

Health Letter

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Bush Administration Plan to Privatize Medicare Would Limit Seniors' Choice of Doctors

A proposal being pushed by the Bush administration and its allies in Congress to encourage Medicare beneficiaries to enroll in private insurance plans for prescription drug coverage would severely restrict those patients' choice of doctors, a new Public Citizen study finds. The report looked at the effects such a proposal would have in Maine, Oregon, Utah, Vermont and West Virginia.

The traditional fee-for-service Medicare system allows seniors to see doctors of their choice, which has made beneficiaries reluctant to enroll in private insurance plans that might reduce their choice of doctors. To overcome that reluctance, the administration and Senate Majority Leader Bill Frist (R-Tenn.) want to offer significant prescription drug coverage only to those willing to join private plans (either PPOs or HMOs). They see the Federal Employees Health Benefits Program (FEHBP) as the model for reforming the Medicare program.

In each of the five states, Public Citizen's study looked at the number of doctors in four counties participating in the Medicare program and examined how many of those doctors participate in FEHBP's preferred provider organizations (PPO).

The report found that most doctors participating in traditional Medicare do not participate in the PPO plans offered through the

FEHBP. In the 20 counties studied, less than half the Medicare general physicians were in the Blue Cross and Blue Shield PPO, the private plan with the most Medicare doctors. Fifty-two percent of Medicare cardiologists and a fourth of Medicare oncologists were in the Blue Cross and Blue Shield plan.

"Being able to choose a doctor is extremely important to seniors, and this study shows that the Bush administration's plan would really place beneficiaries between a rock and a hard place," said Ben Peck, legislative representative with Public Citizen's Congress Watch. "If this plan were to pass, many seniors would be forced to choose between staying with their doctors and paying more for prescription drug coverage, or switching to new doctors just to receive coverage."

PPOs offer patients some coverage for doctors who are not a part of their networks, but enrollees must contend with more paperwork and must pay more — sometimes significantly more — to see out-of-network doctors. According to the Congressional Research Service, FEHBP enrollees who see out-of-network doctors often do not even know how much it will cost to see their doctor until they receive a bill.

The counties included in the study are Franklin, Waldo, Oxford and Penobscot in Maine; Harney, Wasco, Polk and Marion in Oregon; Wayne, Emery, Sanpete and Weber in Utah; Lamoille, Caledonia, Windham and Rutland in Vermont; and Pendleton, Taylor, Jackson and Harrison in West Virginia. The counties were chosen because they were representative of

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The Big Fix: How the Pharmaceutical Industry Rips Off American Consumers

By Katherine Greider,
Public Affairs, 189 pages, \$14.00

This book review by Carl Elliott appeared in the June 13, 2003 edition of The American Prospect Online. Carl Elliott is an associate professor at the University of Minnesota's Center for Bioethics and the author of Better Than Well: American Medicine Meets the American Dream.

A couple of months ago, I was invited to give a presentation for the psychiatry department at another medical school. The topic was medical ethics, and I was planning to talk especially about the growing influence of the drug industry on psychiatry. Just as I was about to be introduced, the psychiatrist who had invited me leaned over and whispered, "Do you mind if I thank Janssen Pharmaceuticals for sponsoring your presentation?"

I should have known. According to *The Wall Street Journal*, the drug industry now funds 40 percent of continuing medical education in United States medical schools. In most fields that figure would be shocking. Imagine nutritionists allowing 40 percent of their professional education to be funded by McDonald's and Burger King, or political scientists allowing 40 percent of their graduate seminars to be paid for by the weapons industry. Yet most American doctors do not seem to be bothered by industry-sponsored education. So ubiquitous are the marks of the drug industry in hospitals and medical schools — logos on pens and notepads, drug reps in the hallways, pizzas for the residents and "consulting fees" for the faculty — that doctors no longer even notice that the industry is there. Having drug companies pick up the bill for medical education has come to be the norm.

The most outspoken voices opposing the growing influence of the drug industry have come not from ethicists but from activist groups and muckraking journalists such as Katherine Greider. Greider's book, *The Big Fix*, which just came out in paperback after being published last year, is a lucid, well-researched account of the ways in which the drug industry — through its political lobbying, advertising, patenting strategies and payoffs to doctors — has managed to become the single most profitable business in America. This is not a book for experts. There is little in *The Big Fix* that has not been reported elsewhere, either in the press or in the medical literature, and, unfortunately, the book is not referenced. But Greider does a fine job of weaving these various strands into a coherent narrative. The result is a timely diagnosis of the industry's current tactics,

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populations throughout the states.

U.S. Sens. John Rockefeller (D-W.Va.) and Debbie Stabenow (D-Mich.) joined Public Citizen at the press conference to release the report. Marilyn Moon, senior fellow at the Urban Institute and former Medicare trustee, also participated.

"Once again, America's health care system has reached a crossroads. Public Citizen's latest report provides more evidence that Medicare privatization is not the right path for America's seniors," Rockefeller said. "Our seniors shouldn't be forced to choose between a doctor they trust and prescription drugs. They deserve both, and Congress must update and enhance the services offered under Medicare to include an affordable, accessible prescription drug benefit."

