabling illness that requires periodic (and expensive) kidney-dialysis treatments. She contracted the condition after joining her present HMO, and theoretically is protected now from dismissal by this health plan — "theoretically" because if the plan shuts down, what are her options? Longobardi, the owner of a small art, antique and framing business, is quoted in the (*Tucson*) *Arizona Daily Star* of October 18, 1998 as saying, "If I lose my HMO coverage, I'm going to have to close my store and go on welfare. There's no way I'll be able to pay my medical bills."

Middle-aged, non-disabled Americans are being caught in the pinch, especially in states where — like Virginia — regulatory agency approval is not required for HMO premium hikes. Thomas and Anne Sullivan of Fairfax VA (he 64 and she 63) were notified by their Kaiser Permanente HMO in October that starting December 1 their \$401.16 monthly health dues would leap to \$897.84 — an annual increase of \$5,960.16, or 123.8 percent. This was reported in an article in the *Washington Post* of October 29, 1998, which also carried the news that "Blue Cross and Blue Shield of the National Capital Area ... has proposed raising rates by as much as 157 percent next year on Medigap insurance policies for the disabled ..."

The other twin in the *L.A. Times* pair of articles, by Craig Schub, president of an HMO called Secure Horizons, USA, acknowledges that "a strange thing is happening all over America," but denies that greed by either bottom-line-conscious corporate accountants or fee-hungry physicians is to blame for seniors' developing plight.

"Unfortunately, as things stand
continued on page 4

Product Recalls

March 17 — April 23, 2005

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

DRUGS AND DIETARY SUPPLEMENTS

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

CLASS I Recall

Name of Drug or Supplement; Class of Recall; Problem

a) **Health & Herbs Eye Rinse Concentrate Formula 1036** Herbal Tincture; b) White Willow Bark (3193) Herbal Tincture; c) Fennel Seed 3126 Herbal Tincture; d) Elderberry Flower 3247 Herbal Tincture; Class I; Non-sterility.

Lot #: Quantity and Distribution; Manufacturer

a) 87/2 oz. bottles; b) 41/2 oz. bottles; c) 35/2 oz. bottles and 1/8 oz bottle; d) 8/2 oz. and 1/32 oz. bottles distributed nationwide; Alternative Health & Herbs Remedies, Albany, OR.

continued on page 5

HMO-MEDICARE CRISIS, from page 3

today, HMOs have no choice but to leave areas where the cost of providing care to seniors outstrips government payment rates," Schub contends. "These difficult decisions are an unintended consequence of the Balanced Budget Act of 1997."

This act of Congress, Schub says, "seemed like a good piece of legislation at the time. Congress sought to extend the life of the Medicare program and expand health care choices. In addition to traditional fee-for-service medicine, seniors would be able to choose a variety of options ... [and] these reforms would bring real choice and support market competition. But it didn't work that way."

Secure Horizons and the only other HMO in Utah "are folding up shop because the cost to treating patients was up to 40 percent more than the government rate," Schub wrote.

And — Schub adds, "physician groups faced with the same troubling equation are canceling HMO contracts

and returning seniors to more expensive fee-for-service medicine."

The question remains: What's a poor senior to do? The time may be ripe, in the wake of the November mid-term election surprise, for Americans to start agitating for effective action on the health care front from a do-nothing Congress and a not-much-more-effective administration. The then-new Clinton administration fumbled the health care ball in 1993 and hasn't done much to recover in the ensuing five years, while the Republican leadership on Capitol Hill has consistently turned its good ear toward the arguments of lobbyists and its deaf one toward the plight of consumers. Reform of health care was one of the chief items of desired action mentioned by voters almost everywhere in the wave of early November's post-mortems.

Doctors — like the ones in Dallas who are locked in a power struggle with Aetna — are frequently heard to urge their patients to pour the heat onto Congress. But patients can

perhaps be forgiven for wondering whose water they will be carrying if they follow organized medicine's recipes for health care reform. What is needed, obviously, is a grass-roots reform movement motivated by something other than some vested interest's bottom line.

With insurance premiums going up through the overhead and with scandalous incidents of malpractice, fraud and just plain bad management rife throughout the whole health industry, the time for action is not now, but about five years ago.

