PUBLIC CITIZEN HEALTH RESEARCH GROUP

Health Letter

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Overselling Donepezil (ARICEPT) and Exploiting Patients with Alzheimers Disease: Why Isn't the FDA Stopping These Ads?

In the 1999 Edition of *Worst Pills, Best Pills*, we urged patients not to use donepezil (ARICEPT), made by Pfizer/Esai, because of a combination of adverse effects such as nausea, diarrhea and vomiting along with serious questions about clinically significant effectiveness. We quoted the prestigious *Medical Letter*, an independent evaluation for physicians of newly approved drugs, which stated "There is no evidence that use of...donepezil... leads to substantial functional improvement or prevents the progression of the disease." Since then, Pfizer/Esai has run ads that claim the drug delays the time to nursing home placement. The claim is misleading and an exaggeration of the drug's extremely modest efficacy. We wish to reinforce this recommendation and highlight the need for the Food and Drug Administration (FDA) to take action: the ads should be halted and Pfizer/Esai should issue a retraction.

In order to boost the sales of this drug, for over a year Pfizer/Esai have run extraordinarily misleading and predictably highly successful full-page ads in leading medical journals such as the *Journal of the American Medical Association* and the *Journal of the American Geriatrics Society*, a journal widely read by geriatricians and others taking care of older patients. The ads proclaim that patients with Alzheimer's disease who "persistently" use donepezil are able to stay in the community and avoid going into a nursing home for almost two years more than patients who have only limited treatment or no treatment with the drug (see advertisement on page 2 for an example). The implication is startling. The families and other friends who are caring for patients with Alzheimer's disease will have a substantial amount of extra time to have their loved ones in the community before they have to go into a nursing home if only the patients are lucky enough to be persistent users of donepezil.

If this conclusion were based on a randomized, placebo-controlled trial (RCT) (the scientific gold standard for medical research) wherein 50 percent of the patients got donepezil and the other 50 percent of exactly the same kinds of patients were randomly assigned to be given a placebo, it would be a major public health breakthrough and a cause for celebration. Unfortunately, it is not based on such a study and is not any cause for celebration.

The study cited as the basis for this seemingly remarkable improvement is flawed. The group on donepezil and the group not on donepezil appear to have been as dissimilar as

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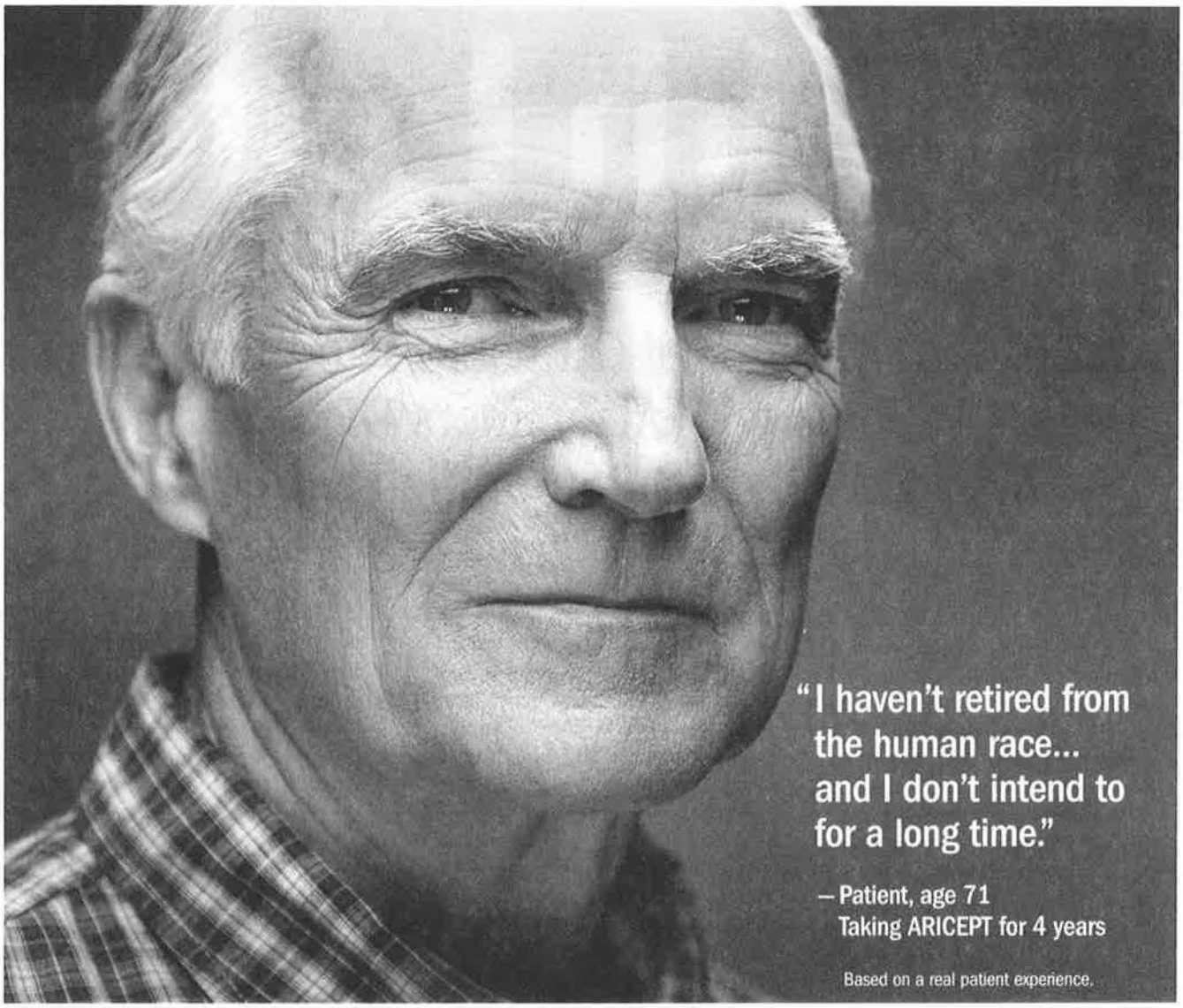