In addition to those states included in the report, Michigan provides another excellent example of how

any attempt to privatize a Medicare prescription drug benefit is a failed option, Stabenow said.

"Even in those areas in Michigan where HMOs have sought to team Medicare coverage with private prescription drug plans — and that's only in nine of the state's 83 counties — more than 35,000 seniors have been dropped from such plans," Stabenow said. "Seniors by a 9-to-1 ratio prefer traditional Medicare to private plans, and a prescription drug benefit for seniors should be offered only through Medicare."

The report finds that:

In the 20 counties surveyed, 1,422 generalist physicians participate in the traditional Medicare program. Just 43 percent of these generalists participate with Blue Cross and Blue Shield, the private plan with the most Medicare participating doctors. At least 75 percent of Medicare doctors do not participate in the six

smaller private plans.

Of the 118 Medicare cardiologists in the 20 counties, just 61 (52 percent) are a part of the Blue Cross and Blue Shield plan. At least 69 percent of Medicare cardiologists do not participate in the six smaller plans.

In the 20 counties, there were 89 oncologists participating in Medicare, 75 percent of whom are not in the private Blue Cross and Blue Shield network. At least 82 percent of Medicare oncologists do not participate in the six smaller plans.

"Prescription drug coverage should be available through the traditional Medicare program," said Frank Clemente, director of Public Citizen's Congress Watch. "It shouldn't be a carrot to lure seniors into private insurance plans. The Medicare program should not be turned over to the private insurance industry."

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problems and methods of influence — and an alarming picture of the industry's power.

Greider informs us, for example, that during the 1999-2000 election cycle, the pharmaceutical industry spent more than any other industry in America on political lobbying — more than automakers, the oil and gas industry, insurance companies or tobacco manufacturers. It spent \$177 million to hire 625 lobbyists from 134 firms, including 21 former members of Congress. It also spent \$60 million on issue ads and gave \$20 million in campaign contributions. A decade ago, according to the Center for Responsive Politics, political contributions from the drug industry were split about equally between the two major parties. Today, three-quarters of drug-industry contributions go to Republicans.

The Big Fix also documents the now familiar ways in which the industry funnels money and gifts to doctors in order to generate more prescriptions — sponsoring “educational events” in exotic locations, distributing gifts and free drug samples, offering doctors honoraria or “consulting fees” to listen to promotional pitches, and paying them to enroll patients in “seeding trials” of newly approved drugs. The number of drug representatives employed to make promotional pitches directly to doctors rose by 57 percent in the 1990s, from 56,000 in 1990 to almost 88,000 in 2000.

Less familiar are the ways in which the industry has begun to sell drugs by selling illnesses. As industry profits have grown, so have the number of new disorders — from social anxiety disorder and premenstrual dysphoric disorder to erectile dysfunction and irritable bowel syndrome. The industry sells these disorders by funding patient-support groups, sponsoring public-awareness campaigns, funding symposia and special journal issues devoted to the disorders its drugs treat, and distributing “educational” literature to physicians. “We’re creating patient populations just as we’re creating

medicines,” says one marketing executive quoted by Greider, “to make sure that products become blockbusters.”

Yet even as the drug industry has stepped up drug promotion at universities and teaching hospitals, it has dramatically decreased its funding of university research. Now much of that funding goes to the private sector. In 1991, 80 percent of drug-industry money for clinical trials went to academic health centers. By 1998, more than half went instead to new commercial entities called Contract Research Organizations (CROs). CROs manage every aspect of a clinical trial. They design it, recruit subjects, analyze the data and submit it to the Food and Drug Administration. They do it for a fee, of course, but they do it faster and more cheaply than university physicians. For academic publication, CROs and the drug industry can rely on another type of commercial firm: medical education and publishing companies, which employ professional writers to ghostwrite academic articles and mainstream academic researchers to sign their names. Ethical oversight is provided by yet another commercial entity: independent, for-profit research ethics boards, or Non-Institutional Review Boards (NIRBs). NIRBs charge CROs and other clients a fee for examining their research and certifying that it is ethically sound.

This new commercial frontier is also proving lucrative for bioethicists, who are soliciting grants from drug companies, working for NIRBs, and serving as paid consultants for the drug and biotech industries. Last year, after some uncomfortable scrutiny by the press, a task force appointed by the American Society for Bioethics and Humanities and the American Society for Law, Medicine and Ethics issued a report on for-profit bioethics consultation with the drug industry. This report was supposed to be the profession's answer to outsiders skeptical of industry-funded bioethicists. Instead, to the astonishment of many observers, the task force fully

endorsed the practice of bioethicists accepting payment from the drug industry. In fact, it even endorsed bioethics advertising. Of the 10 authors of that report, eight disclosed that they had accepted industry funding themselves.