A consciousness is emerging "out there" — beyond the Washington Beltway, that something needs to be done. This was expressed rather well in the Tucson paper's roundup cited earlier, in the words of 79-year-old Leola Drake of Ajo, Arizona:

"You do get the feeling some of the time that people are trying to take advantage of you."

Stay tuned. ■

Name of Drug or Supplement; Class of Recall; Problem

a) **5% Benzoyl Peroxide Gel** packaged in 1-oz. tubes; OTC under various store generic labels; b) Invisible Acne Cream (Benzoyl Peroxide 10%); 1-oz. tubes, OTC, under multiple store generic labels; Class III; cGMP deviations.

Antacid; Mint Flavor; Regular Strength; Class II; Presence of foreign material.

a) **Antacids**, chewable, assorted flavors; b) **Acetaminophen/non-aspirin pain reliever**, 325 mg; c) **Aspirin**, 81 mg tablets; d) **Extra strength non-aspirin pain reliever/sleep aid**, acetaminophen 500mg & diphenhydramine hydrochloride 25mg; e) **Children's non-aspirin pain reliever**, acetaminophen 80 mg, fruit flavored tablets; f) **Diphenhydramine hydrochloride** 25 mg labeled as an allergy medication or sleep aid; distributed under various store brands; Class II; Potential for products to be contaminated with metal particles.

Aplicare Povidone-Iodine USP 7.5%, 4 Fl. Oz. bottle, OTC; Class III; Mislabeled.

APRI (desogestrel and ethinyl estradiol) **Oral Contraceptive Tablets**; 0.15 mg/0.03 mg; Rx only; Class II; "Start" row may contain white inactive placebo tablets rather than active tablets.

BioTouch Instant Numb Topical Anesthetic Ointment; labeled to contain 4% Lidocaine and 15% Benzocaine; Class II; Super-potent for lidocaine and sub-potent for benzocaine.

DORNASE ALPHA PLUMOZYME Inhalation Solution in 2.5 mg/mL ampule, Rx only, Class II; Lack of Assurance of Sterility.

Ibuprofen Tablets USP; 400mg; Rx only; Class II; Adulterated (foreign tablets).

Lorazepam IntenSol Oral Concentrate USP; 2 mg per mL; Rx only; Class II; Degradation failure (3 month stability).

a) **Metronidazole Capsules**, 375mg, Rx only; b) Metronidazole Tablets, 250mg, Rx only; c) Metronidazole Tablets USP, 500mg, Rx only; d) Metronidazole Extended-Release Tablets, 750mg, Rx only; Class III; Mislabeling due to noncompliance with 21CFR201.24.

a) **Paxil CR Tablets** (paroxetine HCl) 12.5 mg Controlled-Released Tablets; Rx only; b) Paxil CR Tablets (paroxetine hydrochloride) 25 mg Controlled-Release Tablets; Rx only; c) Paxil CR (paroxetine hydrochloride) 37.5 mg Controlled-Release Tablets, Rx only; d) Avandamet Tablets (rosiglitazone maleate/metformin HCl), 1mg/500mg; Rx only; Class II; Manufacturing defect.

Lot #: Quantity and Distribution; Manufacturer

Multiple lots and expiration dates; a) 13,080 tubes and b) 98,856 tubes distributed nationwide. Qualis, Inc., Des Moines, IA.

Lot #330660; exp. date Nov 2006; 24 bottles distributed in WA; Magno Humphries, Inc., Tigard, OR.

Multiple lots and expiration dates; 38,824 bottles distributed nationwide; Magno Humphries, Inc., Tigard, OR.

Multiple lots and expiration dates; 3,938 cases distributed nationwide; Aplicare, Inc., Branford, CT.

Lot #590434045; exp. date: Dec 2006; 67,512 blister cards distributed nationwide; Barr Pharmaceuticals, Inc., Cincinnati, OH.

Lot #s 95396 and 95393. 3,381 bottles distributed in TX; Coats Aloe International, Inc, Garland, TX

Lot number L-14222; exp. date Oct 2006; 50,400 units of 6 ampules distributed nationwide; Genentech, Inc, South San Francisco, CA, by letters on February 28, 2005.

Lots # 23248 and 23045, exp.date Aug 2007; 20,124 bottles of 500 ct and 13,056 bottles of 100 ct distributed in CA; BASF Corporation, Shreveport, LA

Multiple lots; 113465 bottles distributed nationwide. Roxane Laboratories, Inc., Columbus, OH.