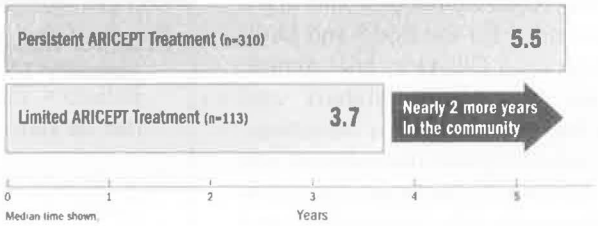
The Strength to Meet Dementia* Head On

Persistent ARICEPT treatment helped keep Alzheimer's disease (AD) patients in the community nearly 2 years longer[1,2†]

† Data are from 2 cohorts of patients in a prospective, observational follow-up of 671 AD patients from ARICEPT clinical trials for whom reason for and time of nursing home placement were obtained. Persistent group=at least 9 to 12 months of ARICEPT; 209 received >2 years of ARICEPT. Limited group=≤6 months of ARICEPT. See adjacent page for a detailed study description.

As with all studies of this type, results may be attributed to various factors. ARICEPT treatment was one such factor. Other analyses (sensitivity analyses) varying the length of exposure, definitions of compliance (80% and 100%), and double-blind study completion status were conducted. These results were consistent with the study findings shown.

Delayed Time to First Dementia-Related Nursing Home Placement



ARICEPT is indicated for mild through moderate Alzheimer's disease. The most common adverse events in clinical trials with ARICEPT were nausea, diarrhea, insomnia, vomiting, muscle cramps, fatigue, and anorexia. In clinical trials, syncopal episodes have been reported (2% for ARICEPT versus 1% for placebo). Clinical studies of ARICEPT have shown no increase, relative to placebo, in the incidence of either peptic ulcer disease or gastrointestinal bleeding. Nevertheless, cholinesterase inhibitors may be expected to increase gastric acid secretion. Therefore, patients (especially those at increased risk for developing ulcers—eg, having a history of ulcer disease, receiving concurrent nonsteroidal anti-inflammatory drugs) should be monitored closely for gastrointestinal bleeding. Responses to ARICEPT include improvement, stabilization, and less than expected decline.

* The majority of all dementia is caused by Alzheimer's disease.[3]

Please see brief summary of prescribing information on adjacent page.

ONCE-A-DAY
ARICEPT®
(donepezil HCl)
5-MG AND 10-MG TABLETS

STRENGTH TO FIGHT DEMENTIA™

DONEPEZIL, *from page 1*
the proverbial apples and oranges rather than being identical in every way except for the drug they were being given, as would have been the case in a properly done randomized placebo-controlled study.

The major flaw is what has been referred to as "drop-out-bias", a flaw in many previous studies claiming to prove meaningful improved social outcomes with drugs such as donepezil. The study used as the basis for the misleading ad was a follow-up to previous studies that were themselves randomized. The drop-out after this first phase occurs when patients were told whether they had been given a drug or a placebo. The bias occurs because people drop out based at least in part on how they felt they did in the RCT and this drop-out almost certainly occurs in an extremely unbalanced way.

How does this bias work? If you are told you got a placebo in the earlier study, you are more likely to volunteer for the continuation of the study, regardless of how you "did" on the placebo, because you would like to see how you might do on a "real" drug. If, instead, you were in the group who got drug treatment and you think your short-term improvement was caused by the drug, you will be more likely to continue taking the drug. Conversely, if after having taken the drug in the previous study you do not perceive an improvement, or even got worse, you are more likely to drop out. Thus, the drop-outs selectively occur in the group who got the drug, not the placebo, in the first part of the study and did not do so well. As a result, the overall short-term mix of that group who becomes the "persistent donepezil" user group is a selected group of responders. That this group subsequently did better than those who were not persistent users of donepezil is preordained.

Buried in the middle of the journal article cited in the ad as the source of this finding is the statement that since it is an observational study, (observing two different groups of people) "the current investigation....could not prove conclusively that taking effective doses of donepezil delayed nursing home placement." The article further stated that the only way to prove this finding of delayed nursing home placement would be to do a randomized double-blind placebo-controlled prospective trial that would assure that the two groups were completely comparable. Similarly buried in the copy of the ads is the statement that in all "studies of this type, results [delayed nursing home placement] may be attributed to various factors."

In addition to the drop-out bias described above, factors such as spousal relationship and willingness to stay in research are factors that have themselves (without drugs) been shown to improve patient outcome and lessen the chances of needing to go into a nursing home. Many of the characteristics of the caregiver and the interaction between the caregiver and the patient with Alzheimer's disease could well be quite different in the group getting "persistent" treatment from the other group. Hence, exposure to donepezil may have had nothing to do with the delay to nursing home.