Yet there are signs that the public mood may be shifting. Last year, TAP Pharmaceuticals (no relation to The American Prospect) paid \$875 million to settle charges that it had illegally manipulated the Medicare and Medicaid programs. Schering-Plough has just announced that it may be indicted in a federal investigation into its drug-marketing practices, and that it may also face charges of obstruction of justice. In April, Bayer paid \$257 million to settle charges that it had hidden the drug prices it was charging Kaiser Permanente for the drug Cipro. Warner-Lambert is currently being investigated for allegedly promoting its epilepsy drug Neurontin illegally for unapproved uses. Warner-Lambert is a subsidiary of Pfizer, which is also the object of a highly publicized lawsuit over its clinical trials of Trovan for bacterial meningitis in Nigeria. (Pfizer, under attack for its ethics, has been very generous to bioethicists, donating money to bioethics and medical humanities programs at the University of Toronto, University College London and the University of Pennsylvania, where it has funded a project titled, appropriately enough, “Ethics and Physician Compensation.”)

Of course, as virtually everyone (except doctors and bioethicists) now concedes, industry money does influence clinical judgment. Studies have demonstrated that doctors who take gifts or consulting fees from a drug company are more likely to prescribe that company's drugs and to ask that these drugs be stocked by their hospital. Clinical researchers who are funded by a drug company are more likely to come up with findings that favor the company's drugs. Two years ago, researchers here in Minneapolis found that prescriptions for a psychiatric drug tripled immedi-

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Product Recalls

May 14, 2003 — June 11, 2003

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

DRUGS AND DIETARY SUPPLEMENTS

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

Name of Drug or Supplement; Class of Recall; Problem

Bisoprolol Fumarate and Hydrochlorothiazide Tablets, a) 2.5 mg/6.25mg, bottles of 100, Rx only, b) 5 mg/6.25mg, bottles of 100, Rx only and c) 10mg/6.25mg, bottles of 30, Rx only; Class III; Impurity failure; product failed to meet the Bisoprolol Fumarate unknown impurity specification

Enalapril Maleate Tablets, 10 mg., 1,000 count bottles; Rx only; Class III; Degradation: related compound specification failure (18 month stability)

Fiber Tabs, a) Fiber Tabs (Calcium polycarbophil) 625mg equivalent to 500mg polycarbophil, 250 caplet count bottles, b) **Fiber Caplets** (Calcium polycarbophil) 625mg equivalent to 500mg polycarbophil, 250 caplet count bottles, and c) **Fiber Lax Caplets** (Calcium polycarbophil) 625mg equivalent to 500mg polycarbophil, 90 count bottles; Class III; Tablet mixup; bottles may contain acetaminophen tablets (500mg)

Levothyroid Tablets (levothyroxine sodium tablets); 25 mcg. and 175 mcg., 100 count bottles, Rx Only; Class II; Contamination: tablets contain trace levels of the solvent isophorone

Levoxyl Tablets, (Levothyroxine Sodium Tablets); 300mcg, 100 and 1,000 count bottles, Rx only; Class II; Subpotency during stability testing

Lot #: Quantity and Distribution; Manufacturer

Numerous lots; 756,230 bottles distributed nationwide; Alpharma Purepac, Elizabeth, NJ

Lot 15741 exp 5/31/03; 1,182 bottles distributed nationwide; Teva Pharmaceuticals USA, North Wales, PA

a) Lot number 2HA0654, b) Lot numbers: 2HA0768, 2HA0905 and 2HA0651, and c) Lot number: 2HA0652; 15,454 distributed nationwide; Leiner Health Products, Carson, CA

Lots 40245, exp. 05/2004, 5023, exp. 05/2004, 5024, exp. 05/2004; 14,131 bottles distributed nationwide; Forest Pharmaceuticals, Inc., Earth City, MO

100 count bottle: Lots 7325 exp. 07/03, 7483 exp.09/03, 7484 exp.09/03, 7776 exp. 01/04 300 mcg; 1,000 count bottles: Lots 7325 exp. 7/03, 7484 exp.9/03, 7775 exp.1/04; 84,844 distributed nationwide; King Pharmaceuticals, Inc., Bristol, TN

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ately after an industry-funded presentation in their hospital.

This may soon change. On April 28, the U.S. Office of the Inspector General (OIG) issued a new guidance paper for drug manufacturers warning that many current marketing practices may violate federal anti-

kickback legislation. The OIG guidance is apparently intended to curb the industry's more outrageous efforts to get doctors to prescribe its drugs — such as paying them honoraria to listen to promotional lectures over dinner or to sign their names to ghostwritten articles. But it is also intended to prohibit the industry

from making secret agreements and payoffs to insurers and managed care organizations to keep drug prices high. The big fix that Katherine Greider documents just might be coming undone.