Multiple lots and expiration dates; 75,468 bottles distributed nationwide; Able Laboratories Inc., South Plainfield, NJ.

a), b), and c) all lots; d) multiple lots and expiration dates; a) 5,690,165 bottles; b) 11,803,780 bottles; c) 2,103,976 bottles; d) 71,048 bottles, 60 count; 43,309 bottles, 100 count distributed nationwide; GlaxoSmithKline, Cidra, PR.

continued on page 6

DRUGS AND DIETARY SUPPLEMENTS *cont.*

Name of Drug or Supplement; Class of Recall; Problem

Prempro (conjugated estrogens/medroxyprogesterone acetate); 0.3mg/1.5 mg tablets; Class III; dissolution failure.

Sulfazine EC 500 mg; Sulfasalazine Delayed Release Tablets, USP 500 mg; Rx only; Class II; Dissolution failure.

Lot #: Quantity and Distribution; Manufacturer

Lot A87961; exp. date 12/2005; 19, 448 cartons of 3 packs each distributed nationwide; Richmond Division of Wyeth, Richmond, VA.

Lot #C0900703A (100 counts), C0900703B (300 counts); 7,123 bottles distributed nationwide; Vintage Pharmaceuticals, Inc., Charlotte, NC.

CONSUMER PRODUCTS

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

Name of Product; Problem

ATVs. The fuel tank used on some all-terrain vehicles could develop a fuel leak. If this occurs, a fire hazard with the possibility of injury and property damage could occur.

ATVs. The rear axle bearings may have not been sufficiently greased. This may cause a breaking of the bearing which could make the ATV unstable. The operator could lose control of the vehicle which could cause injury to the operator.

ATVs. The steering rods can separate, causing the driver to lose steering control. This could cause the ATV to crash and pose a risk of serious injury or death.

Batteries. The battery can overheat and explode while recharging, posing a burn and fire hazard to consumers.

Candles. Some of these tea light candles from one production run can burn with a high flame, due to contamination.

Candles. The candle has a clamp that is used to extinguish the candle. The clamp does not always sever the wax close to the wick and extinguish the candle as intended. This can allow the flame to continue down into the coiled section of the candle and ignite the entire candle.

Candles. The gel used in these candles can catch fire, creating a high flame. This can result in nearby combustibles catching fire and burns to consumers.

Candles. These candles can have a high flame, posing a risk of burn injuries to consumers.

Lot #: Quantity and Distribution; Manufacturer

Arctic Cat FIS and TBX Model ATVs; 16,200 units sold at Arctic Cat dealerships nationwide from Sept 2004-Mar 2005; Arctic Cat Inc., of Thief River Falls, Minn; (800) 279-6851 or www.arctic-cat.com.

Bombardier DS650 ATVs; 2,127 units sold at Bombardier dealers nationwide from Mar 2004-Mar 2005; Bombardier Recreational Products Inc., of Quebec, Canada; (888) 864-2002.

Honda 2004-2005 FourTrax All-Terrain Vehicles (ATVs); about 200,000 units sold at Honda motorcycle dealers nationwide from Aug 2003-Feb 2005; American Honda Motor Co. Inc., of Torrance, Calif.; (866) 784-1870 or www.powersports.honda.com.

Thompson, Inc. portable DVD player batteries; about 47,000 units sold at electronic and department stores nationwide from Sept 2002- July 2003; Thomson Inc., of Indianapolis, Ind.; (800) 821-5875 or www.rca.com/recall.

Fern Warm Comforts Tea Light Candles; about 3,480 units sold at home parties nationwide from Oct 26, 2004-Mar 1, 2005; Southern Living At HOME; (800) 898-0128.

Self-extinguishing Rope Candle; about 2,000 sold by TechnoBrands Inc. doing business as FirstSTREET on their Web site and through their catalog from Nov 2004- Feb 2005; TechnoBrands Inc., of Colonial Heights, Virginia; (866) 660-7150.

Nature's Finest Gel Candles; about 727,000 sold by drug and grocery stores nationwide from June 2001-Feb 2005; Nature's Finest, of Marble Falls, Texas; (800) 964-6804 or www.naturesfinestcandles.com.

Martha Stewart Everyday "sunny meadow" four-piece sanded votive candle sets; about 16,000 sets sold at Kmart stores nationwide from Apr 2004-Jan 2005; Global Gift Industries, of San Diego, Calif.; (800) 622-6353 Ext. 255; cservice@lavaenterprises.com.