Indeed, a randomized, placebo-controlled study in the United Kingdom, known as AD (Alzheimer's Disease) 2000, done by Dr. Richard Gray and his colleagues at the University of Birmingham Clinical Trials Unit, examining the effect of donepezil on outcomes such as nursing home placement, was presented almost two years ago at a medical meeting in Stockholm and has been submitted for publication. That study, lacking the flaws of the study used as the basis of the misleading ad, found no significant delay in nursing home placement in those using donepezil. There was also no improvement in the amount of time needing to be spent by the caregiver with the Alzheimer's patient nor a slowing of the progress of the disability of the patient.

Thus, the conclusion that is the main theme of such ads, that the drug resulted in a substantial delay in the time to nursing home placement, is misleading because it is not supported by scientific evidence. These exploitative ads should have been stopped long ago. Where has the FDA been? Why have these misleading ads, clearly exploiting patients with Alzheimer's disease and their families and friends through the medium of misleading doctors, not been stopped long ago?

As we have mentioned before, the past five years have seen the virtual demise of FDA enforcement of the laws and regulations governing prescription drug advertising. False and misleading advertising, typically overstating the benefits and/or understating the risks, constitutes a health hazard because it may result in a patient getting a prescription for a drug thought to be safer or more effective than it actually is. Therefore there is a relative danger inherent in such a "misprescription" compared to a safer drug that might have otherwise been prescribed. Consequently, FDA enforcement of prescription drug advertising, whether the kind directed at doctors or at patients, is a crucial part of the agency's regulation of the pharmaceutical industry.

In 1998, the FDA stopped 157 illegal prescription drug ads but in 2003, they stopped only 24: an 85 percent decrease in enforcement. This is despite the lack of any evidence that the quality or accuracy of such ads has improved. In the face of a massive increase in prescription drug advertising since 1998 that would, if anything, argue for an increased number of FDA enforcement actions rather than the sharp decrease that has occurred. The continuation of these misleading ads for donepezil for almost one and one-half years without FDA intervention illustrates this problem of a lack of law enforcement very clearly.

What You Can Do

Do not use donepezil (ARICEPT) because, as the Medical Letter has stated, " There is no evidence that use of...donepezil...leads to substantial functional improvement or prevents the progression of the disease."

Product Recalls

January 15 — February 17, 2004

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 Recalls

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
APAP Tablets, (Acetaminophen), 325 mg, 100 count bottles; Mislabeling- bottles labeled to contain 325 mg tablets actually contain 500 mg acetaminophen caplets.	Lot No. 319687; Exp. 03/05; 504 bottles distributed nationwide; Magno Humphries, Inc., Tigard, OR
a)Stamina-Rx(tm) Tablets, Maximum Sexual Stimulant, a dietary supplement, sold in bottles of 30 tablets and individual sample packets of two 550 mg tablets b) Stamina-Rx(tm) for Women Tablets, Maximum Sexual Enhancer, Adult Dietary Supplement, sold in bottles of 12 and 30 as well as, sample packets of two (2) 350 mg tablets; Unapproved new drug; products contain undeclared prescription ingredient Tadalafil.	a) Numerous lots b) Lot No. 02143579; Exp. 9/05; One million tablets per lot distributed nationwide; Hi-Tech Pharmaceuticals, Inc., Norcross, GA
a) Uroprin 502.5 mg Tablets, Adult Dietary Supplement, sold in bottles of 30, labeled to contain a combination of herbal ingredients to increase sexual stamina and arousal; **b) Cyclovar(tm) 250 mg tablets**, Adult Dietary Supplement, sold in bottles of 60 for the support of erectile dysfunction **c) Sigra 550 mg tablets,** Dietary Supplement, sold in bottles of 30 for the support of sexual activity. **d) Spontane-ES(tm) 325 mg tablets,** Adult Dietary Supplement in bottles of 30 for the support of erectile dysfunction; Unapproved New Drug: tablets contain the undeclared prescription ingredient tadalafil.	a) Lot No. 0312683, Exp. 3/05; Lot No. 02126574, Exp. None b) Lot No. SNI734, Exp. 11/04 Lot No. SNI 732, Exp. 11/04; c) Numerous lots d) Lot No. 02148608, Exp. None; One million pills per lot distributed nationwide; National Urological Group, Inc., Norcross, GA
Vigor-Rx Capsules, 545 and 1002 mg; Adult Dietary Supplement in bottles of 60 for advanced support of healthy erectile function; Unapproved New Drug: tablets contain the undeclared prescription ingredient tadalafil.	Lot No. 0310484, Exp. 3/05; 16,666 bottles distributed nationwide; National Urological Group, Inc.; Norcross, GA