Name of Drug or Supplement; Class of Recall; Problem

Liquid Oxygen USP, 45 liter in home cryogenic vessels. Class III; GMP deviations, including but not limited to, failure to maintain records of testing for purity, strength, and identity

Lioresal Intrathecal Refill Kits, Model 8562, (baclofen injection), 10mg/5mL (2000 mcg/mL), 2-5 mL ampules per kit, refill kit/drug prep kit, Rx only; Class II; Lack of assurance of sterility — cracks in refill kit tray (gloves, needles, filter, etc., not drug or drug prep kit)

Methocarbamol Tablets, 500 mg, 100 and 500 count bottles; Watson, Rx Only. Class II; Dissolution failure; 3-month stability sample

Mytussin AC Cough Syrup, MGP, (Guaifenesin, USP 100 mg and Codeine Phosphate, USP 10 mg per (5mL) each teaspoon), Sugar-Free, NET: 4 fl oz (118mL), 1 Pint (473mL) and 1 Gallon (3785mL) bottles. Also sold under the following brand name in each container size — Robafen AC Cough Syrup; Class III; Subpotent (codeine phosphate-18 month Stability test)

Nicotine Polacrilex Gum starter kits and refill kits (active ingredient in each piece 4 mg nicotine); 108 and 48 count blister packs; Class II; Contamination: pieces of latex gloves found in gum

a) **Premarin Tablets** (conjugated estrogens tablets, USP), 0.625 mg, 100 tablet unit dose packages, 100 tablet bottles, and 5,000 tablet bottles. Rx only; b) **Premphase Tablets**, 0.625 mg/5 mg (conjugated estrogens 0.625 mg and medroxyprogesterone acetate 5 mg tablets), Ez-dial dispenser containing 28 tablets, Rx only; Class III; Dissolution failure; 18 month stability station-2 hour time point

Sarapin Injection, Pitcher Plant, 50 ml Multiple Dose Vial, Sterile aqueous solution of soluble salts of the volatile bases; Class II; Lack of assurance of sterility (by manufacturer-Akorn, Inc.)

Senokot Granules (standardized senna concentrate), Natural Vegetable Laxative, 15mg sennosides in each teaspoon, 6 oz and 12 oz bottles; Class III; Mold contamination-Inactive ingredient-Malt syrup lot used in granule manufacturing had expired and was later found to contain surface mold

Senokot-S Tablets (Docusate sodium 50mg and Sennosides 8.6mg) Natural Vegetable Laxative plus Softener, Standardized Senna Concentrate and Docusate Sodium, blisterpack of 4 tablets; professional samples: not for sale; Class III; Mislabeled; Labeling does not indicate dosage instructions for children under 2 years of age

Lot #: Quantity and Distribution; Manufacturer

Serial numbers (vessels): 6089918017, 590001035, 599720020, 599726024, 599725054, 599640003, 599640005, 590001037, 599725060, 599911021, 599950056, 599640004, 599719023, 599739086, 599640002, 599720119, 590136019, 599738091, 599950004, 590136016, 599720116, 599726026; 22 vessels distributed in Washington State; Olympic Pharmacy & Healthcare, Gig Harbor, WA

Lot B03001710N, exp. 05/2003; 68 kits distributed nationwide; Medtronic, Inc, Minneapolis, MN

Lots C2L1076 exp. 12/31/04, C2K1014 exp. 12/31/04; Watson Pharmaceuticals, Inc., Corona, CA

Lots 24071, 24195, 24337, 24421, 24423, 24492, 24535, 24541, 24591, 24650, 24683, 24741, 24071A, 24071E; Distributed nationwide (226,850 — 4 oz; 275,680 — 16 oz; 3,357 — 128 oz bottles); Morton Grove Pharmaceuticals, Inc., Morton Grove, IL

Lots 4NG02021 exp. 07/01/2004, 4NL02133 exp. 11/01/2004; 19,853 distributed nationwide; Watson Diagnostics, Inc., Corona, CA

a) Lot #: A09049 exp. April 2004 (100-tablet bottles); A09041 exp. April 2004 (5,000-tablet bottles); A09067 exp. April 2004 (100-tablet unit dose packages); b) Lot #: A09065 Exp. 11/03; A12270 Exp. 12/03; A09069, Exp. 12/03; 111,605 units distributed nationwide; Robins Division of Wyeth, Richmond, VA

Lot numbers 205722 exp. 05/2005, 205825 exp. 05/2005, 206824 exp. 06/2005; 38,571 vials distributed nationwide and in Canada, Switzerland, Bulgaria, and the Netherlands; High Chemical Co, Levittown, PA

Lot No. RR61 exp. 10/2007; RA02 exp. 10/2007; RA11 exp. 10/2007; Distributed nationwide (4,296 — 6oz. bottles; 2,419 — 12 oz. bottles); The Purdue Frederick Company, Stamford, CT

Lots JV31 exp. 01/04, JV41 exp. 01/04, MA11, exp. 06/04; 924,279 distributed nationwide; Purdue Frederick Company, Stamford, CT

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More Counterfeit Tablets of the Popular Cholesterol Lowering "Statin" Drug Atorvastatin (LIPITOR) Recalled

The Food and Drug Administration (FDA) alerted consumers and health professionals about counterfeit atorvastatin (LIPITOR) on May 23, 2003. Atorvastatin is manufactured by Pfizer, Inc. of New York.