Type of Product; Problem

Children's chairs. The seat portion of the chair can detach from the leg base possibly causing a child to fall to the floor.

Children's fishing poles. The paint on the rods of these fishing poles contains lead. Lead is toxic if ingested by young children and can cause adverse health effects.

Children's jacket and pants sets. The zipper slider and pull on the jackets can detach, if pulled when the jacket is open. They can pose a choking hazard to young children.

Children's overalls. The plastic center of the decorative snaps on these garments can detach, posing a choking hazard.

Crayon balls. Small crayon balls can break loose from the plastic base of the products. This can pose a choking hazard to young children.

Director's chairs. The wooden dowels in the fabric seats are too small and can break or slide out of the fabric sleeves; the fabric seat can tear from the wooden seat frame; and the chair frame also can break at the backrest upright, the armrest and at the leg axis. These failures can cause the chair's occupant to fall to the floor, and possibly sustain injuries.

Karaoke cassette player. The paint on the five control buttons of the karaoke player contains excessive lead, posing a lead poisoning hazard to young children.

Pacifiers and toys. The pacifiers and toys can easily break apart, exposing small parts. This poses a choking hazard to young children.

Pacifiers. The nipple can detach from the base, posing a choking hazard to young children.

Propane heaters. The valve on the propane heaters can leak, posing a fire hazard if an ignition source is present.

Lot #; Quantity and Distribution; Manufacturer

Royal Seating Prima Chair; about 46,000 sold by furniture dealers and catalogs to schools and similar institutions between Feb-Nov 2004; Royal Seating Ltd., of Cameron, Texas; (800) 460-4916.

Children's Fishing Poles; about 1.5 million fishing poles sold at discount department, sporting good and toy stores nationwide from Aug 2001-Mar 2005; W.C. Bradley/Zebco Holdings Inc. doing business as Zebco, of Tulsa, Okla.; (800) 444-5581 Ext. 6217 or www.zebco.com/recall.

Reebok Children's Windwear and Fleece Jacket and Pant Sets; about 8,000 units sold at Gordmans, Fred Meyer, Kids R Us, Ross, Gottschalks and Reebok Corporate Headquarters retail store between Aug 2004- Feb 2005; Adjmi Apparel Group, of New York, N.Y.; (800) 873-5570 or www.reebok.com.

Carter's[®] Infant and Children's Overalls; about 31,000 sold at Carter's retail stores and nationwide from July 2004 through March 2005; style 435-092 and 435-646; Carter's[®], of Atlanta, Ga.; (866) 999-1802 or www.carters.com.

My First Crayon-Ball™ and My First Crayon-Ball™ Activity Set; About 145,000 units sold at discount and toy stores nationwide from June 2004-Mar 2005; Baja Products Inc. of Delray Beach, Fla.; (800) 556-3674.

Director's Chairs and Replacement Director's Chair Padded Seats; about 3,500 sold by L.L. Bean catalog, Web site and L.L. Bean flagship store from Feb 2004- Sept 2004; L.L. Bean Inc., of Freeport, Maine; (800) 555-9717 or www.llbean.com/recall.

Nu-Tronix Karaoke Cassette Player/Recorder; about 220,000 sold at Wal-Mart stores nationwide from June 2003-Mar 2005; Wal-Mart Stores, Inc., of Bentonville, Ark.; (800) 925-6278 or www.walmartstores.com.

Light-up Pacifier, New Style Piano, and High Toys Choochoo Toy Train; about 5,000 sold at swap meets and flea markets in the Los Angeles area from July 2004-Feb 2005; California International Trading, of Los Angeles, Calif.; (800) 416-4491.

Flashing Pacifier or 2-in-1 Flashing Pacifier with Whistle Necklace; about 24,000 sold by small retail stores, distributors, dollar stores and on Solar's Web site from Jan 2004- Feb 2005; Solar Inc. of Tappan, N.Y.; (800) 837-6527.

Mr. Heater "Big Buddy" and "Tough Buddy" portable propane heaters; about 55,000 sold at home centers, sporting goods, and hardware stores nationwide from Sept 2004- Dec 2004; Mr. Heater, Inc., of Cleveland, Ohio; (800) 385-2605 or www.regcen.com/heaterrecall.

continued on page 8

Type of Product: Problem

Propane heaters. The plastic ring on the heater's regulator can crack, causing gas to leak out if the propane tank and heater regulator are turned on. This can create a fire hazard if an ignition source is present.