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
ACEON(r) (Perindopril erbumine) Tablets, 2 mg, 100 count bottles, Rx only; Class III; Degradation Products: Related compound specification failure (I8 month stability).	Lot Nos. 3025305 and 3025306, Exp. 6/30/04; 4,504 bottles distributed nationwide and in Puerto Rico; Solvay Pharmaceuticals Inc.; Marietta, GA
a)Antacid (Calcium carbonate, USP 500 mg), 150 count bottles, Bartell Drugs Mint Flavor Antacid Regular Strength Antacid/calcium supplement sodium free/calcium rich b) Antacid Tablets (Calcium Carbonate USP, 750 mg) 96 count bottles, Bartell Drugs Tropical Fruit Flavors Antacid Extra strength antacid/calcium supplement great taste/calcium rich; a) Misbranding: bottle is incorrectly labeled as containing 200 mg of calcium per serving rather than 400 mg and the percent daily value is incorrectly denoted as 20% rather than 40%; b) Misbranding: bottle is incorrectly labeled as containing 20% daily value of calcium rather than correctly containing 30% daily value of calcium.	Numerous lots; 5,952 bottles distributed nationwide; Magno Humphries Inc.; Tigard, OR
Buspar Tablets (buspirone HCl, USP), 15 mg, 60 Dividose tablet and 180 Dividose tablet bottles, Rx Only; Class III; Mislabeled: Dosing instructions for the 15 mg Dividose tablet is incorrect in that the diagram for two-thirds of a tablet should denote a 10 mg dose rather than a 15 mg dose.	Lot No. 3G74918 Exp. 8/31/06 (60 count bottle); Lot No. 3D68441 Exp. 2/28/05; Lot No. 3B63278 Exp. 4/30/06 (180 count bottle); 39,755 bottles distributed nationwide; Bristol Myers Squibb Co., C.P.O.; Mount Vernon, IN
Butalbital, Aspirin, and Caffeine Capsules, (50 mg Butalbital, 325 mg Aspirin, 40 mg Caffeine),100 count bottles, Rx only; Class III; ANDA/NDA Discrepancies: Manufacturing process used an unapproved source of butalbital.	Lot No. M031552024; 4,772 bottles distributed nationwide; Lannett Co, Inc.; Philadelphia, PA
Entex LA Capsules, phenylephrine HCl extended release 30mg/ guaifenesin immediate release 400mg, 100 count bottles, Rx only; Class III; Mislabeling: Package insert states the color of the capsules as blue and yellow instead of purple and orange.	Lot Nos. 3785, 3786, 3787, 3788, 3789, and 3814; 46,000 bottles distributed nationwide; Andrx Pharmaceuticals, Inc.; Weston, FL
Fluoxetine Capsules, 10mg, 100 count bottles (Aqua Blue/White); Rx Only; Class III; Impurities; Total Impurity level exceeded (12 month).	Lot No. 106805; Exp. 04/04; 11,204 bottles distributed nationwide; IVAX Pharmaceuticals, Inc.; Northvale, NJ
Lithium Carbonate Extended Release Tablets, USP, 300 mg, 100 count bottle, Rx only; Class III; Dissolution Failure: 12 month stability.	Lot No. 403452044T; Exp. 9/04; 3,165 bottles distributed nationwide; Barr Laboratories, Inc.; Forest, VA

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THE PUBLIC CITIZEN HEALTH RESEARCH GROUP
Health Letter

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.

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DRUGS AND DIETARY SUPPLEMENTS *cont.*

Name of Drug or Supplement; Class of Recall; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Nardil Tablets (Phenelzine Sulfate Tablets, USP), 15 mg, 100 count bottles, Rx Only; Class III; Subpotent: (stability).	Numerous lots; 95,933 bottles distributed nationwide; in Canada, Spain, and South Africa; Pfizer Inc.; New York, NY
Oxycodone Hydrochloride Oral Concentrate Solution, 20 mg/mL, 30 mL bottle, Rx only; Class II; Defective Dropper: The ink graduated markings dissolve when stored in the product which may result in an inaccurate administration of prescribed dose.	Numerous lots; 17,130 bottles distributed nationwide; Mallinckrodt Inc.; Hobart, NY

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	*Lot #; Quantity and Distribution; Manufacturer*
CVS Pharmacy One Step Cleaning & Disinfecting Solution No Rub, For soft contact lenses (hydrophilic) replaced in 30 days or less. Contains hydrogen peroxide as the disinfecting agent. 12 Fl. Oz (355 ML); Class II; Product label fails to provide adequate warning for use.	All lot codes. 19,261 units distributed nationwide; CVS; Woonsocket, RI

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	*Lot #; Quantity and Distribution; Manufacturer*
Accessory Skis. The accessory skis sold for Polaris snowmobiles could break, resulting in injury or death.	Accessory Skis for Polaris snowmobiles; 1,700 sold at Polaris dealerships worldwide from November 2001 through December 15, 2003; Polaris Industries Inc.; Medina, MN; (800) 765-2747; www.polarisindustries.com
Acrylic Primer for Nail Care. This methacrylic acid primer is not packaged in child-resistant packaging, as required by the Poison Prevention Packaging Act.	Packaged in amber-colored bottles with black caps, model numbers 508, 509, 510, 511 and 512; 72,000 bottles sold nationwide from June 2000 through January 2004; Sassi America Inc.; Elk Grove Village, IL; (847) 228-0334
Activity Cubes. Small parts can detach from the cube, posing a choking hazard to small children.	PlayWell Crayola(r) Activity Cubes; 9-inch tall wooden cube, each side of which has a different game; 22,200 sold at Shopko Stores nationwide from October 2003 through January 2004; PlayWell Toy Company; West Orange, NJ; (800) 836-7928; www.regcen.com/activitycube
Batteries. The recalled batteries can short-circuit and erupt with force or emit excessive heat, posing a burn hazard to consumers.	Batteries in Kyocera Cell Phones (Model 7135 Smartphones); 140,000 sold nationwide from September 2003 through December 2003; Kyocera Wireless Corp.; San Diego, CA; (800) 349-4478