The counterfeit atorvastatin was repackaged and distributed by Med-Pro, Inc., of Lexington, Neb., and the labels say "Repackaged by: MED-PRO, Inc. Lexington, Neb." in the lower left-hand corner.

The following lots were recalled:

20722V — 90-tablet bottles,
Expiration 09-2004

04132V — 90-tablet bottles,
Expiration 01-2004

16942V — 90-tablet bottles,
Expiration 09-2004

Additional lots of counterfeit atorvastatin were recalled by the FDA on June 3, 2003:

20722V — 90-tablet bottles, 10
mg., Expiration 09-2004

04132V — 90-tablet bottles, 10
mg., Expiration 01-2004

16942V — 90-tablet bottles, 10
mg., Expiration 09-2004

20842V — 90-tablet bottles, 10
mg., Expiration 09-2004

16092V — 90-tablet bottles, 10
mg., Expiration 07-2004

D270481 — 90-tablet bottles,
20 mg., Expiration not avail-
able.

What You Can Do

You should check the packaging very carefully before using atorvastatin. If you have any of the product (labeled as "Repackaged by MED-PRO, Inc.") with the lot numbers listed above you should not take the drug, and should return the product to your pharmacist.

MEDICAL DEVICES

Device recalls are classified in a manner similar to drugs: Class I, II or III, depending on the seriousness of the risk presented by leaving the device on the market. Contact the company for more information. You can also call the FDA's Device Recall and Notification Office at (301) 443-4190. To report a problem with a medical device, call (800) FDA-1088. The FDA web site is www.fda.gov.

Name of Device; Class of Recall; Problem

Focus DAILIES Toric (nelfilcon), One-Day Contact Lenses, Daily Disposable (hydrophilic) soft contact lens, Rx only, Sterile, -1.50, -1.75 x 090, BC 8.6, DIA 14.2, 15 and 30 count packs; Class III; Lenses may be labeled with the incorrect axis

Permobil Chairman 2K powered wheelchair; Class II; One of the wheelchair motors needed a grounding strap to ensure that the motors are at the same voltage potential as the chassis of the wheelchair

Twister (tm) Cube Back-Cane Short, a wheelchair back seat support strap, part number WPHS; Class II; Stitching in wheelchair seat back is not effective and may not support user

Vicks brand Warm Mist Humidifier, Model V610, Class II; humidifiers may overheat

Lot #: Quantity and Distribution; Manufacturer

Numerous lots; 8,572 packs (181,440 lenses) distributed nationwide, in Canada and Europe; Ciba Vision Corporation, Duluth, GA

Serial numbers: 1100155 to 1102472 and 4100019 to 4100225; 1319 distributed nationwide, in Canada and Puerto Rico; Permobil, Inc., Lebanon, TN

Lots IA702, II327, IK454, and IM236; 40 units distributed nationwide and internationally; Action Products Incorporated, Hagerstown, MD

Lots ending in 2KUO or 3KUO; 110,000 units distributed nationwide; KAZ, Inc, Hudson, NY

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

Bearista Bear Tumbler Cups. When the flexible straw on the cups is chewed, small pieces of plastic can detach, posing a choking hazard to young children.

Catlike Kompact(tm) Bike Helmets. Helmets fail required CPSC impact testing, violating Consumer Product Safety Act

Ceiling Light Fixtures; wiring in the lights can short, posing a fire hazard to consumers

Children's Art Supply Sets; The sets contain mini-cutters with razor blades which pose a laceration hazard to young children

Dive Sticks; Children can fall or land on the dive sticks in shallow water and may suffer impalement injuries

Extension Cords; Undersized conductors and no over-current protection which causes overheating, presenting a shock and fire hazard

Gas Boilers; Loose gas fittings could result in leaking gas, fire and/or explosions that could cause bodily injuries or property damage

High-Leg Recliner Chairs; Mechanism in footrest can create a pinch point that can cause injury if consumers open or recline the chair by reaching underneath footrest

Pancake Express Pancake Makers; The handles on the pancake makers are unable to withstand the heat of the device, causing the handle to fail to provide support because of melting or breaking

Lot #: Quantity and Distribution; Manufacturer

Blue and green translucent plastic cups in the shape of a bear; 38,000 sold in the United States, Canada, and Taiwan from April 2002 to May 2003; Starbucks Coffee Co. of Seattle, WA (800) 235-2883 Starbucks.com or Starbuckscollectibles.com or write to Starbucks Coffee Company at Customer Relations, Starbucks Coffee Company, mailstop S-RC1, P.O. Box 3717, Seattle, WA 98124-3717

Various colors, with label inside reading "Kompact" and "SM/MD" or "LG/XL." 2250 sold at bicycle shops nationwide between March 2002 and February 2003; Monarch Velo, LLC, doing business as Catlike USA, of Houston, Texas (877) 228-5646 www.catlike-usa.com