Scooters. The wheels of the scooter can break or become damaged, and users of the scooters can fall and suffer injuries.

Televisions. Power button can break allowing objects to be inserted through the opening. Foreign materials such as crayons, metal objects or straws can ignite posing a fire hazard.

Throw rugs. Certain rugs fail to meet the federal mandatory standard for flammability. If the rugs ignite, they may not self-extinguish, presenting a risk of burn injuries.

Toasters. An interruption of power to the toaster can cause the heating elements to unexpectedly self-start and could ignite any flammable items left on top of the unit, posing a fire hazard.

Toddler beds. A child's arm, leg or foot can become entrapped between the slats in the guard rails or footboard. This can result in broken bones, sprains and other injuries to young children.

Tree stand safety harness. The harnesses could fail during use, resulting in consumers falling from tree stands and suffering serious injuries or death.

Vacuum cleaners. The recalled vacuums have defective on-off switches that can overheat the handle and toolholder areas of the vacuum, resulting in a fire hazard.

Lot #: Quantity and Distribution; Manufacturer

"ALL-PRO", "Reddy Heater" and "MASTER" Infrared (Tank Top) Propane Heaters; about 88,000 sold at hardware stores nationwide from Sept 2002- Jan 2005; DESA Heating Products, of Bowling Green, Ky., and Scheu Manufacturing Co., of Upland, Calif.; (866) 279-3225.

Bratz™ Stylin' Scooter™; about 297,000 units sold at toy and discount stores nationwide from Sept 2003-Nov 2004; Item No. 266563, made by Jurong Dumar Bicycle, Inc.; MGA Entertainment Inc., of Van Nuys, Calif.; (800) 222-4685 or www.mgae.com.

27-Inch Sharp Conventional Tube (CRT) televisions; about 373,000 sold at electronics retailers, department stores and mass merchandisers nationwide from Mar 2001-Feb 2005; Sharp Electronics Corp., of Mahwah, N.J.; (800) 291-4289 or www.sharpusa.com/tv or TV@sharpsec.com.

Hellenic Rug Imports' "Mazarakis Flokati 3A" and "Mazarakis Floco" white flokati rugs; about 1,600 rugs sold by Web and catalog retailers nationwide from Jan 2003-Feb 2004; Hellenic Rug Imports, of Brooklyn, N.Y.; (888) 356-5284 or www.flokati.com.

KitchenAid(r) ProLine® Toasters; about 40,000 sold by various catalogs and specialty retailers nationwide from Aug 2003-Jan 2005; Whirlpool Corp., of Benton Harbor, Mich.; (800) 874-0608 or www.KitchenAid.com/repair.

Graco Toddler Bed; about 1.2 million units sold at discount and department nationwide from Feb 1994-Mar 2001; Graco Children's Products Inc. of Exton, Pa.; (800) 837-4404 or www.gracobaby.com.

Safety Harnesses Sold with Tree Stands; about 500,000 sold at hunting and sporting good stores nationwide beginning in Jan 2004; model number 3333; Hunter's View, of Peoria, Ill.; (888) 878-0440.

Hoover Self-Propelled Upright Vacuum Cleaners; about 636,000 units sold at household appliance and floorcare retailers nationwide from May 1998-July 2000; Hoover Co., of North Canton, Ohio; (800) 250-6075 or www.maytag.com or www.hoover.com.

Editor.....Sidney M. Wolfe, MD
Managing Editor.....Meredith Larson
Production Mgr.....Kristy I. Jackson
Proofreader.....Nicholas Stine

President.....Joan Claybrook

THE PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

Copyright © Health Letter, 2005
 Published Monthly by
 Public Citizen Health Research Group
 All rights reserved. ISSN 0882-598X

The Health Research Group was co-founded in 1971 by Ralph Nader and Sidney Wolfe in Washington, D.C. to fight for the public's health, and to give consumers more control over decisions that affect their health.

Material in the *Health Letter* may not be re-printed without permission from the Editor. Send letters and requests to HEALTH LETTER, Editor, 1600 20th St., NW, Washington, D.C., 20009.