CONSUMER PRODUCTS *cont.*

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Candle Sets. Paint on the exterior surface of the candles can sustain a flame posing a potential fire hazard.	Luminessence(tm) T-Lite Candles with Glass Holder; eight tea light candles and one flower-shaped glass holder; 68,400 sold nationwide from September 2003 through October 2003; Dollar Tree Stores, Inc.; Chesapeake, VA (800) 876-8077; www.dollartree.com
Carbon Monoxide (CO) Alarms. The recalled units fail to detect carbon monoxide after 1 year of operation due to an internal software error. These CO alarms do not provide an "end of life" signal or other indication of inoperability, even if the test button is depressed.	ESL SafeAir 240-COE Carbon Monoxide alarms; About 74,000 sold nationwide from November 2000 through October 2003; GE Security, Inc.; Tualatin, OR; (800) 648-7422; www.ge-interlogix.com
Children's Jackets. The zipper pull on the jacket can come off and pose a choking hazard to small children	Kids Falls Creek PU Jacket with Polar Fleece in Hood; 58,000 sold at Meijer retail stores in Michigan, Ohio, Indiana, Kentucky and Illinois from August 2003 through December 2002; Meijer Distribution Inc.; Grand Rapids, MI; (866) 280-8419; www.meijer.com
Children's Sweatshirts. The sweatshirts have drawstrings in the hood. Children can get entangled and strangle in the drawstrings that can catch on playground equipment, fences or tree branches.	"Emergency Exit" fleece sweatshirts in children's sizes 4-18; 18,655 sold at Meijer retail stores in Michigan, Ohio, Indiana, Kentucky and Illinois from August 2003 through January 2004; Meijer Distribution Inc.; Grand Rapids, MI; (866) 280-8419; www.meijer.com
Fitness Machines. First, while being used in the incline position, the machine's backboard bench can unexpectedly collapse and break, posing a risk of injury to the user. Second, the "Lat Tower," can rotate forward and fall during use, posing a risk of injury to the user.	Bowflex Power Pro XL, XTL and XTLU systems with the "Lat Tower" attachment; 420,000 sold nationwide from January 1995 through December 2003; Nautilus Direct; Vancouver, WA; (888) 424-3020; www.bowflex.com
Flagpoles. A partially crimped sleeve on these flagpoles can allow the cable to pull through the sleeve causing the loop to release. When the assembly is raised with no flag attached, it can allow a seven pound counter weight to drop to the ground, possibly hitting people nearby.	Internal Halyard Flagpoles have a hinged door and a metal cable on the outside of the pole; 118 sold nationwide from August 2003 through October 2003; Kearney-National, Hapco Division; Abingdon, VA; (800) 368-7171; www.americanflagpole.com
Flashlight Batteries. The batteries can short out, causing the flashlight's canister to rupture and pose injury to the consumer.	Browning CR123A lithium batteries sold with Browning Black Ice flashlights; 12,500 sold at hunting and sporting goods stores nationwide during December 2003; Browning; Morgan, UT; (800) 637-0230; www.Browning.com/recall
Flashlight Batteries. The batteries may overheat, leak, or rupture, presenting a potential for fire and injury.	Fuji Power and A&T Fuji Power CR123A 3-volt lithium batteries originally provided with the Dorcy Spyder Tactical Xenon Light (Product 41-4200), also sold in packages of two flashlights under the name Dorcy Xenon Tactical Light. 20,000 sold nationwide; Dorcy International Inc.; Columbus, OH; (800) 837-8558
Crescent Light Bathroom Fixtures. The lamp holders on the fluorescent lights can overheat, causing the fixture to melt or burn, presenting a fire hazard.	2-, 3- and 4-foot lengths with a ribbed, plastic lens covering the fluorescent tube; Progress Lighting catalog numbers 717430-EBO, 717330-EBO and 717230-EBO; 11,000 sold nationwide from January 1998 through April 2003; Progress Lighting; Spartanburg, SC; (800) 447-0573; www.progresslighting.com
Footballs. The football contains a hard plastic interior frame that can pose a risk of facial cuts if a child is hit during play.	NERF(r) Big Play Football(tm); 294,000 sold nationwide from August 2003 through January 2004; Hasbro Inc.; Pawtucket, RI; (866) 637-3244; www.nerf.com

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New Jersey Slow to Police Problem Physicians

The following article, written by Mary Jo Layton, appeared in the January 25, 2004 issue of The Record *(Bergen County, NJ).*

Dr. Richard Kaul was dubbed "killer doc" by a British tabloid when he was convicted of manslaughter after the death of a patient in England. He'd been chatting on his cellphone when he should have been monitoring the woman, according to court testimony. Forbidden from practicing medicine in England, Kaul moved to the United States — where he had no problem renewing his New Jersey medical license. He just didn't tell regulators here about the death.

Even when the state learned of Kaul's past, the anesthesiologist was allowed to practice for two years before the medical board suspended him in December for hiding his conviction.

During that time, he worked briefly at Hackensack University Medical Center. St. Clare's Hospital in Denville allowed him to treat patients there until last month, even though administrators knew of his manslaughter conviction. He also treated patients at pain management clinics in Saddle Brook and Pompton Plains.

Last month, a 39-year-old Sussex County man sued the doctor, claiming Kaul's treatment caused permanent numbness and left him "hopelessly addicted to painkillers."