Model numbers 5359-01, 5359-02, 5359-15, 5370-15, 5370-98, and 5372-02; 7,100 sold by electrical supply dealers and contractors (not sold at retail stores); Sea Gull Lighting Inc., Riverside, N.J. (800) 347-5483 www.seagulllighting.com

The 87-piece art supply sets were sold in solid wood grain boxes. The sets contain crayons, markers, scissors, water and oil paints, brushes, etc. A label on the box reads "JUMBO ART CASE 87 pieces" and "Item No. 11519;" sold by Bigg's stores in Ohio and Kentucky from August 2002 through March 2003; (888) 678-8697

Swim Ways Deluxe Dive Buddies are plastic tubes about 7.5 inches long and an inch in diameter with character heads and feet; 25,000 packages of four dive sticks sold in specialty pool stores nationwide between December 2002 and May 2003; Swimways Corp., Virginia Beach, VA (800) 889-7946 www.swimways.com

Yellow and brown, approximately 9-, 25-, 50-, 100-foot long sold nationwide by United General Supply between October 1999 and March 2001 for between \$1 and \$16; United General Supply Co., Lee-Tools Extension Cords, Houston, Texas (800) 456-0022

1700 sold nationally at plumbing and heating wholesale distributors to plumbers and contractors from December 2002 through February 2003; Weil-McLain Company, Michigan City, Ind. (219) 879-6561

Three-position, high-leg recliner chairs that have a five-digit style number beginning with 026 or 027 and a shipping date prior to May 2002; 620,000 sold at furniture stores nationwide between December 1989 and April 2,002 Lane Furniture Industries, Tupelo, Mississippi, (800) 467-9555 www.lanefurniture.com

Two-sided stove top skillets constructed of aluminum with black plastic handles; 590 sold nationwide at Acme, Wal-Green's, Hy-Vee and Osco Drug stores; Trivett Industries, Inc., of Deland, Fla.

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Name of Product; Problem

Stihl Chain Saws; In some units, the fuel tank vent could be installed incorrectly and become dislodged. If this occurs, fuel could leak and result in a fire

"Tiffany" and "Josephine" model cribs. The slats on the drop-side rails can come loose or detach. A child's head can get caught in the space left by loose or missing slats, presenting an entrapment hazard. In addition, children can fall through the slat opening.

Toy Drumsticks; tip of the drumstick can break off, posing a choking hazard to young children

Toy Vehicles; Small parts on the vehicles can detach, posing a choking hazard to young children

Trisonic Nightlights; The nightlight poses a serious electrocution, electric shock, burn and fire hazard to consumers

Weather Works Ventilaire Electric Heaters; The electric heater can overheat internal plastic components and damage the wiring, posing a fire and electrocution hazard to consumers

Weed Cutting Attachment Blades; The blades can break off and hit consumers causing severe impact and laceration injuries.

Lot #: Quantity and Distribution; Manufacturer

Saws with serial numbers from 255923345 through 260340097; Stihl dealers nationwide sold 13,000 chain saws from August 2002 through March 2003 for between \$350 and \$430; Stihl Inc., Virginia Beach, Va (800) 610-6677 www.stihlusa.com.

The "Tiffany" and "Josephine" model cribs are made of solid natural wood with a chest of drawers attached to the footboard. The cribs can be converted into a toddler bed and an adult bed. Tiffany cribs with production date codes (four middle numbers) 0601, 0701, 0801, 0901 and 1001 and Josephine cribs with production date codes (four middle numbers) 0101, 0201, 0301, 0401, 0501, 0601, 0701, 0801, 0901, and 1001; 2,000 sold by Babies R Us from July 2001 through January 2003; Babi Italia, a division of LaJobi Industries Inc., of Edison, N.J.; (877) 440-2224; www.babiitalia.com

Yellow and blue drumsticks about 9 inches long, sold with the Step2 Toddle Tunes Big Band Drum set, models 7135B2 and 7135KR; 800 sold nationwide by toy stores and online retailers between February 2002 and April 2003; Step 2 Company, Streetsboro, Ohio (800) 347-8372

The Viking Mini Chubbies are toy wagons, tractors, helicopters, cars, airplanes, and jeeps measuring about 3-inches long and red, blue and yellow, model numbers AW01119, AW41111, AW61005 and AW81119. 126,000 sold in specialty toy stores nationwide between April 2002 and March 20003; International Playthings Inc., Parsippany, N.J. (800) 445-8347

The recalled nightlights have a yellow exterior shaped like a smiley face; 12,000 sold at dollar stores in the eastern portion of the United States between April 2001 through March 2003; Trisonic/Eastern America Trio Products, of Flushing, N.Y.; (800) 434-8155

The portable electric heater is beige, constructed of a plastic housing, and has the "Weather Works" logo printed on the front side of the fan; 2,400 sold at retail chain stores in Florida, such as The Andersons, Chase- Pitkin Home & Garden, and Florida Hardware, from June 2002 through March 2003; Weather Works Inc., of Miami, Fla.; (888) 269-9247

Cast aluminum metal alloy blades measure 1/4 inch thick, 1 inch wide and 4 inches long, and are a dull silver color. Blades that are either smooth on the bottom or have ridges are included in the recall. 1.1 million blades sold by home improvement and hardware stores nationwide from November 1999 through December 2001; Conceptual Marketing & Development Inc., Lincoln, CA, (800) 210-9949

NEW WARNING!