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

OUTRAGE, from page 12

pharmaceutical companies spend on DTC advertising and what drugs patients are most often requesting from physicians.” The advertising “is definitely driving patients to the doctor’s office, and in many cases, leading patients to request the drugs by name.” The problems with DTC advertising are best summed up in an article written by a physician more than 15 years ago in the *New England Journal of Medicine*, before the current binge had really begun: “If direct [to consumer] advertising should prevail, the use of prescription medication would be warped by misleading commercials and hucksterism. The choice of a patient’s medication, even of his or her physician, could then come to depend more on the attractiveness of a full-page spread or prime-time commercial than on medical merit...such advertising would serve only the ad-makers and the media, and might well harm our patients.”

The Food and Drug Administration (FDA)

Attempting to fend off FDA-weakening legislation even worse than that which was signed into law in 1997, the FDA has bent over backwards to approve more drugs, culminating in 1996 and 1997 when the agency approved a larger number than had ever been approved in any two-year period. Thousands of people were injured or killed after taking one of three such recently approved drugs (which have subsequently been recalled from the market). These drugs were the weight-loss drug dexfenfluramine (REDUX), the heart drug mibefradil (POSICOR), and the painkiller bromfenac (DURACT). Other drugs that would not have gotten approved in a more cautious era at the FDA have also been approved, but are likely either to be banned or to be forced to carry severe warnings that will substantially reduce their use. Many of these are included in *Worst Pills, Best Pills* and on our web site, www.worstpills.org, and listed as **Do Not Use** drugs.

In the more than 30 years since the Public Citizen’s Health Research Group

started monitoring the FDA and the drug industry, the current pro-industry attitude at the FDA is as bad and dangerous as it has ever been. In addition to record numbers of approvals of questionable drugs, FDA enforcement over advertising has all but disappeared. From a peak number of 157 enforcement actions to stop illegal prescription drug ads that understate risks and/or overstate benefits in 1998, the number has decreased to only 24—an 85% decrease—in 2003. There is no evidence that the accuracy or legality of these ads has increased during this interval, and the amount of such advertising has clearly increased. The division at FDA responsible for policing prescription drug advertising has never been given adequate resources to keep up with the torrent of newly approved drugs. More recently, however, it has also been thwarted by marching orders from higher up in the agency to, effectively, go easy on prescription drug advertising. As a result, the drug industry correctly believes it can get away with more violative advertising than in the past. The role of the United States Congress in pushing the FDA into approving more drugs, and passing, with the FDA’s reluctant approval, legislation to further weaken the FDA’s ability to protect the public, cannot be overlooked.

Physicians

The well-financed promotional campaigns by drug companies would not have as much of an impact as they do were there not such an educational vacuum about proper prescribing of drugs, a serious problem that must be laid at the feet of medical school and residency training. The varieties of overprescribing and misprescribing of drugs by doctors — **the seven all-too-often-deadly sins of prescribing referred to in last month’s portion** — are all strongly enhanced by the mind-altering properties of drug promotion. The best doctors, of whom there are many, do not waste their time talking to drug sales people, toss promotional materials away, and ignore drug ads in medical journals. Too many other doctors, however, are heavily influenced by drug companies,

accepting free meals, free drinks, and free medical books in exchange for letting the drug companies “educate” them at symposia in which the virtues of certain drugs are extolled. Unfortunately, many of these doctors are too arrogant to realize that there is no such thing as a free lunch. The majority of doctors attending such functions have been found to increase their prescriptions for the targeted drugs following attendance at the “teach-in.”

Beyond traditional advertising and promotion and their influence, bias of drug-company-sponsored research, as published in medical journals, also can sway doctors toward more favorable impressions about drugs. An analysis was done of 56 trials that were paid for by drug companies and reported in 52 medical journals about drugs for arthritis and pain — NSAIDs. (These drug-company-sponsored studies represented 85% of those that the researchers originally looked at.) In studies identifying the company’s drug as less toxic than another drug, in barely one-half of the studies was there justification for the finding of less toxicity. This certainly explains why, contrary to fact, newer arthritis drugs almost always “seem” safer than older, usually much less expensive ones.

A final example demonstrates the ignorance of many physicians, especially in dealing with prescribing drugs to older adults. A study of physicians who treat Medicare patients found that 70% of the doctors who took an examination concerning their knowledge of prescribing for older adults failed to pass the test. The majority of physicians who were contacted for participation in the study refused to take the test, often giving as their reason that they had a “lack of interest in the subject.” The authors concluded “many of these physicians [who failed the exam] had...not made good use of the best information on prescribing for the elderly.”