Kaul's saga highlights once again the gaps in New Jersey's system to protect patients against problem physicians, a process increasingly criticized as too slow, too lenient, and far too secretive.

"The New Jersey board does not generally do a good job of disciplining doctors, and this case makes the point again," said Dr. Sidney Wolfe, executive director of Public Citizen's Health Research Group, a Washington, D.C., patient advocacy group.

Wolfe was especially concerned that when the state learned of Kaul's past in 2001, he was allowed to continue to practice medicine until his six-month suspension began last month. He criticized the state for not providing patients with easy access to information about doctors.

"If you saw on a Web site that this doctor had been convicted of

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CONSUMER PRODUCTS *cont.*

Name of Product; Problem	*Lot #; Quantity and Distribution; Manufacturer*
Kids' Pottery Wheel Kits. The brown clay contained in the Pottery Wheel kits could contain excess levels of bacteria, posing a risk of illness to users.	Discovery Kids Imaginative Arts Pottery Wheel Kits; about 150 sold at Discovery Channel stores and catalogs, and on web site during October 2003; Curiosity Kits Inc.; Hunt Valley, MD; (800) 373-7706; http://shopping.discovery.com
Overfill Protection Devices (OPD valves). When the cylinder on the gas grill is filled to capacity and exposed to increased temperatures, liquid propane instead of gas vapor can leak out and cause the gas regulator valve to freeze. When the regulator valve thaws, if it has not been turned off, gas will flow to the grill. The resulting build-up of gas in the grill can pose a serious fire hazard to consumers.	SCG Liquid Propane Overfill Protection Devices (OPD valves); installed on 20-pound liquid propane gas cylinders manufactured by the Sahamitr Pressure Container Public Co. Ltd; 21,000 sold nationwide from August 2002 to August 2003; SCG Miyairi (Thailand) Company, LTD; Thailand; (800) 636-9346; www.scgmiyairi.com
Pool Filters. The Posi-Lok(tm) locking ring, which secures the filter's upper tank shell to the lower tank shell (see diagram below), can disengage from the lower tank shell allowing the top shell of the filter to blow off causing injury to nearby consumers.	Sta-Rite System 2 and AquaTools Filters and Filter Systems for use with above-ground pools and small in-ground pools; 8,500 sold nationwide from January 2003 through October 2003; Sta-Rite Industries, Inc.; Delavan, WI; (866) 681-9148; www.starite.com
Swings. The plastic handle on the Mega Rider swing could crack at the seat connection allowing the metal connecting rod to pull out. If this occurs, a child on the swing could fall to the ground.	Swing-N-Slide "Mega Rider" Swings; 1,220 sold nationwide from March 2003 through October 2003; Swing-N-Slide; Janesville, WI; (800) 888-1232
Toy Cars. The air motor in the toy cars can burst while being pumped up, causing parts of the motor or car to break off. Some of these parts can have sharp points and pose a risk of eye or laceration injuries.	"Mud Boggers" and "Street Shredders" Pump Up Racers; about 14,000 sold nationwide between November 2003 and December 2003; K'NEX Industries Inc.; Hatfield, PA; (800) 543-5639; www.knex.com
Tree Climbers. The steel back brace on the tree climber can weaken and fail, posing a serious injury hazard to the user.	BBK 10010 Tree Climbers; 630 sold nationwide from August 2003 through October 2003; BBK Enterprises Inc.; San Antonio, TX; (800) 228-4846; www.bbkhuntingsystems.com.

PROBLEM DOCTORS, *from page 8*
manslaughter and had lost his license for five years, would you go to him?" Wolfe asked "Would you choose an anesthesiologist who admits he was inattentive?"

The handling of Kaul's case also was criticized by a New Jersey appellate court several weeks ago. The judges not only denied Kaul's motion to have his suspension overturned, but they wrote: "If anything, the six-month period of active suspension was lenient."

Dr. David Wallace, president of the Board of Medical Examiners, declined to comment.

Kaul, of Convent Station in Morris County, could not be reached for comment. His attorneys, Susan Volkert and Joseph Gorrell, who represented him on his appeal, did not return calls.

The receptionist at the clinic where he worked in Saddle Brook would say only that he is on leave.

The case rankles lawmakers, injured patients, and malpractice attorneys, who say it's imperative for the board to become more muscular in weeding out incompetent doctors practicing in New Jersey and alerting patients to their misdeeds.

"This case really brings up the absolute ineffectiveness of how New Jersey reviews a doctor's competence," said malpractice attorney Jack Hoyt. He is representing Richard Ayers, the man who claims to have been injured by Kaul.

"He came right into this country and started working on patients, and our medical board never even had information that he killed a woman," Hoyt said.

On Thursday, a bill that would radically overhaul how the state disciplines doctors was approved with strong bipartisan support by an Assembly committee, said Assemblywoman Loretta Weinberg D- Teaneck, a sponsor of the bill.

"Practically every committee member had a war story to tell about their dealings with the Board of Medical Examiners," Weinberg said. "There are just too many cases where patients aren't being protected."

The bill would add public members to the panel, which is now dominated by doctors. It would require greater scrutiny of physicians paying out malpractice claims to injured patients.

Kaul's troubles in England began in March 1999 when a 56-year-old woman, visiting London for her daughter's wedding, underwent routine dental care and asked for anesthesia. Shortly after the procedure, the woman suffered a heart attack. She died six days later in a hospital, never having regained consciousness, according to New Jersey medical board records.