Risk of Stroke When The Antipsychotic Risperidone (RISPERDAL) Is Prescribed For Dementia

The manufacturer of the antipsychotic drug risperidone (RISPERDAL), announced on April 16, 2003, that an important new warning had been added to the professional product labeling, or package insert, for the drug concerning cerebrovascular adverse effects, including stroke and transient ischemic attack (temporary reduction of blood flow to the head), when the drug is used to treat elderly patients for dementia. In some of these cases the result was death. Risperidone is produced by Janssen Pharmaceutica Inc. of Titusville, NJ.

The use of risperidone to treat dementia is not approved by the Food and Drug Administration (FDA), and the drug's only approved use is in the treatment of schizophrenia. When the use of a drug is not approved by the FDA it is referred to as an "off-label" use because only uses of a drug that have been shown to be safe and effective after FDA review can be listed on a drug's approved product labeling.

In many instances, new warnings are added to drug labels as a result of voluntary reports of adverse reactions submitted to pharmaceutical companies and the FDA by health

<p align="center">Cerebrovascular Adverse Events, Including Stroke, in Elderly Patients With Dementia</p> <p>Cerebrovascular adverse events (e.g., stroke, transient ischemic attack), including fatalities, were reported in patients (mean age 85 years; range 73-97) in trials of risperidone in elderly patients with dementia-related psychosis. In placebo-controlled trials, there was a significantly higher incidence of cerebrovascular adverse events in patients treated with risperidone compared to patients treated with placebo. RISPERDAL has not been shown to be safe or effective in the treatment of patients with dementia-related psychosis.</p>
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professionals and patients. Voluntary reports are not ironclad proof that a drug has caused an adverse reaction, though they are extremely important evidence that the drug may be the cause of serious adverse effects.

In the case of risperidone the new warning comes as the result of four controlled clinical trials. Controlled clinical trials are the best type of evidence for establishing a cause and effect relationship. The four clinical trials that compared risperidone to a placebo lasted between one and three months and involved more than 1,200 patients with Alzheimer's disease or vascular dementia. Adverse cerebrovascular events were twice as

common in those patients treated with risperidone (4%) compared to placebo (2%).

Canadian healthcare professionals were warned on October 11, 2002, six months before Americans were, about the cerebrovascular adverse effects of risperidone. In this communication, Canadian authorities indicated that worldwide there had been 37 cases of cerebrovascular adverse events associated with the use of risperidone.

The exact number of cerebrovascular adverse events associated with the use of risperidone is unknown. The FDA estimates that only between

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THE PUBLIC CITIZEN HEALTH RESEARCH GROUP

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1-in-100 and 1-in-10 serious adverse drug reactions are ever reported to the agency. The adverse reaction reporting system is voluntary and there are no laws or regulations that require health professionals to report serious adverse effects to the authorities.

Dementia places a tremendous burden on all involved: patients and the family members of patients who are their caregivers. But, the decision to use an antipsychotic drug to manage the symptoms of dementia must be made carefully. The new warning for risperidone is clear, the drug "has not been shown to be safe or effective in the treatment of patients with dementia-related psychosis." Currently, the relative safety and effectiveness of other antipsychotic drugs such as haloperidol

(HALDOL), olanzapine (ZYPREXA), clozapine (CLOZARIL), or quetiapine (SEROQUEL) in the management of dementia is similarly unknown.

If the decision is made to use an antipsychotic drug, family members of patients with dementia must inform themselves of the risks of drug treatment. The antipsychotic drugs can create serious problems for patients with cardiovascular disease, including a previous heart attack or chest pain (angina), cerebrovascular disease, or electrical conduction abnormalities of the heart. Patients taking these drugs should be watched closely for excessive sedation, low blood pressure (especially if they are already taking blood pressure lowering drugs), movement disorders, and cerebrovascular adverse reactions. Patients must also be monitored for

neuroleptic malignant syndrome, a potentially fatal symptom complex that includes a high temperature, muscle rigidity, altered mental status and evidence of an irregular pulse or blood pressure, fast heart rate, sweating, and heart rhythm disturbances.

What You Can Do

If a family member is currently receiving risperidone to manage dementia, you should discuss the drug's new cerebrovascular warning with the prescribing physician. If the decision is made to try another drug, you should learn about the drug's risks before the drug is given to your family member.

You can report serious adverse reactions to the FDA MedWatch program by phone (1-800-FDA-1088), by fax (1-800-FDA-0178), or online (www.fda.gov/medwatch).

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seeking techniques for reducing the risk of AIDS from transfusions. In February 1984, Cutter became the last of the four major blood products manufacturers to get FDA approval for heat-treated Factor VIII, a treatment that apparently killed HIV in Factor VIII products.