Pharmacists

A small fraction of pharmacists have, in our view, betrayed their professional ethics and are working for drug ***continued on page 10***

OUTRAGE, from page 9

companies, engaging in such activities as calling doctors to get them to switch patients from drugs made by a company other than the one the pharmacist works for to the pharmacist's employer's drugs. In addition, pharmacy organizations such as the American Pharmaceutical Association and others have fought hard to prevent the FDA from requiring accurate patient package information to be dispensed with each prescription filled.

Too many pharmacists, despite having computers to aid them, have been willing to fill prescriptions for pairs of drugs that, because of life-threatening adverse drug interactions if used at the same time, should never be dispensed to the same person.

- Sixteen (32%) of 50 pharmacies in Washington, D.C., filled prescriptions for erythromycin and the now-banned terfenadine (SELDANE) without comment. These two drugs, if used in combination, can cause fatal heart arrhythmias.

- In another study, of 245 pharmacists in seven cities, about one-third of pharmacists did not alert consumers to the potentially fatal and widely publicized interaction between Hismanal, a commonly used but now banned antihistamine, and Nizoral, an often-prescribed antifungal drug. Only 4 out of 17 pharmacists warned of the interaction between oral contraceptives and Rimactane, an antibiotic that could decrease the effectiveness of the oral contraceptive. Only 3 out of 61 pharmacists issued any verbal warnings about the interaction between Vasotec

and Dyazide — two drugs for treating hypertension — which may lead to dangerously high levels of potassium in the blood.

- In yet another study, concurrent use of terfenadine (SELDANE) and contraindicated drugs declined over time. The rate of same-day dispensing declined by 84%, from an average of 2.5 per 100 persons receiving terfenadine in 1990 to 0.4 per 100 persons during the first six months of 1994, while the rate of overlapping use declined by 57% (from 5.4 to 2.3 per 100 persons). Most cases involved erythromycin. Despite substantial declines following reports of serious drug-drug interactions and changes in product labeling, concurrent use of terfenadine and contraindicated antibiotics such as erythromycin and clarithromycin (BIAXIN) and antifungals such as ketoconazole (NIZORAL) continued to occur.

Patients

For too many patients, the system is stacked against you — drug companies, doctors, and pharmacists are too often making decisions that ultimately derive from what is best for the drug companies, doctors, and pharmacists, and not necessarily from what is best for you. The information found in *Worst Pills, Best Pills* and on www.worstpills.org has been researched and written to help you come out ahead in the struggle with our health care industry.

In the sections on *Adverse Drug Reactions* and *Drug-Induced Diseases*, you can learn which common medical

problems — depression, insomnia, sexual disorders, parkinsonism, falls and hip fractures, constipation, and many others — can actually be caused by drugs. Once you recognize these problems, you will be enabled to better take care of yourself and your family, and bring such problems to an end by discussing safer alternatives with your physician.

Both the book and web site list the drugs we and our consultants think you should not use. For each of these, we recommend safer alternatives. Each drug profile lists drug combinations that should not be used because of serious interactions.

In *Protecting Yourself and Your Family from Preventable Drug-Induced Injury*, we present a detailed strategy, beyond information on specific adverse effects and drugs, to help you to use drugs more safely, including Ten Rules for Safer Drug Use and how to use and maintain your own Drug Worksheet for Patient, Family, Doctor, and Pharmacist. This is your personalized plan for avoiding becoming a victim of overprescribing or misprescribing.

Finally, in *Saving Money When Buying Prescription Drugs*, we discuss the latest information about generic drugs and show you how and why you can and should save hundreds of dollars a year or more. In short, our book, *Worst Pills, Best Pills* and our website, www.worstpills.org, are intended to help you and your family to improve your health by using drugs, if necessary, more carefully and recognizing those you should avoid. ■

Next month...

Look for Public Citizen's Health Research Group's newly released annual report
Ranking of State Medical Boards' Serious Disciplinary Actions, 2002-2004.