A dental assistant testified that Kaul was talking on his cellphone and not monitoring the patient. Kaul also had reportedly turned off a monitor because the noise annoyed him. Kaul disputed that at his trial, yet admitted the tragic error, according to state records.

"I made a grave mistake which had fatal consequences," he testified. "A brief period of inattention led to another person's demise. Every day since it's happened, I've thought about my actions and about how if only I had done my job properly that day, [the patient] would still be alive."

Kaul was convicted of manslaughter in February 2001 and later lost his license for five years. British regulators said the doctor failed to adequately monitor his patient's blood-oxygen level, which had fallen during the treatment.

Kaul, who had completed his residency at Albert Einstein Medical School in New York City, first obtained a New Jersey medical license in 1996, before moving to England.

His career in shambles, he returned to the United States.

On his applications in New Jersey, he wasn't as forthcoming as he was at his trial.

In his renewal application to the New Jersey medical board in 2000, Kaul checked "no" when asked if had been convicted of a crime and whether his license had been suspended or revoked, the state charged.

In an April 2001 application for employment at Hackensack University Medical Center, he also checked "no" to the same questions.

If he had practiced in the United States, his past would have been recorded in the National Practitioner Data Bank, a federal repository that contains disciplinary actions and malpractice payouts made by every doctor in the country. Hospitals and medical boards are required by law to check this data bank before hiring or licensing a physician.

Kaul began working in pain management at the Hackensack hospital in October 2001, and it wasn't long before administrators learned of his past.

"Information came into the medical staff offices that said the doctor had a history we needed to look into," said Dr. Mark Schlesinger, chief of anesthesiology.

Schlesinger said he told the doctor he was suspending him while the hospital confirmed the information. "He resigned at that point," Schlesinger said. State records indicate that the hospital suspended Kaul in November 2001.

The hospital then reported the fact that Kaul had lost his license in England to state regulators, yet it would take New Jersey nearly a year before it filed a complaint against Kaul on Sept. 20, 2002, citing the manslaughter conviction and his misrepresentations on applications.

While the state was building its case against Kaul — and even after it filed its complaint — he was allowed to continue treating patients. And even after the board decided to suspend him for six months last May, he was allowed to continue practicing while he appealed his case in court. In fact, during the appeal, the state renewed his license once again, according to Jeff Lamm, a spokesman for the medical board.

During the investigation, patients would not have been able to find out about the state's concerns. Only when a doctor is charged is that information made public.

State officials also are reviewing the board's operations. Reni Erdos,

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PROBLEM DOCTORS, *from page 9*
director of the Division of Consumer Affairs, which oversees the medical board, is expected to make recommendations soon on how the board can operate more effectively. The report has been sent to the state attorney general for review.

Erdos announced her plans to examine the board in July, when presented with findings by *The Record* which revealed that the board disciplines only a small percentage of the state's 30,000 licensed physicians.

New Jersey is one of a dozen or so states that does not offer details of a doctor's history online. A state Web site only indicates if the license is active or if an investigation is pending. Patients need to be courthouse sleuths or savvy on the Internet, like Richard Ayers, who investigated Kaul after his treatment went terribly wrong, his attorney said.

Ayers was treated in Pompton Plains for chronic pain caused by a slipped disc in his lower back, Hoyt said. Kaul repeatedly punctured the man's disc when he injected anesthesia for an epidural, Hoyt said. He also injected medication into a spinal nerve, creating numbness that has yet to go away, Hoyt said. Ayers is now also "hopelessly addicted" to painkillers which were overprescribed by Kaul, Hoyt said.

"You can call the state board and you'll never learn anything about your doctor," Hoyt said. "My patient had to do his own research to find out about this physician's past."

Shortly after New Jersey filed the complaint against Kaul for the manslaughter conviction and misrepresenting himself, he again failed to divulge the truth, according to state records.

In September 2002, he applied for a job at St. Clare's. This time, he took a different approach — he hired a lawyer and told hospital administrators what occurred in England. But once again, he lied on his application — he never mentioned the Hackensack hospital suspension. He never mentioned that he was under investigation by the medical board, according to state medical board records.

"He was very open about the case in England," said Joseph Vitale, director of marketing at the hospital.

The hospital's credentialing committee determined that the patient death in England would have been handled as a standard malpractice case in U.S. courts and would not have been subject to criminal charges, Vitale said.

In fact, at hearings before the state medical board, David Lundquist, St. Clare's chief executive officer, testified as an employer and patient on Kaul's behalf. Kaul's pain management service, he testified "is growing and meeting the needs of the community."

The physician and nursing staff, Lundquist said, insisted that Kaul "goes the extra mile with the patients."

On Dec. 10, Kaul's six-month suspension began. He must also serve on probation for 18 months.

Kaul was also ordered to pay $41,600 in fines and costs and must complete an ethics course.

Protecting Yourself from Mad Cow Disease Infection

On December 23, 2003, the United States Department of Agriculture (USDA) announced the discovery of the first case of Mad Cow Disease in the United States. According to the leading theory, the disease is caused by a misfolded protein and has been transmitted between cattle by the feeding of cattle to one another and then to about 150 humans (mostly in Britain) who ate the infected cattle. Almost 90% of the infectious material in an animal with Mad Cow Disease is in the brain and spinal cord. The USDA has now completed its investigation of this case (which turned out to originate in Canada) and found no additional cases of Mad Cow Disease. However, because the cattle-tracking system in this country is extremely weak, most cattle from the infected animal's herd were not located.