However, as a November 1984 internal Cutter document, part of a larger number of company documents obtained by the *New York Times*, illustrates, "There is excess nonheated inventory." Moreover, the company had "several large fixed-price contracts," according to another memo. Because Cutter believed that the unheated Factor VIII was cheaper to produce than the safer, heated product, there was a clear incentive to continue to make the unheated product since the safer, heated product would reduce the company's profit margin.

But who would buy the unsafe product? A few logic-resistant U.S. buyers continued to purchase the unheated product in the mistaken belief that heating would diminish the activity of Factor VIII, but by far the greatest sales were to Taiwan,

Singapore, Malaysia, Indonesia, Hong Kong, Japan and Latin America. In fact, Cutter actually admitted continuing to produce unheated Factor VIII until August 1984, six months after FDA approval of the heat-treated product, and to shipping unheated product until July 1985. (It appears that Cutter was not alone in this unscrupulous behavior. Three other blood products companies, Armour Pharmaceutical, Baxter International and Alpha Therapeutic, also continued to sell unheated product, but the *New York Times*, which obtained the documents and did the reporting on which this article is based, did not have similarly detailed documentary evidence for these companies.)

During this period some doctors in Asia were clamoring for the heated product, but were put off by reassurances from Cutter's distributors. After the first hemophiliacs tested positive for HIV in Hong Kong, Cutter placated a distributor in Hong Kong who was interested in the heat-treated product by claiming that the unheated product posed "no severe hazard," describing the unsafe product as the "same fine product

we have supplied for years." Similarly, a doctor in Hong Kong was told by a distributor to continue using the old product and "not to be afraid." In May 1985, Cutter explained to its Hong Kong distributor that the heat-treated factor was going to the U.S. and Europe, but that there was a small amount available for the "most vocal patients" elsewhere. When told about Cutter's marketing practices, the doctor in Hong Kong said the company "should tell the whole world, not just Europe and America."

"These are the most incriminating internal pharmaceutical industry documents I have ever seen," said Dr. Sidney Wolfe, Director of Public Citizen's Health Research Group. He called on the governments of the affected countries to initiate criminal prosecutions of the Cutter officials involved.

In addition to the problem of the dumping of substandard products in foreign markets (akin in some respects to conducting unethical experiments in developing countries, see *Health Letter*, April 2001), an underlying issue is the continued

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presence on the market of products superseded by superior ones. The Health Research Group has raised this issue before, in the context of intravenous catheters and infusion lines that remain on the market even after effective devices with lower risks of needlestick injury (and thus of hepatitis and HIV) to healthcare workers have been approved by the FDA (see *Health Letter*, January 2001).

In this case, the FDA appears to have believed that Cutter would voluntarily withdraw the unheated product after the February 1984 approval of the heated product. Fifteen months later, the agency learned that the company had not done so. Rather than denouncing Cutter's practices or ordering a recall for as yet unused unheated product, the agency elected to collude with Cutter. In a meeting with manufacturers of blood products, FDA regulator Dr. Harry Meyer asked that the issue be "quietly solved without alerting the Congress, the medical community and the public."

The international epidemic of HIV infection contains no shortage of examples of bureaucratic indecisiveness, governmental indifference and political opportunism. Add to the list (and not for the first time) corporate malfeasance and government collusion with industry. The absence of any of these might have

greatly reduced the burden of suffering from an infection that is

currently taking over three million lives each year.

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Blood Money: How Bayer Shipped HIV-containing Blood Products to Asia and Latin America

The information in this article is based on an article that appeared on the front page of the May 22, 2003 New York Times.

Ladies and Gentlemen, it is time for Public Citizen's periodic pharmaceutical executive ethics quiz.

Picture this scenario. It is February 1984. You've been producing a medical product that you learn can cause AIDS when injected into people with hemophilia. Although HIV, the virus that causes AIDS, has not yet been identified and so there is no blood test to detect it, leading scientists believe that heat treatment of your product will make it much safer. The U.S. Food and Drug

Administration (FDA) has just given your company approval to market the heat-treated product. You still have some of the unheated product in stock. Do you

A. stop producing unheated product and sell only heated product

B. continue producing unheated product

C. ship the inventoried unheated product to Asia and Latin America?

And the correct answers are ... B and C, at least if you're working for Cutter Biologicals. But lest, in a fit of commitment to the global public health rarely seen in many drug company boardrooms, you selected Option A, let us explain how Options

B and C came to be selected.

Cutter, a division of the German company Bayer, produced a product called Factor VIII, a blood-clotting component lacking in persons with hemophilia A, the most common of the hemophilias. In order for their blood to clot normally, patients with hemophilia A require frequent injections of Factor VIII, which is produced by pooling blood from thousands of donors. If a small number of those donors is infected with HIV, the entire pool can be contaminated.

The first case of AIDS among hemophiliacs was reported in July 1982 and thereafter companies producing blood products began

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