Now available at <http://www.citizen.org/medboard>

Over 2.2 Million copies of *Worst Pills, Best Pills* books sold

Order *Worst Pills, Best Pills* book
and get a 6 mo. subscription
to worstpills.org
FREE

Inside you'll find easy-to-understand information on
538 prescription drugs, including 200 top-selling drugs like
Celebrex, Crestor and Paxil.

We'll tell you:

- Which 181 drugs you should not use under any circumstances
- Less expensive, more effective alternatives
- Warnings about drug interactions
- Safer alternatives to harmful drugs
- Ten rules for safer drug use

Worst Pills, Best Pills gives you the information you need
to defend yourself from harmful and ineffective drugs.

Order your copy TODAY of the 2005 edition of *Worst Pills, Best Pills* book for only \$19.95* and **you'll receive a FREE 6-month trial subscription to worstpills.org website**, Public Citizen's searchable online drug database.

* Cost includes a non-refundable \$5 shipping and handling charge.

Don't wait another day. Order by visiting
www.citizen.org/wpbp/HLad55
PLUS, you'll get a 6 month FREE trial subscription to worstpills.org
Expires 12/31/05

Special worstpills.org
introductory
subscription offer

If you research drugs online, you shouldn't miss worstpills.org

WorstPills.org website is Public Citizen's searchable,
online drug database that includes:

- The entire 2005 edition of the *Worst Pills, Best Pills* book. Plus, regular updates (see what's in WPBP book above)
- Analyses of pricing, advertising and other drug-related issues,
- Monthly updates delivered by email
- Up-to-the-minute email alerts about newly discovered drug dangers

All for only \$15 — a special introductory rate.

Many websites have information about prescription drugs, but worstpills.org is the only site where rigorous scientific analysis is applied to identify drugs that consumers should not use under any circumstances.

To order your worstpills.org subscription,
go to worstpills.org and when prompted,
type in promotional code: [HLMAY](#)
Expires 12/31/05

The Causes of Misprescribing and Overprescribing

This item is a continuation of the item from the April Health Letter on the same topic. It is excerpted from the 2005 edition of Worst Pills, Best Pills (see our ad on page 11 for more information). Last month, we told you how drugs are misprescribed and overprescribed by healthcare professionals, often endangering patients. This month, we'll examine why these practices exist and what you can do.

The Drug Industry

The primary culprit in promoting the misprescribing and overprescribing of drugs is the pharmaceutical industry, which now sells about \$216 billion worth of drugs in the United States alone. The industry uses loopholes in the law not requiring proof of superiority over existing drugs for approval, and otherwise intimidates the Food and Drug Administration

(FDA) into approving record numbers of me-too drugs (drugs that offer no significant benefit over drugs already on the market) that often have dangerous adverse effects. In addition, the industry spends well in excess of \$21 billion a year to promote drugs using advertising and promotional tricks that push at or through the envelope of being false and misleading. This industry has been extremely successful in distorting, in a profitable but dangerous way, the rational processes for approving and prescribing drugs. Two studies of the accuracy of ads for prescription drugs widely circulated to doctors both concluded that a substantial proportion of these ads contained information that was false or misleading and violated FDA laws and regulations concerning advertising.

The fastest-growing segment of drug advertising is directed not at doctors

but at patients. It has been estimated that from 1991 to 2002 DTC (direct-to-consumer) advertising expenditures in the United States grew from about \$60 million a year to \$3 billion a year, an increase of 50-fold in just eleven years, employing misleading advertising campaigns similar to those used for doctors. A study by Consumer Reports of 28 such ads found that "only half were judged to convey important information on side effects in the main promotional text," only 40% were "honest about efficacy and fairly described the benefits and risks in the main text," and 39% of the ads were considered "more harmful than helpful" by at least one reviewer. This campaign has been extremely successful. According to a drug industry spokesman, "There's a strong correlation between the amount of money

continued on page 9

Non-Profit Org.
U.S. POSTAGE
PAID
Wash., DC
Permit No. 8314

Printed on recycled paper 

CHAA44

Enclose your check or money order made out to Health Letter.

One year \$18 Two year \$30 Three year \$42

SUBSCRIPTION

CITY, STATE ZIP

ADDRESS

NAME

mailing label. Mail to ~~xxxx~~

Please enter corrections or subscription information below. Return current

CORRECTION?

MOVING? SUBSCRIPTION? ADDRESS

Health Letter, Public Citizen Health Research Group
1600 20th Street, N.W., Washington, D.C. 20009