Over the years, the government has implemented a number of steps designed to protect against the human form of Mad Cow Disease, variant Creutzfeldt-Jakob Disease (vCJD). The most important of these were the ban on the importation of ruminants (cud-chewing mammals) and ruminant products from countries with Mad Cow Disease (1989) and a ban on the feeding of ruminants to other ruminants (1997). In addition, in recent years, the United States has tested the brains of about 20,000 cattle annually. None has been positive for the disease.

Public Citizen has been a critic of various aspects of those protections (see *Health Letter*, March and May 2001) as well as some of the new protections put into place after the first U.S. case of Mad Cow Disease was discovered. Our purpose here is not to revisit the limitations of the government's actions to date, but rather to provide you with some guidance on how to protect yourself from vCJD, by avoiding products still on the market that can contain brain or other nervous tissue.

- Avoid brains and beef cheeks
- Avoid any meat that comes close to the spinal column (e.g., neck bones) or contains bone that is part of the spinal cord (e.g., T-bone steak)
- Avoid ground beef unless the butcher grinds it him- or herself from a whole piece of muscle meat. Ground beef often contains materials recovered through advanced meat recovery (the use of belts and bone presses to remove meat from bone)

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MAD COW DISEASE, *from page 10*

that can include nervous tissue as a contaminant. Pizza toppings, taco fillings, hot dogs, salami and bologna may also contain cattle material obtained through this process.

- Avoid beef stock, extract and flavoring. Although spinal cord-contaminated products cannot be labeled "meat," believe it or not they can still be labeled "beef."
- Do not use dietary supplements that indicate that they contain animal parts, particularly brain or spinal cord from cattle.

OUTRAGE, *from page 12*

uncorrected, would warrant termination from the Medicare program. Serious deficiencies commonly found during surveys included medication errors, contamination of water used for dialysis, and insufficient physician involvement in patient care. Infrequent, poorly targeted, and inadequate inspections allow facilities' quality of care problems to go undetected or remain uncorrected.

Specifically:

- Although ESRD survey activity has increased in recent years, only nine state survey agencies consistently met CMS's goal to inspect 33 percent of ESRD facilities annually.
- A substantial number of facilities go many years between inspections. In fiscal year 2002, 216 facilities nationwide went 9 or more years without an inspection.
- Deficiencies may not have been detected during an inspection if the surveyors had little experience in assessing dialysis quality.

Even when deficiencies are identified and facilities take corrective action, little incentive exists for these facilities to remain in compliance. Data show a pattern of repeated serious deficiencies in successive inspections of an individual facility. No effective sanctions are available to enforce compliance, short of terminating the facility from the Medicare program, which is rarely done.Federal monitoring of state agencies' performance of surveys and technical assistance provided is uneven across CMS regions. CMS substantially increased its funding for ESRD surveys from an estimated $3.1 million in fiscal year 1998 to $8.2 million in fiscal year 2002. At the same time, several CMS regional offices in our study did not actively oversee how the state agencies used these funds to improve survey activities. CMS has not taken steps needed to facilitate information sharing between federally funded ESRD networks and state agencies on the performance of individual dialysis facilities-information that could help states to target their inspection resources. In addition, CMS has not offered adequate training opportunities for surveyors inspecting ESRD facilities.

GAO suggests that Congress consider authorizing CMS to impose immediate sanctions, such as monetary penalties or denying payment for new Medicare patients, on dialysis facilities cited with serious deficiencies in consecutive surveys. GAO recommends that the CMS Administrator create incentives for facilities to maintain compliance with quality standards, increase use of expert staff in conducting ESRD facility surveys, and enhance the support and monitoring of state survey agencies. CMS did not indicate an intention to implement five of our six recommendations."

KIDNEY DIALYSIS FACILITIES
Serious Problems of Compliance with Medicare Quality Standards

A recent GAO report examined the compliance with Federal standards for the Federally-funded end stage renal dialysis (ESRD) programs upon which 220,000 people in this country depend for removing the toxins from their bodies. Most patients go to these centers for dialysis several times a week. It should be noted that an earlier GAO report in 2000 was similarly critical of inadequate government oversight of what the GAO called a big business that seemed willing to cut corners to keep up their profit margin. GAO said, in this earlier report, that "To stay alive, a patient with ESRD must receive either a kidney transplant or regular kidney dialysis treatments. Such treatments use a machine to do the kidneys' job of removing impurities from the blood. If performed improperly, such treatments can contaminate patients' blood, causing serious complications and even death."

Below are excerpts from the more recent October, 2003 GAO report with findings not only very critical of the quality of care in the largely for-profit kidney dialysis centers but also of the Centers for Medicare and Medicaid Services (CMS) for its failed oversight of the program and its refusal to follow GAO recommendations for improvement

"A substantial number of ESRD facilities do not achieve minimum patient outcomes specified in clinical practice guidelines, with significant proportions of their patients receiving inadequate dialysis or treatment for anemia. Similarly, inspections of dialysis facilities by state survey agencies have uncovered numerous problems that put patient health at risk. Between fiscal years 1998 and 2002, these inspections, commonly called surveys, revealed that 15 percent of facilities surveyed had serious quality problems that, if left

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